ORDIN Nr. 1301/500/2008 din 11 iulie 2008 - Partea a II-a

pentru aprobarea protocoalelor terapeutice privind prescrierea medicamentelor aferente denumirilor comune internaţionale prevăzute în Lista cuprinzând denumirile comune internaţionale corespunzătoare medicamentelor de care beneficiază asiguraţii, cu sau fără contribuţie personală, pe bază de prescripţie medicală, în sistemul de asigurări sociale de sănătate, aprobată prin Hotărârea Guvernului nr. 720/2008

*Text în vigoare începând cu data de 27 iulie 2017*

*REALIZATOR: COMPANIA DE INFORMATICĂ NEAMŢ*

*Text actualizat prin produsul informatic legislativ LEX EXPERT în baza actelor normative modificatoare, publicate în Monitorul Oficial al României, Partea I, până la 27 iulie 2017.*

***Act de bază***

**#B**: *Ordinul ministrului sănătăţii publice şi al preşedintelui Casei Naţionale de Asigurări de Sănătate nr. 1301/500/2008*

***Acte modificatoare***

**#M1**: *Ordinul ministrului sănătăţii publice şi al preşedintelui Casei Naţionale de Asigurări de Sănătate nr. 1745/780/2008*

**#M2**: *Ordinul ministrului sănătăţii publice şi al preşedintelui Casei Naţionale de Asigurări de Sănătate nr. 1941/872/2008*

**#M3**: *Ordinul ministrului sănătăţii şi al preşedintelui Casei Naţionale de Asigurări de Sănătate nr. 461/477/2010*

**#M4**: *Ordinul ministrului sănătăţii şi al preşedintelui Casei Naţionale de Asigurări de Sănătate nr. 423/118/2012*

**#M5**: *Ordinul ministrului sănătăţii şi al preşedintelui Casei Naţionale de Asigurări de Sănătate nr. 961/536/2013*

**#M6**: *Ordinul ministrului sănătăţii şi al preşedintelui Casei Naţionale de Asigurări de Sănătate nr. 361/238/2014*

**#M7**: *Ordinul ministrului sănătăţii şi al preşedintelui Casei Naţionale de Asigurări de Sănătate nr. 773/484/2014*

**#M8**: *Ordinul ministrului sănătăţii şi al preşedintelui Casei Naţionale de Asigurări de Sănătate nr. 275/162/2015*

**#M9**: *Ordinul ministrului sănătăţii şi al preşedintelui Casei Naţionale de Asigurări de Sănătate nr. 968/524/2015*

**#M10**: *Ordinul ministrului sănătăţii şi al preşedintelui Casei Naţionale de Asigurări de Sănătate nr. 1317/993/2015*

**#M11**: *Ordinul ministrului sănătăţii şi al preşedintelui Casei Naţionale de Asigurări de Sănătate nr. 1379/1023/2015*

**#M12**: *Rectificarea publicată în Monitorul Oficial al României, Partea I, nr. 850 din 16 noiembrie 2015*

**#M13**: *Ordinul ministrului sănătăţii şi al preşedintelui Casei Naţionale de Asigurări de Sănătate nr. 1463/1036/2016*

**#M14**: *Ordinul ministrului sănătăţii şi al preşedintelui Casei Naţionale de Asigurări de Sănătate nr. 192/142/2017*

**#M15**: *Ordinul ministrului sănătăţii şi al preşedintelui Casei Naţionale de Asigurări de Sănătate nr. 475/308/2017*

**#M16**: *Ordinul ministrului sănătăţii şi al preşedintelui Casei Naţionale de Asigurări de Sănătate nr. 618/405/2017*

**#M17**: *Ordinul ministrului sănătăţii şi al preşedintelui Casei Naţionale de Asigurări de Sănătate nr. 846/818/2017*

*Modificările şi completările efectuate prin actele normative enumerate mai sus sunt scrise cu font italic. În faţa fiecărei modificări sau completări este indicat actul normativ care a efectuat modificarea sau completarea respectivă, în forma* ***#M1****,* ***#M2*** *etc.*

**#B**

Văzând Referatul de aprobare al Direcţiei generale politici, strategii şi managementul calităţii în sănătate din cadrul Ministerului Sănătăţii Publice nr. E.N. 7.547 din 11 iulie 2008 şi al directorului general al Casei Naţionale de Asigurări de Sănătate nr. D.G. 2.004 din 11 iulie 2008,

având în vedere prevederile:

- art. 406 alin. (1) lit. g) şi art. 243 din Legea nr. 95/2006 privind reforma în domeniul sănătăţii, cu modificările şi completările ulterioare;

- art. 4 din Hotărârea Guvernului nr. 720/2008 pentru aprobarea Listei cuprinzând denumirile comune internaţionale corespunzătoare medicamentelor de care beneficiază asiguraţii, cu sau fără contribuţie personală, pe bază de prescripţie medicală, în sistemul de asigurări sociale de sănătate;

în temeiul art. 281 alin. (2) din Legea nr. 95/2006, cu modificările şi completările ulterioare, al art. 7 alin. (4) din Hotărârea Guvernului nr. 862/2006\*) privind organizarea şi funcţionarea Ministerului Sănătăţii Publice, cu modificările şi completările ulterioare, şi al art. 17 alin. (5) din Statutul Casei Naţionale de Asigurări de Sănătate, aprobat prin Hotărârea Guvernului nr. 972/2006, cu modificările şi completările ulterioare,

**ministrul sănătăţii publice** şi **preşedintele Casei Naţionale de Asigurări de Sănătate** emit următorul ordin:

**#CIN**

***\*)*** *Hotărârea Guvernului nr. 862/2006 a fost abrogată. A se vedea Hotărârea Guvernului nr. 144/2010.*

**#B**

ART. 1

Se aprobă protocoalele terapeutice privind prescrierea medicamentelor aferente denumirilor comune internaţionale prevăzute în Lista cuprinzând denumirile comune internaţionale corespunzătoare medicamentelor de care beneficiază asiguraţii, cu sau fără contribuţie personală, pe bază de prescripţie medicală, în sistemul de asigurări sociale de sănătate, aprobată prin Hotărârea Guvernului nr. 720/2008, denumite în continuare protocoale terapeutice, prevăzute în anexele nr. 1 şi 2, care fac parte integrantă din prezentul ordin.

ART. 2

(1) În înţelesul prezentului ordin, termenii şi noţiunile folosite au următoarele semnificaţii:

a) prescriere limitată - prescrierea medicamentelor în cadrul sistemului de asigurări sociale de sănătate este limitată la indicaţia/indicaţiile medicală/medicale prevăzută/prevăzute în protocoalele terapeutice;

b) cod de restricţie - cod unic atribuit unei prescrieri limitate. Modalitatea de implementare a codurilor de restricţie se va stabili prin ordin al ministrului sănătăţii şi al preşedintelui Casei Naţionale de Asigurări de Sănătate.

(2) Condiţiile privind prescrierile limitate ale medicamentelor aferente denumirilor comune internaţionale prevăzute în Lista cuprinzând denumirile comune internaţionale corespunzătoare medicamentelor de care beneficiază asiguraţii, cu sau fără contribuţie personală, pe bază de prescripţie medicală, în sistemul de asigurări sociale de sănătate, aprobată prin Hotărârea Guvernului nr. 720/2008, şi codurile de restricţie ale acestora sunt prevăzute în anexa nr. 2.

ART. 3

(1) Protocoalele terapeutice constituie baza de prescriere şi monitorizare a medicamentelor care se acordă asiguraţilor pe bază de prescripţie medicală eliberată de medicii care sunt în relaţie contractuală cu casele de asigurări de sănătate.

(2) Respectarea schemelor terapeutice stabilite conform protocoalelor terapeutice prevăzute în anexele nr. 1 şi 2 este obligatorie pentru medicii aflaţi în relaţie contractuală cu casele de asigurări de sănătate.

**#M2**

*(3) Până la data de 31 decembrie 2008, medicii aflaţi în relaţie contractuală cu casele de asigurări de sănătate au obligaţia de a proceda la evaluarea bolnavilor pe care îi au în evidenţă, în vederea adaptării schemelor terapeutice în conformitate cu prevederile prezentului ordin.*

**#B**

ART. 4

Iniţierea şi continuarea tratamentului specific unei afecţiuni de către medicii aflaţi în relaţie contractuală cu casele de asigurări de sănătate se realizează cu respectarea prevederilor fiecărui protocol terapeutic.

**#M6**

ART. 5

*Prescrierea, eliberarea şi decontarea medicamentelor corespunzătoare denumirilor comune internaţionale prevăzute în Lista cuprinzând denumirile comune internaţionale corespunzătoare medicamentelor de care beneficiază asiguraţii, cu sau fără contribuţie personală, pe bază de prescripţie medicală, în sistemul de asigurări sociale de sănătate, aprobată prin Hotărârea Guvernului nr. 720/2008, cu modificările şi completările ulterioare, în baza protocoalelor terapeutice, se realizează după cum urmează:*

*a) în conformitate cu prevederile Contractului-cadru privind condiţiile acordării asistenţei medicale în cadrul sistemului de asigurări sociale de sănătate, aprobat prin hotărâre a Guvernului, şi ale Normelor metodologice de aplicare a Contractului-cadru privind condiţiile acordării asistenţei medicale în cadrul sistemului de asigurări sociale de sănătate, aprobate prin ordin al ministrului sănătăţii şi al preşedintelui Casei Naţionale de Asigurări de Sănătate, pentru denumirile comune internaţionale cuprinse în lista menţionată mai sus, notate cu (\*\*) şi (\*\*\*) în sublista A, (\*\*), (\*\*\*) şi (\*\*\*\*) în sublista B, (\*\*), (\*\*\*) şi (\*\*\*\*) în secţiunea C1 a sublistei C şi (\*\*) în secţiunea C3 a sublistei C;*

*b) în conformitate cu prevederile Hotărârii Guvernului pentru aprobarea programelor naţionale de sănătate şi ale Normelor tehnice de realizare a programelor naţionale de sănătate, aprobate prin ordin al ministrului sănătăţii şi al preşedintelui Casei Naţionale de Asigurări de Sănătate, pentru denumirile comune internaţionale cuprinse în lista menţionată mai sus, notate cu (\*\*), (\*\*\*) şi (\*\*\*\*) în secţiunea C2 a sublistei C.*

**#B**

ART. 6

Protocoalele terapeutice vor fi revizuite periodic.

ART. 7

Direcţiile de specialitate ale Ministerului Sănătăţii Publice, Casa Naţională de Asigurări de Sănătate, autorităţile de sănătate publică, casele de asigurări de sănătate şi furnizorii de servicii medicale vor duce la îndeplinire prevederile prezentului ordin.

ART. 8

Prezentul ordin se publică în Monitorul Oficial al României, Partea I.

ANEXA 1

**#CIN**

***NOTĂ:***

*Partea I a anexei nr. 1 se găseşte în Ordinul ministrului sănătăţii publice şi al preşedintelui Casei Naţionale de Asigurări de Sănătate nr. 1301/500/2008 - Partea I.*

**#M15**

***DCI: NIVOLUMABUM***

***Indicaţie: Melanomul malign***

***I. Indicaţii:***

*Nivolumab este indicat în monoterapie pentru tratamentul melanomului în stadiu avansat (nerezecabil sau metastazat) la adulţi.*

***II. Criterii de includere***

*• Pacienţi cu vârsta mai mare de 18 ani*

*• Melanom avansat local şi/sau regional, inoperabil, sau metastazat, confirmat histologic*

*• Evaluarea extensiei bolii locale, regionale şi la distanţă (imagistică standard) pentru a certifica încadrarea în stadiile IIIC sau IV de boală*

*• Status de performanţă ECOG 0 - 2\**

*• Este permisă prezenţa metastazelor cerebrale, cu condiţia ca acestea să fie tratate şi stabile, fără corticoterapie de întreţinere mai mult de echivalentul a 10 mg prednison (ca doză de întreţinere)\**

***III. Criterii de excludere***

*• Hipersensibilitate la substanţă activă sau la oricare dintre excipienţi*

*• Pacienta însărcinată sau care alăptează*

*• Tratament anterior cu imunoterapie (antiPD1/antiPDL1 sau antiCTLA4 etc.)*

*• Prezenţa unei afecţiuni auto-imune, inclusiv diabet zaharat prin mecanism auto-imun; afecţiunile cutanate autoimune (vitiligo, psoriazis) care nu necesită tratament sistemic imunosupresor nu reprezintă contraindicaţie pentru nivolumab\**

*• Boala interstiţială pulmonară simptomatică\**

*• Insuficienţa hepatică severă\**

*• Hepatita virală C sau B în antecedente (boala prezentă, evaluabilă cantitativ - determinare viremie)\**

*• Pacientul urmează tratament imunosupresiv pentru o afecţiune concomitentă (inclusiv corticoterapie în doză zilnică mai mare decât echivalentul a 10 mg de prednison)\**

***\* Observaţie:*** *pentru pacienţii cu status de performanţă ECOG > 2, determinări secundare cerebrale netratate sau instabile neurologic, boală inflamatorie pulmonară pre-existentă, afecţiuni autoimune pre-existente, tratamente imunosupresoare anterioare, necesar de corticoterapie în doză mai mare de 10 mg de prednison pe zi sau echivalent, hepatită cronică cu virus B sau C tratată, controlată, cu viremie redusă semnificativ sau absenţa după tratamentul specific, insuficienţă hepatică severă, nu există date din trialurile clinice de înregistrare, nefiind înrolaţi în aceste studii clinice pivot. Deoarece nu există o alternativă terapeutică eficientă pentru indicaţia curentă (mai ales pentru pacienţii fără mutaţii la nivelul BRAF), nivolumab poate fi utilizat cu precauţie, chiar şi în absenţa datelor, pentru aceste grupe de pacienţi, după o analiză atentă a raportului risc potenţial-beneficiu, efectuată individual, pentru fiecare caz în parte.*

***IV. Tratament***

***Evaluare pre-terapeutică:***

*• Evaluare clinică şi imagistică pentru certificarea stadiilor IIIC şi IV*

*• Confirmarea histologică a diagnosticului*

*• Evaluare biologică: hemoleucogramă, GOT, GPT, lipază, amilază, TSH, T3, T4, glicemie, creatinină, uree, ionogramă serică, şi alţi parametrii în funcţie de decizia medicului curant*

***Doze, tehnică administrare, valabilitate:***

*•* ***Nivolumab în monoterapie:*** *doza recomandată este de 3 mg/kg administrat intravenos pe durata a 60 de minute la fiecare 2 săptămâni.*

*• Tratamentul cu nivolumab trebuie continuat atât timp cât se observă beneficii clinice sau până la apariţia unei toxicităţi inacceptabile.*

***Grupe speciale de pacienţi:***

*Pacienţii care urmează o dietă cu restricţie de sodiu - fiecare ml din acest medicament conţine sodiu 0,1 mmol (sau 2,5 mg). Acest lucru trebuie avut în vedere la pacienţii ce urmează o dietă cu restricţie de sodiu.*

*Copii şi adolescenţi - siguranţa şi eficacitatea Nivolumab la copii cu vârsta sub 18 ani nu au fost încă stabilite. Nu există date disponibile din trialurile clinice de înregistrare.*

*Pacienţi vârstnici - nu este necesară ajustarea dozelor la pacienţii vârstnici (>/= 65 de ani).*

*Insuficienţă renală - pe baza rezultatelor de farmacocinetică populaţională, nu este necesară ajustarea dozei la pacienţii cu insuficienţă renală uşoară sau moderată. Datele provenite de la pacienţii cu insuficienţă renală severă sunt limitate pentru a putea permite formularea unor concluzii referitoare la această grupă de pacienţi.*

*Insuficienţă hepatică - pe baza rezultatelor de farmacocinetică populaţională, nu este necesară ajustarea dozei la pacienţii cu insuficienţă hepatică incipientă. Datele provenite de la pacienţii cu insuficienţă hepatică moderată sau severă sunt limitate pentru a permite formularea unor concluzii referitoare la aceste grupe de pacienţi. Nivolumab trebuie administrat cu precauţie la pacienţii cu insuficienţă hepatică moderată (bilirubină totală > 1,5 - 3 x limita superioară a valorilor normale [LSVN] şi orice valoare a transaminazelor) sau severă (bilirubină totală > 3 x LSVN şi orice valoare a transaminazelor).*

***Modificarea dozei:***

*•* ***Nu se recomandă creşterea sau reducerea dozei****. Poate fi necesară* ***amânarea*** *sau* ***oprirea*** *administrării tratamentului în funcţie de profilul individual de siguranţă şi tolerabilitate.*

*• În funcţie de severitatea reacţiei adverse, tratamentul cu* ***nivolumab trebuie întrerupt temporar*** *şi administraţi corticosteroizi.*

*• Doza necesară de* ***metilprednisolon*** *administrat intravenos este de* ***1 - 4 mg/kgc****, în funcţie de tipul efectului secundar şi de intensitatea acestuia.*

*• Se va adăuga* ***terapie specifică fiecărui tip de efect secundar:*** *anti-diareice uzuale (loperamid, Smecta (R)), hidratare intravenoasă, substituţie de săruri (per os sau intravenos - soluţie Ringer) - pentru sindrom diareic, antibiotice - pentru pneumonită interstiţială, hepato-protectoare - pentru reacţia hepatitică etc.*

*• Se va adăuga* ***terapie cu rol imunosupresiv*** *diferită de corticoterapie în cazul în care se constată o agravare sau nu se observă nicio ameliorare în pofida utilizării corticosteroizilor.*

*• Conform recomandărilor de mai sus, corticoterapia sistemică şi alte terapii imunosupresoare pot fi utilizate după iniţierea administrării nivolumab în scopul tratării reacţiilor adverse mediate imun. Rezultatele preliminare arată că utilizarea terapiei imunosupresoare sistemice după iniţierea tratamentului cu nivolumab nu exclude răspunsul la nivolumab.*

***V. Monitorizarea tratamentului:***

*• Examen imagistic - examen CT efectuat regulat pentru monitorizarea răspunsului la tratament (la interval de 8 - 12 săptămâni) şi/sau alte investigaţii paraclinice în funcţie de decizia medicului (RMN, scintigrafie osoasă, PET-CT).*

*• Pentru a confirma etiologia reacţiile adverse mediate imun suspectate sau a exclude alte cauze, trebuie efectuată o evaluare adecvată şi se recomandă consult interdisciplinar.*

*• Pacienţii trebuie monitorizaţi continuu (timp de cel puţin 5 luni după administrarea ultimei doze) deoarece o reacţie adversă la imunoterapie poate apărea în orice moment în timpul sau după oprirea terapiei.*

***VI. Efecte secundare. Managementul efectelor secundare mediate imun***

***Cele mai frecvente reacţii adverse (>/= 10%; foarte frecvente):*** *fatigabilitatea (33%), erupţia cutanată (20%), pruritul (18%), diareea (16%) şi greaţa (14%), creşterea valorii AST, ALT, bilirubinei totale, creşterea valorii fosfatazei alcaline, creşterea valorii creatininei, limfopenie, trombocitopenie, anemie. Majoritatea reacţiilor adverse au fost de intensitate uşoară până la moderată (grad 1 sau 2).*

***Reacţii adverse frecvente (între 1% şi 10% incidenţă):*** *infecţii ale tractului respirator superior, reacţie la administrarea în perfuzie, hipotiroidism, hipertiroidism, hiperglicemie, hiponatremie, scăderea apetitului alimentar, neuropatie periferică, cefalee, ameţeli, hipertensiune arterială, pneumonită, dispnee, tuse, colită, stomatită, vărsături, durere abdominală, constipaţie, vitiligo, xeroză cutanată, eritem, alopecie, durere musculo-scheletică, artralgie, febră, edem (inclusiv edem periferic), creşterea valorii lipazei, creşterea valorii amilazei, neutropenie.*

***Reacţii adverse mai puţin frecvente (sub 1% incidenţă):*** *reacţie anafilactică, hipersensibilitate, insuficienţă suprarenaliană, hipopituitarism, hipofizită, tiroidită, cetoacidoză diabetică, diabet zaharat, sindrom Guillain-Barré, demielinizare, sindrom miastenic, neuropatie autoimună (inclusiv pareză a nervilor facial şi abducens), uveită, aritmie (inclusiv aritmie ventriculară), pancreatită, eritem polimorf, psoriazis, rozacee, nefrită tubulo-interstiţială, insuficienţă renală.*

***Efecte secundare (toxicitate) specifice - mediate imun***

***Pneumonită mediate imun*** *În cazul tratamentului cu nivolumab, s-au observat cazuri severe de pneumonită sau afecţiune pulmonară interstiţială, inclusiv decese. Se impune monitorizare pentru depistarea semnelor clinice şi radiologice şi a simptomelor sugestive pentru pneumonită: modificări radiologice (de exemplu, opacităţi focale cu aspect de sticlă de geam mat, infiltrate difuze), dispnee şi hipoxie. Trebuie excluse cauzele infecţioase şi cele asociate bolii.*

*• În cazul pneumonitei de grad 3 sau 4, tratamentul cu* ***nivolumab trebuie întrerupt permanent*** *şi trebuie iniţiată corticoterapia în doze echivalente cu* ***2 - 4 mg/kg/zi de metilprednisolon****.*

*• În cazul pneumonitei de grad 2 (cu simptomatologie), trebuie* ***amânată administrarea nivolumab*** *şi iniţiată corticoterapia în doze echivalente cu* ***1 mg/kg/zi de metilprednisolon****. După ameliorare, se poate relua administrarea nivolumab după întreruperea treptată a corticoterapiei. În cazul în care se observă o agravare sau nu se obţine nicio ameliorare în pofida iniţierii corticoterapiei, trebuie crescută doză de corticosteroid până la doze echivalente cu 2 - 4 mg/kg/zi de metilprednisolon şi tratamentul cu nivolumab trebuie întrerupt permanent.*

***Colită mediată imun*** *În cazul tratamentului cu nivolumab, s-au observat cazuri severe de diaree sau colită. Pacienţii trebuie monitorizaţi pentru depistarea diareei şi a altor simptome ale colitei, cum sunt durerea abdominală şi prezenţa de mucus sau sânge în materiile fecale. Trebuie excluse cauzele infecţioase şi cele asociate bolii.*

*• În cazul diareei sau al colitei de grad 4, trebuie întrerupt permanent tratamentul cu nivolumab şi trebuie iniţiată corticoterapia în doză echivalentă cu 1 - 2 mg/kg/zi de metilprednisolon.*

*• În cazul diareei sau al colitei de grad 3, trebuie amânată administrarea nivolumab şi iniţiată corticoterapia în doză echivalentă cu 1 - 2 mg/kg/zi de metilprednisolon. După ameliorare, se poate relua administrarea nivolumab după întreruperea treptată a corticoterapiei. În cazul în care se observă o agravare sau nu se obţine nicio ameliorare în pofida iniţierii corticoterapiei, tratamentul cu nivolumab trebuie întrerupt permanent.*

*• În cazul diareei sau al colitei de grad 2, trebuie amânată administrarea nivolumab. În cazul în care diareea sau colita sunt persistente, se utilizează corticoterapie în doză echivalentă cu 0,5 - 1 mg/kg/zi de metilprednisolon. După ameliorare, se poate relua administrarea nivolumab după întreruperea treptată a corticoterapiei, dacă a fost necesară. În cazul în care se observă o agravare sau nu se obţine nicio ameliorare în pofida iniţierii corticoterapiei, trebuie crescută doza de corticosteroid până la o doză echivalentă cu 1 - 2 mg/kg/zi de metilprednisolon şi tratamentul cu nivolumab trebuie întrerupt permanent.*

***Hepatită mediată imun*** *În cazul tratamentului cu nivolumab, s-au observat cazuri de hepatită severă. Pacienţii trebuie monitorizaţi pentru depistarea semnelor şi simptomelor sugestive pentru hepatită, cum sunt creşterea concentraţiilor plasmatice ale transaminazelor şi ale bilirubinei totale. Trebuie excluse cauzele infecţioase şi cele asociate bolii.*

*• În cazul creşterilor de grad 3 sau 4 ale concentraţiilor plasmatice ale transaminazelor sau bilirubinei totale, tratamentul cu nivolumab trebuie întrerupt permanent şi trebuie iniţiată corticoterapia în doză echivalentă cu 1 - 2 mg/kg/zi de metilprednisolon.*

*• În cazul creşterilor de grad 2 ale concentraţiilor plasmatice ale transaminazelor sau bilirubinei totale, trebuie amânată administrarea nivolumab. În cazul în care aceste valori crescute ale testelor de laborator persistă, trebuie utilizată corticoterapie în doză echivalentă cu 0,5 - 1 mg/kg/zi de metilprednisolon. După ameliorare, se poate relua administrarea nivolumab după întreruperea treptată a corticoterapiei, dacă a fost necesară. În cazul în care se observă o agravare sau nu se obţine nicio ameliorare în pofida iniţierii corticoterapiei, se cresc dozele de corticosteroid până la doze echivalente cu 1 - 2 mg/kg/zi de metilprednisolon şi tratamentul cu nivolumab trebuie întrerupt permanent.*

***Nefrită sau disfuncţie renală mediată imun*** *În cazul tratamentului cu nivolumab, s-au observat cazuri de nefrită severă sau de disfuncţie renală severă. Pacienţii trebuie monitorizaţi pentru depistarea semnelor şi simptomelor sugestive pentru nefrită şi disfuncţie renală. Majoritatea pacienţilor se prezintă cu creşteri asimptomatice ale concentraţiilor serice ale creatininei. Trebuie excluse cauzele asociate bolii.*

*• În cazul creşterilor de grad 4 ale concentraţiilor serice ale creatininei, tratamentul cu nivolumab trebuie întrerupt permanent şi trebuie iniţiată corticoterapia în doză echivalentă cu 1 - 2 mg/kg/zi de metilprednisolon.*

*• În cazul creşterilor de grad 2 sau 3 ale concentraţiilor serice ale creatininei, trebuie amânată administrarea nivolumab şi trebuie iniţiată corticoterapia în doză echivalentă cu 0,5 - 1 mg/kg/zi de metilprednisolon. După ameliorare, se poate relua administrarea nivolumab după întreruperea treptată a corticoterapiei. În cazul în care se observă o agravare sau nu se obţine nicio ameliorare în pofida iniţierii corticoterapiei, trebuie crescută doza de corticosteroid până la doze echivalente cu 1 - 2 mg/kg/zi de metilprednisolon şi tratamentul cu nivolumab trebuie întrerupt permanent.*

***Endocrinopatii mediate imun*** *În cazul tratamentului cu nivolumab, s-au observat endocrinopatii severe:* ***hipotiroidism, hipertiroidism, insuficienţă suprarenaliană, hipofizită, diabet zaharat sau cetoacidoză diabetică****. Pacienţii trebuie monitorizaţi pentru apariţia semnelor şi simptomelor endocrinopatiilor şi pentru modificări ale funcţiei tiroidiene (la începutul tratamentului, periodic pe parcursul tratamentului şi aşa cum este indicat pe baza evaluării clinice). Pacienţii pot avea stări de oboseală, cefalee, modificări ale stării mentale, dureri abdominale, modificări ale tranzitului intestinal şi hipotensiune arterială sau simptome nespecifice care pot fi asemănătoare altor cauze, precum metastaze cerebrale sau o afecţiune de fond. Semnele şi simptomele endocrinopatiilor trebuie considerate mediate imun, cu excepţia cazului în care a fost identificată o altă etiologie.*

*• În cazul hipotiroidismului simptomatic, trebuie amânată administrarea nivolumab şi trebuie iniţiată terapia de substituţie cu hormon tiroidian, după cum este necesar.*

*• În cazul hipertiroidismului simptomatic, trebuie amânată administrarea nivolumab şi trebuie iniţiat tratamentul cu metimazol, după cum este necesar. Corticoterapia în doză echivalentă cu 1 - 2 mg/kg/zi de metilprednisolon trebuie avută în vedere în cazul în care se suspectează inflamaţia acută a glandei tiroide. După ameliorare, se poate relua administrarea nivolumab după întreruperea treptată a corticoterapiei, dacă a fost necesară. Monitorizarea funcţiei tiroidiene trebuie continuată pentru a asigura utilizarea terapiei adecvate de substituţie hormonală.*

*• În cazul insuficienţei suprarenaliene simptomatice, trebuie amânată administrarea nivolumab şi trebuie iniţiată corticoterapia de substituţie fiziologică, după cum este necesar. Monitorizarea funcţiei glandelor suprarenale şi a concentraţiilor de hormon trebuie continuată pentru a asigura utilizarea terapiei adecvate de substituţie cu corticosteroid.*

*• În cazul hipofizitei simptomatice, trebuie amânată administrarea nivolumab şi trebuie iniţiată, după cum este necesar, terapia de substituţie hormonală. Corticoterapia în doză echivalentă cu 1 - 2 mg/kg/zi de metilprednisolon trebuie avută în vedere în cazul în care se suspectează inflamaţia acută a hipofizei. După ameliorare, se poate relua administrarea nivolumab după întreruperea treptată a corticoterapiei, dacă a fost necesară. Monitorizarea funcţiei hipofizare şi a concentraţiilor de hormoni trebuie continuată pentru a asigura utilizarea terapiei adecvate de substituţie hormonală.*

*• În cazul diabetului zaharat simptomatic, trebuie amânată administrarea nivolumab şi trebuie iniţiată, după cum este necesar, terapia de substituţie cu insulină. Monitorizarea glicemiei trebuie continuată pentru a asigura utilizarea adecvată a substituţiei cu insulină.*

***Erupţii cutanate mediate imun*** *În cazul tratamentului cu nivolumab, s-au observat erupţii cutanate severe care pot fi mediate imun.*

*• În cazul erupţiilor cutanate de grad 3, tratamentul cu nivolumab trebuie amânat,*

*• În cazul erupţiilor cutanate de grad 4 acesta trebuie întrerupt. Erupţiile cutanate severe trebuie tratate cu doze mari de corticosteroizi echivalente cu 1 - 2 mg/kg/zi de prednison. Trebuie precauţie atunci când se ia în considerare utilizarea nivolumab la pacienţii care au avut anterior o reacţie adversă cutanată severă sau care a pus viaţa în pericol în cazul tratamentului anterior cu alte medicamente imunostimulatoare antineoplazice.*

***Alte reacţii adverse mediate imun*** *La mai puţin de 1% dintre pacienţii trataţi cu doze diferite de nivolumab în studiile clinice care au vizat tipuri tumorale diferite, au fost raportate următoarele reacţii adverse:* ***pancreatită, uveită, demielinizare, neuropatie autoimună (inclusiv pareza nervilor facial şi abducens), sindrom Guillain-Barré, hipopituitarism şi sindrom miastenic****. În cazul reacţiilor adverse mediate imun suspectate, se impune evaluarea adecvată în vederea confirmării etiologiei sau a excluderii altor cauze. Pe baza severităţii reacţiei adverse, trebuie* ***amânată administrarea nivolumab şi administrată corticoterapie****. După ameliorare, se poate relua administrarea nivolumab după întreruperea treptată a corticoterapiei. Tratamentul cu nivolumab trebuie întrerupt permanent în cazul recidivei oricărei reacţii adverse mediate imun severe şi al oricărei reacţii adverse mediate imun care pune viaţa în pericol.*

***Reacţii legate de administrarea perfuziei*** *În studiile clinice, au fost raportate reacţii severe legate de administrarea perfuziei. În cazul unei reacţii severe legate de administrarea perfuziei, trebuie întreruptă perfuzia cu nivolumab şi administrat tratamentul medical adecvat. Pacienţii cu reacţii adverse uşoare sau moderate pot fi trataţi cu nivolumab sub supraveghere atentă.*

***VII. Criterii de întrerupere a tratamentului***

*•* ***Progresia obiectivă a bolii (examene imagistice şi clinice) în absenţa beneficiului clinic****. Cazurile cu progresie imagistică, fără deteriorare simptomatică, trebuie evaluate cu atenţie, având în vedere posibilitatea de apariţie a falsei progresii de boală, prin instalarea unui răspuns imunitar anti-tumoral puternic. În astfel de cazuri, nu se recomandă întreruperea tratamentului. Se va repeta evaluarea imagistică, după 8 - 12 săptămâni şi numai dacă există o nouă creştere obiectivă a volumului tumoral sau deteriorare simptomatică se va avea în vedere întreruperea tratamentului cu nivolumab.*

*• Tratamentul cu nivolumab trebuie* ***oprit definitiv în cazul reapariţiei oricărei reacţii adverse severe mediată imun*** *cât şi în cazul* ***unei reacţii adverse mediată imun ce pune viaţa în pericol*** *- în funcţie de decizia medicului curant, după informarea pacientului.*

*• Decizia medicului sau a pacientului*

***VIII. Prescriptori***

*Iniţierea se face de către medicii din specialitatea oncologie medicală. Continuarea tratamentului se face de către medicul oncolog.*

**#M15**

***DCI: VEMURAFENIBUM***

***Indicaţie: Melanomul malign***

***I. Indicaţii:***

*Vemurafenib este indicat în monoterapie pentru tratamentul pacienţilor adulţi cu melanom inoperabil sau metastatic, pozitiv la mutaţia BRAF V600*

***II. Criterii de includere***

*• Pacienţi cu vârsta mai mare de 18 ani*

*• Melanom avansat local şi/sau regional, inoperabil, sau metastazat, confirmat histologic*

*• Prezenţa mutaţiei BRAF V600; vemurafenib nu trebuie utilizat la pacienţii cu melanom malign cu alte tipuri de mutaţii BRAF (altele decât V600E sau V600K).*

***III. Criterii de excludere***

*• Hipersensibilitate la substanţă activă sau la oricare dintre excipienţi*

*• Sarcina şi alăptarea sunt contraindicaţii relative (vezi mai jos punctul IV)*

*• Tratament anterior cu alţi inhibitori BRAF*

***IV. Tratament***

***Evaluare pre-terapeutică:***

*• Evaluare clinică şi imagistică pentru demonstrarea stadiului inoperabil sau metastatic*

*• Confirmarea histologică a diagnosticului*

*• Statusul mutant al BRAF V600*

*• Examen dermatologic; orice leziune suspectă trebuie excizată şi evaluată histopatologic*

*• Examen ORL*

*• Examen ginecologic şi urologic*

*• Evaluare cardiologică, EKG, ionogramă serică (inclusiv magneziu seric) - datorită riscului de apariţie a prelungirii intervalului QT*

*• Evaluare biologică a cărei complexitate o stabileşte medicul curant de la caz la caz, dar obligatoriu transaminaze, bilirubină totală, fosfatază alcalină, ionogramă serică, inclusiv magneziu*

***Doze, administrare:***

*Doza recomandată de vemurafenib este de 960 mg (4 comprimate filmate de 240 mg) de două ori pe zi (echivalent cu o doză zilnică totală de 1920 mg). Vemurafenib poate fi administrat cu sau fără alimente, dar trebuie evitată administrarea consecventă a ambelor doze zilnice pe stomacul gol. Tratamentul cu vemurafenib trebuie continuat atât timp cât se observă beneficii clinice sau până la apariţia unei toxicităţi inacceptabile.*

*Vemurafenib este destinat administrării orale. Comprimatele trebuie înghiţite întregi, cu apă. Acestea nu trebuie mestecate sau sfărâmate. Se recomandă ca dozele de vemurafenib să fie luate la aceleaşi ore în fiecare zi, cu un interval de aproximativ 12 ore între doze.*

***Doze omise:***

*Dacă o doză este omisă, poate fi administrată cu până la 4 ore înainte de următoarea doză, pentru a se menţine regimul de administrare de două ori pe zi. Nu trebuie administrate ambele doze în acelaşi timp.*

*Dacă apar vărsături după administrarea vemurafenib, pacientul nu trebuie să utilizeze o doză suplimentară de medicament, dar tratamentul trebuie continuat ca de obicei.*

***Grupe speciale de pacienţi:***

*Copii şi adolescenţi - siguranţa şi eficacitatea vemurafenib la copii şi adolescenţi (< 18 ani) nu au fost încă stabilite. Nu sunt disponibile date clinice.*

*Pacienţi vârstnici - nu este necesară ajustarea dozelor la pacienţii vârstnici (> 65 de ani).*

*Insuficienţă renală - la pacienţii cu insuficienţă renală sunt disponibile date limitate. Nu poate fi exclus riscul de expunere crescută la pacienţii cu insuficienţă renală severă. Pacienţii cu insuficienţă renală severă trebuie atent monitorizaţi.*

*Insuficienţă hepatică - la pacienţii cu insuficienţă hepatică sunt disponibile date limitate. Deoarece vemurafenib este metabolizat la nivelul ficatului, pacienţii cu insuficienţă hepatică moderată sau severă pot prezenta expunere crescută şi trebuie atent monitorizaţi.*

*Alăptarea - nu se cunoaşte dacă vemurafenib se excretă în laptele uman. Nu poate fi exclus riscul pentru nou-născuţi/sugari. Luând în considerare beneficiul alăptării pentru copil şi beneficiul tratamentului pentru mamă, trebuie luată decizia fie a întreruperii alăptării, fie a întreruperii tratamentului cu vemurafenib.*

*Fertilitatea - nu au fost efectuate studii specifice cu vemurafenib la animale pentru a evalua efectul asupra fertilităţii. Cu toate acestea, în studii de toxicitate după doze repetate la şobolani şi câini, nu au fost înregistrate modificări histopatologice la nivelul organelor reproductive; vemurafenib poate reduce eficienţa contraceptivelor orale (hormonale).*

*Sarcina - vemurafenib nu trebuie administrat femeilor gravide decât dacă beneficiul posibil pentru mamă depăşeşte riscul posibil pentru făt. Medicamentul nu a avut efecte teratogene asupra embrionului/fătului la animale, experimental. În cazul în care pacienta rămâne însărcinată în timpul tratamentului cu vemurafenib, aceasta trebuie să fie informată cu privire la riscurile potenţiale pentru făt (medicamentul traversează bariera feto-placentară).*

***Asocierea cu alte medicamente:***

*a. Efectele vemurafenib asupra altor medicamente*

*- Vemurafenib creşte expunerea plasmatică a medicamentelor metabolizate predominant de CYP1A2 (de exemplu agomelatină, alosteron, duloxetină, melatonină, ramelteon, tacrină, tizanidină, teofilină)*

*- Vemurafenib scade expunerea plasmatică a medicamentelor metabolizate predominant de CYP3A4, incluzând contraceptivele orale.*

*- Dacă vemurafenib este administrat concomitent cu warfarina, este necesară precauţie şi trebuie monitorizat INR.*

*- Vemurafenib poate creşte expunerea plasmatică a medicamentelor care reprezintă substraturi pentru gp-P, fiind necesară prudenţă şi luată în considerare scăderea dozei şi/sau monitorizarea suplimentară a concentraţiei medicamentelor care sunt substraturi pentru gp-P (de exemplu digoxină, dabigatran etexilat, aliskiren).*

*b. Efectele altor medicamente asupra vemurafenib*

*- Farmacocinetica vemurafenib poate fi modificată de medicamente care inhibă sau influenţează gp-P (de exemplu verapamil, claritromicină, ciclosporină, ritonavir, chinidină, dronedaronă, amiodaronă, itraconazol, ranolazină).*

*- Administrarea concomitentă a inductorilor puternici ai gp-P, ai glucuronidării, ai CYP3A4 trebuie evitată (de exemplu rifampicină, rifabutină, carbamazepină, fenitoină sau sunătoare [hipericină]). Pentru a menţine eficacitatea vemurafenib, trebuie avut în vedere un tratament alternativ cu potenţial inductor mai mic.*

*- Administrare concomitentă cu ipilimumab a fost asociată cu creşteri asimptomatice de grad 3 ale valorilor transaminazelor (ALT/AST > 5 x LSN) şi bilirubinei (bilirubină totală > 3 x LSN). Pe baza acestor date preliminare, nu se recomandă administrarea concomitentă de ipilimumab şi vemurafenib.*

***Modificarea dozei în funcţie de gradul oricăror evenimente adverse (EA):***

***A. Grad 1 sau Grad 2 (tolerabil):***

*- se menţine doza de vemurafenib la 960 mg de două ori pe zi.*

***B. Grad 2 (intolerabil) sau Grad 3***

***a. Prima apariţie a oricărui EA de grad 2 sau 3***

*- Întrerupeţi tratamentul până la gradul 0 - 1. Reluaţi administrarea cu doza de 720 mg de două ori pe zi (sau 480 mg de două ori pe zi dacă doza a fost deja scăzută).*

***b. A 2-a apariţie a oricărui EA de grad 2 sau 3 sau persistenţa după întreruperea tratamentului***

*- Întrerupeţi tratamentul până la gradul 0 - 1. Reluaţi administrarea cu doza de 480 mg de două ori pe zi (sau întrerupeţi permanent dacă doza a fost deja scăzută la 480 mg de două ori pe zi).*

***c. A 3-a apariţie a oricărui EA de grad 2 sau 3 sau persistenţa după a 2-a reducere a dozei***

*- Întrerupeţi permanent.*

***C. Grad 4***

***a. Prima apariţie a oricărui EA de grad 4***

*- Întrerupeţi permanent sau temporar tratamentul cu vemurafenib până la gradul 0 - 1. Reluaţi administrarea cu doza de 480 mg de două ori pe zi (sau întrerupeţi permanent dacă doza a fost deja scăzută la 480 mg de două ori pe zi).*

***b. A 2-a apariţie a oricărui EA de grad 4 sau persistenţa oricărui EA de grad 4 după prima reducere a dozei***

*- Întrerupeţi permanent.*

***Observaţii:***

*- Prelungirii intervalului QTc poate necesita scăderea dozei, întreruperea temporară şi/sau oprirea tratamentului (prelungirea QTc dependenţa de expunere a fost observată într-un studiu clinic de faza II)*

*- Nu se recomandă ajustări ale dozei rezultând o doză mai mică de 480 mg de două ori pe zi.*

*- În cazul în care pacientul prezintă carcinom spinocelular (CSC), se recomandă continuarea tratamentului fără modificarea dozei de vemurafenib*

***V. Monitorizarea tratamentului:***

*• Examen imagistic - examen CT efectuat regulat pentru monitorizarea răspunsului la tratament (la interval de 8 - 12 săptămâni) şi/sau alte investigaţii paraclinice în funcţie de decizia medicului (RMN, scintigrafie osoasă, PET-CT).*

*• Examen ORL periodic (alături de evaluarea imagistică pentru surprinderea precoce a unui eventual al 2-lea cancer; în acelaşi scop, examen ginecologic şi urologic, la iniţierea tratamentului, la finalizarea acestuia sau ori de câte ori se impune din punct de vedere clinic*

*• Pacienţii trebuie monitorizaţi timp de minim 6 luni după finalizarea tratamentului, deoarece o a 2-a neoplazie malignă poate apărea atât în timpul cât şi după oprirea terapiei.*

*• Examen dermatologic periodic, ce va fi continuat încă 6 luni după finalizarea tratamentului cu vemurafenib*

*• EKG, ionogramă serică şi examen cardiologic - pentru excluderea riscului de apariţie a prelungirii intervalului QT.*

*• Examen oftalmologic pentru surprinderea precoce a toxicităţilor oftalmologice*

*• Transaminaze, bilirubină totală, fosfatază alcalină periodic*

***VI. Efecte secundare care impun întreruperea temporară sau definitivă a tratamentului şi/sau modificarea dozelor***

***Reacţie de hipersensibilitate*** *- au fost raportate reacţii grave de hipersensibilitate, incluzând anafilaxie, în timpul tratamentului cu vemurafenib. Reacţiile severe de hipersensibilitate pot include sindromul Stevens-Johnson, erupţie cutanată tranzitorie generalizată, eritem sau hipotensiune arterială. La pacienţii care prezintă reacţii severe de hipersensibilitate, tratamentul cu vemurafenib trebuie întrerupt permanent.*

***Reacţii dermatologice*** *- au fost raportate reacţii dermatologice severe, incluzând cazuri rare de sindrom Stevens-Johnson şi necroliză epidermică toxică. În perioada ulterioară punerii pe piaţă a medicamentului a fost raportată, în asociere cu tratamentul cu vemurafenib reacţia adversă la medicament însoţită de eozinofilie şi simptome sistemice (DRESS). La pacienţii care prezintă o reacţie dermatologică severă, tratamentul cu vemurafenib trebuie întrerupt permanent.*

***Potenţarea toxicităţii determinate de iradiere*** *- s-a raportat reapariţia leziunilor post-iradiere sau de sensibilizare la iradiere la pacienţii trataţi cu radioterapie anterior, în timpul sau după tratamentul cu vemurafenib. Majoritatea cazurilor au reprezentat leziuni la nivel cutanat, dar anumite cazuri, care au implicat leziuni la nivelul organelor viscerale, au condus la deces. Vemurafenib trebuie utilizat cu precauţie atunci când este administrat concomitent sau ulterior radioterapiei.*

***Prelungirea intervalului QT*** *- a fost observată prelungirea intervalului QT dependentă de expunere. Prelungirea intervalului QT poate determina un risc crescut de aritmii ventriculare, incluzând torsada vârfurilor. Tratamentul cu vemurafenib nu este recomandat la pacienţii cu tulburări electrolitice care nu pot fi corectate (incluzând magneziul), sindrom de QT prelungit sau care utilizează medicamente despre care se cunoaşte că prelungesc intervalul QT. Trebuie monitorizate electrocardiograma (ECG) şi valorile electroliţilor (ionograma serică incluzând magneziul) pentru toţi pacienţii înainte de începerea tratamentului cu vemurafenib, după o lună de tratament şi după modificarea dozei. Se recomandă monitorizarea ulterioară în special la pacienţii cu insuficienţă hepatică moderată sau severă lunar, în primele 3 luni de tratament, apoi la fiecare 3 luni sau mai des, aşa cum este indicat din punct de vedere clinic. Iniţierea tratamentului cu vemurafenib nu este recomandată la pacienţii cu QTc > 500 milisecunde (ms). Dacă în timpul tratamentului valoarea QTc depăşeşte 500 ms, tratamentul cu vemurafenib trebuie întrerupt temporar, tulburările electrolitice (incluzând magneziul) trebuie corectate şi factorii de risc cardiologici pentru prelungirea intervalului QT (de exemplu insuficienţă cardiacă congestivă, bradiaritmii) trebuie monitorizaţi. Reluarea tratamentului trebuie să aibă loc atunci când valoarea QTc scade sub 500 ms şi utilizând o doză mai mică. Dacă creşterea QTc atinge atât o valoare > 500 ms, cât şi o modificare faţă de valoarea pretratament > 60 ms, se recomandă întreruperea permanentă a tratamentului cu vemurafenib.*

***Carcinom cutanat cu celule scuamoase (cuSCC)*** *- soluţia terapeutică este excizia dermatologică şi continuarea tratamentului cu vemurafenib, fără ajustarea dozei.*

***Carcinom non-spinocelular (non-CSC)*** *- au fost raportate cazuri de non-CSC în cadrul studiilor clinice la pacienţii trataţi cu vemurafenib. Pacienţii trebuie supuşi unei examinări a capului şi gâtului, constând cel puţin din inspecţia vizuală a mucoasei orale şi palparea ganglionilor limfatici, înaintea iniţierii tratamentului şi la fiecare 3 luni în timpul tratamentului (examen ORL). În plus, pacienţii trebuie supuşi unei tomografii computerizate (CT) a toracelui înaintea tratamentului şi la fiecare 6 luni în timpul tratamentului. Înaintea şi la finalul tratamentului sau atunci când este indicat din punct de vedere clinic, se recomandă efectuarea unor examinări urologice şi ginecologice (pentru femei). Monitorizarea pentru non-CSC, descrisă mai sus, trebuie să continue timp de până la 6 luni sau până la iniţierea altei terapii antineoplazice. Rezultatele anormale trebuie tratate conform practicilor clinice curente.*

***Melanom primar, nou apărut*** *- aceste cazuri pot fi tratate prin excizie şi nu necesită modificarea tratamentului.*

***Alte afecţiuni maligne*** *- datorită mecanismului de acţiune, vemurafenib poate determina progresia afecţiunilor maligne asociate cu mutaţii RAS. Trebuie cântărite cu atenţie beneficiile şi riscurile înainte de administrarea vemurafenib la pacienţii cu o afecţiune malignă anterioară sau concomitentă asociată cu mutaţia genei RAS.*

***Afectare vizuală*** *- uveită, irită şi ocluzie a venei retiniene la pacienţii trataţi cu vemurafenib. Pacienţii trebuie monitorizaţi oftalmologic cu atenţie.*

***Pancreatită*** *- au fost raportate cazuri de pancreatită la pacienţii trataţi cu vemurafenib. În cazul unor dureri abdominale inexplicabile, acestea trebuie să fie investigate imediat prin evaluarea amilazei şi a lipazei serice precum şi prin teste imagistice. Pacienţii trebuie atent monitorizaţi după reluarea tratamentului cu vemurafenib în urma unui episod de pancreatită.*

***Leziuni hepatice*** *- S-au raportat cazuri de leziuni hepatice, inclusiv leziuni hepatice severe, asociate tratamentului cu vemurafenib. Valorile enzimelor hepatice (transaminazele şi fosfatază alcalină) şi ale bilirubinei trebuie măsurate înaintea iniţierii tratamentului şi monitorizate lunar în timpul tratamentului, sau aşa cum este indicat din punct de vedere clinic. Valorile anormale ale testelor de laborator trebuie corectate prin scăderea dozei, întreruperea tratamentului sau oprirea tratamentului.*

***Toxicitate renală*** *- au fost raportate cazuri de toxicitate renală asociată tratamentului cu vemurafenib, aceasta variind de la creşterea creatininei serice la nefrită interstiţială acută şi necroză tubulară acută. Valoarea creatininei serice trebuie măsurată înainte de începerea tratamentului şi monitorizată în timpul tratamentului, aşa cum este indicat din punct de vedere clinic.*

***Fotosensibilitate*** *- la pacienţii cărora li s-a administrat vemurafenib a fost raportată fotosensibilitate uşoară până la severă. Toţi pacienţii trebuie sfătuiţi să evite expunerea la soare în timpul tratamentului cu vemurafenib. În timpul tratamentului, atunci când sunt în aer liber, pacienţii trebuie sfătuiţi să poarte haine protectoare şi să utilizeze creme cu factor de protecţie mare împotriva razelor ultraviolete A (UVA)/ultraviolete B (UVB) şi balsam de buze (factor de protecţie solară >/= 30), pentru a fi protejaţi împotriva arsurilor solare. Pentru fotosensibilitate de grad 2 (intolerabilă) sau mai mare, se recomandă modificarea dozei*

***VII. Criterii de întrerupere a tratamentului***

*•* ***Progresia obiectivă a bolii (examene imagistice şi clinice) în absenţa beneficiului clinic****.*

*•* ***Toxicitate semnificativă*** *care impune întreruperea definitivă a tratamentului cu vemurafenib.*

*•* ***Decizia medicului*** *sau a* ***pacientului***

***VIII. Prescriptori***

*Iniţierea se face de către medicii din specialitatea oncologie medicală. Continuarea tratamentului se face de către medicul oncolog sau pe baza scrisorii medicale de către medicii de familie desemnaţi.*

**#M15**

***DCI: COMBINAŢII DABRAFENIBUM + TRAMETINIBUM)***

***Indicaţie: Melanomul malign***

***I. Indicaţii:***

*Dabrafenib, administrat în asociere cu trametinib, este indicat în tratamentul pacienţilor adulţi cu melanom inoperabil sau metastatic, pozitiv la mutaţia BRAF V600.*

***II. Criterii de includere***

*• Pacienţi cu vârsta mai mare de 18 ani*

*• Melanom avansat local şi/sau regional, inoperabil, sau metastazat, confirmat histologic*

*• Prezenţa mutaţiei BRAF V600*

*• Pacienţi cu determinări secundare cerebrale stabile din punct de vedere neurologic (determinări secundare cerebrale asimptomatice la momentul iniţierii tratamentului cu dabrafenib şi trametinib)*

***III. Criterii de excludere***

*• Hipersensibilitate la substanţă activă sau la oricare dintre excipienţi*

*• Pacienta care alăptează (sarcina este o contraindicaţie relativă - vezi mai jos punctul IV)*

*• Tratament anterior cu alţi inhibitori BRAF*

***IV. Tratament***

***Evaluare pre-terapeutică:***

*• Evaluare clinică şi imagistică pentru demonstrarea stadiului inoperabil sau metastatic*

*• Confirmarea histologică a diagnosticului*

*• Statusul mutant al BRAF V600*

*• Examen ORL*

*• Examen ginecologic şi urologic*

*• Evaluare cardiologică (datorită riscului de apariţie a insuficienţei ventriculare stângi, a scăderii FEVS sau a evenimentelor trombo-embolice)*

*• Evaluare biologică a cărei complexitate o stabileşte medicul curant de la caz la caz*

***Doze, tehnică administrare, valabilitate:***

*• Doza recomandată de* ***dabrafenib****, administrat în asociere cu trametinib, este de 150 mg (două capsule de 75 mg) de două ori pe zi (echivalentul unei doze zilnice totale de 300 mg).*

*• Doza recomandată de* ***trametinib****, administrat în asociere cu dabrafenib, este de 2 mg o dată pe zi.*

*• Tratamentul cu dabrafenib + trametinib trebuie continuat atât timp cât se observă beneficii clinice sau până când nu mai sunt tolerate de pacient.*

***Doze omise***

*În cazul omiterii unei doze de* ***dabrafenib****, aceasta nu trebuie să fie administrată dacă intervalul de timp până la următoarea doză programată este mai mic de 6 ore.*

*Dacă este omisă o doză de* ***trametinib****, când dabrafenib este administrat în asociere cu trametinib, se administrează numai doza de trametinib dacă mai sunt peste 12 ore până la următoarea doză.*

***Mod de administrare***

*Capsulele de dabrafenib trebuie înghiţite întregi, cu apă. Capsulele nu trebuie mestecate sau deschise şi nici amestecate cu alimente sau lichide din cauza instabilităţii chimice a dabrafenib. Dabrafenib trebuie luat cu minimum o oră înaintea unei mese sau la minimum două ore după masă. Dacă pacientul vomită după administrarea dabrafenib, nu trebuie să ia doza din nou, ci doza următoare programată.*

*Se recomandă ca dozele de dabrafenib să fie luate la aceleaşi ore în fiecare zi, cu un interval de aproximativ 12 ore între doze. Când dabrafenib şi trametinib sunt administrate concomitent, doza zilnică de trametinib trebuie administrată la aceeaşi oră în fiecare zi, fie cu doza de dimineaţă, fie cu doza de seară de dabrafenib.*

***Grupe speciale de pacienţi:***

*Copii şi adolescenţi - Siguranţa şi eficacitatea dabrafenib la copii şi adolescenţi (< 18 ani) nu au fost încă stabilite. Nu sunt disponibile date clinice. Studiile pe animale tinere au indicat reacţii adverse ale dabrafenib care nu au fost observate şi la animalele adulte. Nu există date disponibile din trialurile clinice de înregistrare.*

*Pacienţi vârstnici - nu este necesară ajustarea dozelor la pacienţii vârstnici (>/= 65 de ani).*

*Insuficienţă renală - Nu este necesară o ajustare a dozei la pacienţii cu insuficienţă renală uşoară sau moderată. Nu sunt disponibile date clinice pentru pacienţii cu insuficienţă renală severă, astfel încât nu poate fi stabilită o eventuală necesitate de modificare a dozei. Dabrafenib trebuie administrat cu precauţie la pacienţii cu insuficienţă renală severă când este administrat în monoterapie sau în asociere cu trametinib.*

*Insuficienţă hepatică - Nu este necesară o ajustare a dozei la pacienţii cu insuficienţă hepatică uşoară. Nu sunt disponibile date clinice pentru pacienţii cu insuficienţă hepatică moderată şi severă, astfel încât nu poate fi stabilită o eventuală necesitate de modificare a dozei. Metabolizarea hepatică şi secreţia biliară constituie principalele căi de eliminare a dabrafenib şi a metaboliţilor săi, astfel încât pacienţii cu insuficienţă hepatică moderată şi severă pot prezenta expunere crescută. Dabrafenib trebuie să fie administrat cu precauţie la pacienţii cu insuficienţă hepatică moderată şi severă când este administrat în monoterapie sau în asociere cu trametinib.*

*Pacienţi cu metastaze cerebrale - condiţia necesară pentru iniţierea tratamentului cu dabrafenib şi trametinib la aceşti pacienţi este ca aceştia să fie asimptomatici din punct de vedere al metastazelor cerebrale (fără manifestări neurologice, doza fixă de corticoterapie, fără nevoie de tratament depletiv). Pacienţii trebuie să prezinte un interval de minim 4 săptămâni de stabilitate din punct de vedere neurologic. Pot urma tratament cu anticonvulsivante dacă acesta a fost iniţiat cu mai mult de 4 săptămâni anterior şi nu a mai prezentat stări convulsivante în ultimele 4 săptămâni.*

*Sarcina - Dabrafenib nu trebuie administrat femeilor gravide decât dacă beneficiul posibil pentru mamă depăşeşte riscul posibil pentru făt. În cazul în care pacienta rămâne însărcinată în timpul tratamentului cu dabrafenib, aceasta trebuie să fie informată cu privire la riscurile potenţiale pentru făt.*

***Asocierea cu alte medicamente:***

*- Administrarea concomitentă a dabrafenib cu* ***warfarină*** *determină scăderea ratei de expunere a warfarinei. Atunci când dabrafenib este administrat concomitent cu warfarină şi la întreruperea tratamentului cu dabrafenib, este necesară precauţie şi trebuie avută în vedere monitorizarea INR*

*- Administrarea concomitentă a digoxinei cu dabrafenib poate determina scăderea expunerii digoxinei. Este necesară prudenţă şi se recomandă monitorizarea suplimentară a digoxinei când digoxina (substrat transportor) este utilizată concomitent cu dabrafenib şi la întreruperea tratamentului cu dabrafenib*

*- Dabrafenib este un substrat al enzimelor CYP2C8 şi CYP3A4. Asocierea cu inductori potenţi ai acestor enzime trebuie evitată pe cât posibil, deoarece aceşti agenţi pot diminua eficacitatea dabrafenib (de exemplu, rifampicină, fenitoină, carbamazepină, fenobarbital sau sunătoare)*

*- Medicamentele care constituie inhibitori puternici ai enzimelor CYP2C8 sau CYP3A4 pot să crească concentraţiile de dabrafenib. Este necesară precauţie atunci când dabrafenib este administrat împreună cu inhibitori puternici (de exemplu, ketoconazol, gemfibrozil, nefazodonă, claritromicină, ritonavir, saquinavir, telitromicină, itraconazol, voriconazol, posaconazol, atazanavir)*

*- Agenţii care măresc pH-ul gastric pot reduce biodisponibilitatea dabrafenib şi astfel trebuie să fie evitaţi pe cât posibil*

***Modificarea dozei:***

*Reguli generale pentru* ***modificări ale dozelor în funcţie de intensitatea evenimentelor adverse*** *- Grad (CTC-AE)\* pentru dabrafenib administrat în monoterapie sau în asociere cu trametinib:*

*Grad 1 sau grad 2 (tolerabil) - Continuaţi şi monitorizaţi tratamentul conform indicaţiilor clinice.*

*Grad 2 (intolerabil) sau grad 3 - Întrerupeţi tratamentul până la gradul de toxicitate 0 - 1 şi reduceţi cu un nivel doza la reluarea acestuia.*

*Grad 4 - Opriţi definitiv sau întrerupeţi terapia până gradul de toxicitate ajunge la 0 - 1 şi reduceţi doza cu un nivel la reluarea acestuia.*

***Reducerea dozei de dabrafenib administrat în monoterapie sau în asociere cu trametinib:***

*Doza iniţială - 150 mg de două ori pe zi*

*Prima reducere a dozei - 100 mg de două ori pe zi*

*A doua reducere a dozei - 75 mg de două ori pe zi*

*A treia reducere a dozei - 50 mg de două ori pe zi*

***Reducerea dozei de trametinib administrat în asociere cu dabrafenib***

*Doza iniţială - 2 mg o dată pe zi*

*Prima reducere a dozei - 1.5 mg o dată pe zi*

*A doua reducere a dozei - 1 mg o dată pe zi*

*A treia reducere a dozei - 1 mg o dată pe zi*

***V. Monitorizarea tratamentului:***

*• Examen imagistic - examen CT efectuat regulat pentru monitorizarea răspunsului la tratament (la interval de 8 - 12 săptămâni) şi/sau alte investigaţii paraclinice în funcţie de decizia medicului (RMN, scintigrafie osoasă, PET-CT).*

*• Examen ORL periodic (alături de evaluarea imagistică pentru surprinderea precoce a unui eventual al 2-lea cancer; în acelaşi scop, examen ginecologic şi urologic, la iniţierea tratamentului, la finalizarea acestuia sau ori de câte ori se impune din punct de vedere clinic)*

*• Pacienţii trebuie monitorizaţi timp de minim 6 luni după finalizarea tratamentului, deoarece o a 2-a neoplazie malignă poate apărea atât în timpul cât şi după oprirea terapiei.*

***VI. Efecte secundare care impun întreruperea temporară sau definitivă a tratamentului şi/sau modificarea dozelor***

***Carcinom cutanat cu celule scuamoase (cuSCC)*** *- soluţia terapeutică este excizia dermatologică şi continuarea tratamentului cu dabrafenib cu/fără trametinib, fără ajustarea dozei.*

***Melanom primar, nou apărut*** *- aceste cazuri pot fi tratate prin excizie şi nu necesită modificarea tratamentului.*

***O altă neoplazie malignă/recurentă non-cutanată*** *- pe parcursul tratamentului cu inhibitori BRAF poate să apară o a 2-a neoplazie: leucemie mielomonocitară cronică sau SCC non-cutanat al capului şi al gâtului; în timpul tratamentului cu dabrafenib în monoterapie pot să apară: adenocarcinom pancreatic, adenocarcinom al căilor biliare; în timpul tratamentului cu dabrafenib asociat cu trametinib pot să apară: cancer colorectal, cancer pancreatic. Datorită acestor riscuri este necesară o evaluare atentă, periodică, prin examen ORL, examen CT al toracelui şi abdomenului. Examen urologic sau ginecologic trebuie efectuate la iniţierea şi la finalizarea tratamentului sau atunci când este indicat clinic. Diagnosticarea unei a 2-a neoplazii cu mutaţie BRAF, impune întreruperea dabrafenib. Nu este necesară modificarea dozei de trametinib când acesta este administrat în asociere cu dabrafenib.*

***Hemoragie*** *- evenimente hemoragice, inclusiv evenimente hemoragice majore şi hemoragii letale, au avut loc la pacienţii cărora li s-a administrat asocierea de dabrafenib cu trametinib.*

***Afectare vizuală*** *- uveită, iridociclită şi irită la pacienţii trataţi cu dabrafenib în monoterapie şi în asociere cu trametinib. Nu sunt necesare modificări ale dozei atâta timp cât terapiile locale eficace pot controla inflamaţia oftalmică. Dacă uveita nu răspunde terapiei locale oftalmice, se întrerupe administrarea dabrafenib până la rezolvarea inflamaţiei oftalmice, apoi se reia administrarea dabrafenib la o doză redusă cu un nivel. Nu este necesară modificarea dozei de trametinib când acesta este administrat în asociere cu dabrafenib după stabilirea diagnosticului de uveită.*

***Pirexie*** *- a fost raportată febră în studiile clinice efectuate cu dabrafenib administrat în monoterapie şi în asociere cu trametinib. Pacienţii cu evenimente febrile neinfecţioase grave au răspuns bine la întreruperea dozei şi/sau scăderea dozei şi la tratamentul de susţinere. Nu este necesară modificarea dozei de trametinib când acesta este administrat în asociere cu dabrafenib.*

***Scădere FEVS/Insuficienţă ventriculară stângă*** *- s-a raportat că dabrafenib în asociere cu trametinib scade FEVS. Este un efect secundar cauzat de trametinib exclusiv. Nu este necesară modificarea dozei de dabrafenib când acesta este administrat în asociere cu trametinib.*

***Insuficienţă renală*** *- dacă creatinina este crescută, tratamentul cu dabrafenib trebuie să fie întrerupt după caz. Dabrafenib nu a fost studiat la pacienţii cu insuficienţă renală (creatinină > 1,5 x LSN), prin urmare, se recomandă prudenţă în acest context.*

***Evenimente hepatice*** *- se recomandă ca pacienţilor care primesc tratamentul cu trametinib să li se monitorizeze funcţiile hepatice la fiecare patru săptămâni timp de 6 luni după începerea tratamentului cu trametinib.*

***Boală pulmonară interstiţială (BPI)/Pneumonită*** *- dacă este administrat în asociere cu trametinib atunci tratamentul cu dabrafenib poate fi continuat la aceeaşi doză.*

***Erupţii cutanate tranzitorii*** *- nu este necesară modificarea dozei de dabrafenib sau trametinib.*

***Rabdomioliză*** *- nu este necesară modificarea dozei de dabrafenib.*

***Pancreatită*** *- pancreatita a fost raportată la un procent mai mic de 1% din subiecţii trataţi cu dabrafenib în monoterapie şi în asociere cu trametinib. În cazul unor dureri abdominale inexplicabile, acestea trebuie să fie investigate imediat prin teste care să includă măsurarea amilazei şi a lipazei serice. Pacienţii trebuie atent monitorizaţi după reluarea tratamentului cu dabrafenib în urma unui episod de pancreatită.*

***Tromboză venoasă profundă (TVP)/Embolie pulmonară (EP)*** *- dacă pacienţii prezintă simptome ale emboliei pulmonare sau tromboză venoasă profundă (dispnee, durere toracică sau umflare a braţelor sau picioarelor), trebuie să solicite imediat asistenţă medicală. Se va întrerupe definitiv administrarea trametinib şi dabrafenib în cazul apariţiei emboliei pulmonare care poate fi letală.*

***VII. Criterii de întrerupere a tratamentului***

*•* ***Progresia obiectivă a bolii (examene imagistice şi clinice) în absenţa beneficiului clinic****.*

*•* ***Toxicitate semnificativă*** *care impune întreruperea definitivă a tratamentului cu dabrafenib asociat sau nu cu trametinib.*

*• Decizia medicului sau a pacientului*

***VIII. Prescriptori***

*Iniţierea se face de către medicii din specialitatea oncologie medicală. Continuarea tratamentului se face de către medicul oncolog sau pe baza scrisorii medicale de către medicii de familie desemnaţi.*

**#M15**

***DCI: ICATIBANTUM***

***I. Definiţie***

*Angioedemul ereditar (AEE) este o boală genetică, rară, debilitantă şi cu potenţial letal.*

*Este cauzat, în majoritatea cazurilor, de deficienţa de C1-inhibitor esterază (C1-INH).*

*Clinic, AEE se manifestă prin episoade recurente de edem subcutanat dureros localizat, atacuri dureroase abdominale recurente şi obstrucţie a căilor respiratorii superioare.*

*Atacurile recurente dureroase abdominale mimează abdomenul acut chirurgical.*

*Edemul facial se complică în 30% din cazuri cu edem al căilor respiratorii superioare şi risc de asfixiere prin edem laringian. Mortalitatea pacienţilor netrataţi cu AEE este de aproximativ 30%.*

*Între atacuri pacientul este asimptomatic. Numărul atacurilor poate varia de la un atac pe an la 2 - 3 atacuri pe lună. Durata atacurilor este de 2 - 5 zile. Calitatea vieţii acestor pacienţi este profund alterată.*

***II. Diagnostic***

*Diagnosticul de AEE se suspicionează pe baza anamnezei familiale (pozitivă în 75% din cazuri, 25% fiind mutaţii spontane), a simptomelor caracteristice bolii şi este confirmat prin examenul de laborator.*

*Diagnosticul tipului 1 şi 2 de AEE se stabileşte prin valori scăzute sub 50% faţă de valoarea minimă a normalului a C1-INH activitate. În AEE de tip 1 C1-INH proteina este scăzută, iar în tipul 2 este normală sau crescută. Nu există diferenţe de manifestare clinică între cele două tipuri.*

***III. Indicaţii terapeutice***

*Icatibant este un antagonist de receptor de bradikinină B2 indicat pentru tratamentul atacului de angioedem ereditar prin deficienţă de C1 inhibitor esterază la pacienţii adulţi (peste vârsta de 18 ani).*

***IV. Criterii de includere în tratament***

*În programul naţional de tratament cu Icatibant al atacurilor de AEE se vor include exclusiv pacienţii adulţi (peste 18 ani) cu diagnosticul confirmat de AEE de către Centrul de Referinţă/Pilot de AEE şi înregistraţi în Registrul Naţional de AEE. Scrisoarea medicală eliberată de Centrul de Referinţă/Pilot va fi înnoită anual, cu ocazia vizitei anuale obligatorii.*

***V. Criterii de excludere din tratament***

*Nu beneficiază de tratament cu Icatibant pacienţii cu hipersensibilitate la substanţa activă sau excipienţii produsului.*

*Se recomandă precauţie la pacienţii cu boală cardiacă ischemică acută şi accident vascular cerebral recent.*

*Nu există date clinice disponibile privind utilizarea Icatibant la gravide şi lăuze. În timpul sarcinii Icatibant trebuie utilizat doar dacă beneficiul potenţial justifică riscul potenţial pentru făt (de exemplu, pentru tratamentul edemului laringian cu potenţial letal), în absenţa disponibilităţii concentratului de C1-INH.*

*Nu se cunoaşte dacă Icatibant se excretă în laptele matern, dar femeilor care alăptează şi doresc să utilizeze Icatibant li se recomandă să nu alăpteze 12 ore după tratament.*

*În rarele cazuri în care răspunsul la Icatibant nu este satisfăcător şi necesită repetarea exagerată a dozelor, este necesară revizuirea indicaţiei.*

***VI. Mod de administrare***

*Icatibant se administrează subcutanat, de preferinţă în zona abdominală.*

*Icatibant poate fi autoadministrat sau administrat de către persoana care asigură îngrijirea pacientului, după instruirea prealabilă de către medic sau asistent medical.*

*Se recomandă ca prima administrare şi prima autoadministrare să fie efectuată sub supraveghere medicală.*

*Pacientul va fi instruit cu privire la păstrarea corectă a medicamentului (între 2 şi 25°C).*

***VII. Doze***

*Doza recomandată este de 30 mg Icatibant administrat lent subcutanat (o seringă preumplută).*

*În unele cazuri, doza de Icatibant se poate repeta, doza maximă pe zi fiind de 3 seringi a 30 mg.*

***VIII. Monitorizarea tratamentului***

*O dată pe an tratamentul fiecărui pacient va fi vizat la Centrul de Referinţă prin evaluarea jurnalului, eliberat de Centrul de Referinţă/Pilot de AEE.*

*În caz de edem de căi respiratorii superioare (laringian) pacientul necesită supraveghere medicală atentă într-un serviciu de urgenţă timp de 24 de ore datorită impredictibilităţii evoluţiei severităţii obstrucţiei.*

*Intubarea traheală, traheotomia şi alte tratamente eficace în atacul de AEE (C1-INH esterază umană, recombinantă sau plasma proaspăt congelată) se iau în considerare în cazul edemului progresiv al căilor aeriene superioare care nu răspunde la Icatibant.*

***IX. Prescriptori***

*Icatibant este prescris de medicii din specialităţile alergologie, dermatologie, medicină internă şi medicii de familie, numai pe baza scrisorii medicale de la Centrul de Referinţă/Pilot de AEE.*

*Iniţial, pacientului cu mai multe atacuri pe an i se vor prescrie 3 seringi de Icatibant. Prescripţiile ulterioare se vor efectua individualizat prin dovedirea utilizării primelor două doze şi prin notarea de către pacient în jurnalul propriu a datei şi orei administrării, localizării atacului şi lipirea etichetei medicaţiei.*

**#M15**

***DCI: COMBINAŢII (INDACATEROLUM + GLICOPIRONIUM)***

***I. Indicaţie terapeutică:***

*BronhoPneumopatie Obstructivă Cronică (BPOC) pentru tratamentul bronhodilatator de întreţinere pentru ameliorarea simptomelor la pacienţii adulţi*

***II. Diagnostic:***

*Diagnostic de BPOC conform GOLD, îndeplinind toate criteriile de mai jos:*

*• spirometrie cu raport VEMS / CV < 0.70 post-bronhodilatator; la pacienţii cu comorbidităţi VEMS/CV sub limita inferioară a normalului*

*• istoric de expunere la factori de risc (fumat > 20 PA, inf. resp. recurente, expunere noxe/gaze)*

*• adult*

*• simptome respiratorii (evaluate şi cu chestionarul mMRC sau CAT-Tabel 2):*

*- dispnee*

*- şi/sau tuse cronică*

*- şi/sau producţie de spută*

*- senzaţie de constricţie toracică*

*• absenţa criteriilor de astm.*

***III. Criterii de includere:***

*1. Vârsta peste 18 ani*

*2. Diagnostic de BPOC documentat conform criteriilor de mai sus*

*3. Unul din (Tabel 1):*

*a) Grup GOLD B*

*- pentru pacienţii cu dispnee persistentă la terapia cu un sigur bronhodilatator cu lungă durată de acţiune (LAMA sau LABA)*

*- terapie de primă intenţie la pacienţii cu dispnee severă (evaluată pe scala mMRC de >/= 2)*

*b) Grup GOLD C*

*- pacienţii cu profil exacerbator persistent sub monoterapia cu LAMA (conform recomandărilor GOLD studiile clinice au arătat un efect superior în reducerea ratei de exacerbări LAMA versus LABA).*

*- înaintea terapiei combinate LABA/ICS pentru pacienţii exacerbatori sub terapia cu LAMA din cauza riscului de pneumonie asociat terapiei ICS*

*c) Grup GOLD D*

*- tratament de primă intenţie la pacienţii din grupul D*

*- tratament alternativ după reevaluarea schemei terapeutice la pacienţii trataţi anterior cu combinaţia LABA/ICS şi/sau LAMA/LABA/ICS*

***IV. Criterii de excludere:***

*- Apariţia semnelor de hipersensibilitate: reacţii alergice, angioedem (inclusiv dificultăţi la respiraţie sau înghiţire, umflare a limbii, buzelor şi feţei), urticarie sau erupţie cutanată*

*- Bronhospasm paradoxal*

*- Apariţia efectelor sistemice*

*- Efecte anticolinergice*

*- apariţia efectelor cardiovasculare: creşterea alurii ventriculare, a tensiunii arteriale, semn EKG (aplatizarea undei T, prelungirea intervalului QT, subdenivelarea segmentului QT)*

*- Hipokaliemia semnificativă care poate genera reacţii cardiovasculare*

*- Hiperglicemia semnificativă în special la pacienţii cu diabet zaharat*

*- Refuzul pacientului.*

***V. Tratament:***

*Doze: Doza recomandată este de indacaterol 85 µg şi glicopironiu 43 µg/capsulă, constând în inhalarea conţinutului unei capsule, o dată pe zi, la aceeaşi oră, utilizând inhalatorul Ultibro Breezhaler.*

*Durata: Tratamentul se administrează pe termen lung, în funcţie de eficacitate (stabilită în principal prin gradul de ameliorare al dispneei şi/sau reducerii numărului de exacerbări).*

***VI. Monitorizarea tratamentului:***

*Monitorizarea pacientului se face la 1 - 3 luni de la debutul medicaţiei pentru a evalua eficacitatea acesteia, dar şi tehnica inhalatorie adecvată, ulterior cel puţin anual.*

*Eficacitatea medicaţiei este evaluată pe baza evaluării clinice (subiective) a pacientului şi a unor scale de dispnee (CAT sau mMRC) (Tabel 2).*

*Modificarea parametrilor spirometrici nu contribuie la evaluarea eficienţei tratamentului.*

*Testul de mers de 6 minute ar putea constitui un element suplimentar de evaluare a eficacităţii tratamentului.*

***VII. Întreruperea tratamentului:***

*a. Decizia pacientului de a întrerupe tratamentul.*

*b. Decizia medicului de întrerupere a tratamentului în cazul intoleranţei, reacţiilor adverse sau efectului insuficient.*

***VIII. Contraindicaţii:***

*Hipersensibilitate la substanţele active (indacaterolum sau glicopironium) sau la oricare dintre excipienţi (lactoză monohidrat, stearat de magneziu)*

***IX. Prescriptori:***

*Tratamentul se iniţiază de medicii în specialitatea pneumologie sau medicină internă şi poate fi continuat şi de către medicul de familie în dozele şi pe durata recomandată în scrisoarea medicală.*

***Tabel nr. 1***

***A. Clasificarea BPOC în grupuri GOLD***

*Grupul A: Dispnee minoră (scor mMRC 0 - 1 şi/sau CAT < 10), fără risc de exacerbări (cel mult 1 exacerbare fără spitalizare în ultimul an)*

*Grupul B: Dispnee semnificativă (scor mMRC >/= 2 şi/sau CAT > 10), fără risc de exacerbări (cel mult 1 exacerbare fără spitalizare în ultimul an)*

*Grupul C: Dispnee minoră (scor mMRC 0 - 1 şi/sau CAT < 10), cu risc de exacerbări (minim 1 sau 2 exacerbări cu spitalizare în ultimul an)*

*Grupul D: Dispnee semnificativă (scor mMRC >/= 2 şi/sau CAT > 10), cu risc de exacerbări (minim 1 sau 2 exacerbări cu spitalizare în ultimul an)*

*Note:*

*BronhoPneumonia Obstructivă Cronică (BPOC) este o boală obişnuită ce poate fi prevenită/tratată, caracterizată prin simptome respiratorii persistente, limitarea fluxului de aer, datorate anomaliilor de căi aeriene/alveolare, ca urmare a expunerii îndelungate la noxe particulate sau gaze.*

*VEMS (volumul expirator maxim în prima secundă) folosit pentru diagnostic, prognostic şi evaluarea spirometrică GOLD pe clasele 1 - 4 este cel măsurat postbronhodilatator (i.e. la 20 - 30 minute după administrarea a 400 µg salbutamol inhalator, de preferinţă printr-o cameră de inhalare).*

*Exacerbarea este definită ca o agravare acută a simptomatologiei respiratorii din BPOC care determină terapia adiţională specifică.*

*Exacerbare severă este definită prin una din:*

*- spitalizare continuă pentru exacerbare BPOC*

*- prezentare la camera de gardă/UPU pentru exacerbare BPOC*

*Terapia de întreţinere cu bronhodilatatoare de lungă durată trebuie iniţiată cât mai curând posibil, înainte de externarea din spital.*

*LAMA (Long Acting Muscarinic Antagonist) = Anticolinergic cu durată lungă de acţiune*

*LABA (Long Acting β2-agonist) = β2-agonist cu durată lungă de acţiune*

*ICS (Inhaled Corticosteroid) = Corticosteroid inhalator*

***Tabel nr. 2***

***Scala mMRC pentru măsurarea dispneei***

*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

*| Grad | Descriere |*

*|\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|*

*| 0 | Am respiraţie grea doar la efort mare |*

*|\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|*

*| 1 | Am respiraţie grea când mă grăbesc pe teren plat sau când urc o pantă |*

*| | lină |*

*|\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|*

*| 2 | Merg mai încet decât alţi oameni de vârsta mea pe teren plat datorită |*

*| | respiraţiei grele, sau trebuie să mă opresc din cauza respiraţiei |*

*| | grele când merg pe teren plat în ritmul meu |*

*|\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|*

*| 3 | Mă opresc din cauza respiraţiei grele după ce merg aproximativ 100 de |*

*| | metri sau câteva minute pe teren plat |*

*|\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|*

*| 4 | Respiraţia grea nu îmi permite să ies din casă, sau am respiraţie |*

*| | grea când mă îmbrac sau mă dezbrac |*

*|\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|*

*Pacientul trebuie să aleagă varianta care se potriveşte cel mai bine situaţiei sale.*

*Unii pacienţi folosesc diferiţi termeni pentru respiraţie grea: respiraţie îngreunată, respiraţie dificilă, sufocare, oboseală etc.*

***A. Scala CAT pentru evaluarea simptomelor***

*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

*|* ***Pentru fiecare întrebare se marchează cu X cifra/celula care descrie cel mai*** *|*

*|* ***bine starea*** *|*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|*

*|* ***EXEMPLU:*** *| | |* ***SCOR*** *|*

*|* ***Mă simt foarte bine*** *| |* ***Mă simt foarte rău*** *| |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_|*

*| Nu tuşesc niciodată | \_ \_ \_ \_ \_ \_ | Pieptul meu este plin | |*

*| | (0)(1)(2)(3)(4)(5) | de mucus/secreţii | |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_|*

*| Nu am secreţii/mucus | \_ \_ \_ \_ \_ \_ | Îmi simt pieptul | |*

*| | (0)(1)(2)(3)(4)(5) | foarte încărcat | |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_|*

*| Nu îmi simt pieptul | \_ \_ \_ \_ \_ \_ | Obosesc atunci când urc| |*

*| încărcat deloc | (0)(1)(2)(3)(4)(5) | o pantă sau urc scările| |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_|*

*| Nu obosesc atunci când | \_ \_ \_ \_ \_ \_ | Mă simt foarte limitat | |*

*| urc o pantă sau urc | (0)(1)(2)(3)(4)(5) | în desfăşurarea | |*

*| scările | | activităţilor casnice | |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_|*

*| Nu sunt deloc limitat | \_ \_ \_ \_ \_ \_ | Nu mă simt încrezător | |*

*| în desfăşurarea | (0)(1)(2)(3)(4)(5) | să plec de acasă din | |*

*| activităţilor casnice | | cauza condiţiei mele | |*

*| | | pulmonare | |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_|*

*| Sunt încrezător să plec | \_ \_ \_ \_ \_ \_ | Nu pot dormi din cauza | |*

*| de acasă în ciuda | (0)(1)(2)(3)(4)(5) | condiţiei mele | |*

*| condiţiei mele pulmonare| | pulmonare | |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_|*

*| Am multă energie | \_ \_ \_ \_ \_ \_ | Nu am energie deloc | |*

*| | (0)(1)(2)(3)(4)(5) | | |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_|*

*|* ***Scorul Total*** *| |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_|*

**#M15**

***DCI: COMBINAŢII (TIOTROPIUM + OLODATEROLUM)***

***I. Indicaţie terapeutică:***

*BronhoPneumopatie Obstructivă Cronică (BPOC) pentru ameliorarea simptomelor, ca tratament bronhodilatator de întreţinere*

***II. Diagnostic:***

*Diagnostic de BPOC conform GOLD, îndeplinind toate criteriile de mai jos:*

*- spirometrie cu raport VEMS / CV < 0.70 post-bronhodilatator; la pacienţii cu comorbidităţi VEMS/CV sub limita inferioară a normalului*

*- istoric de expunere la factori de risc (fumat > 20 PA, inf. resp. recurente, expunere noxe/gaze)*

*- adult*

*- simptome respiratorii (evaluate şi cu chestionarul mMRC sau CAT-Tabel nr. 2):*

*• dispnee*

*• şi/sau tuse cronică*

*• şi/sau producţie de spută*

*• constricţie toracică*

*- absenţa criteriilor de astm*

***III. Criterii de includere:***

*1. Vârsta peste 18 ani*

*2. Diagnostic de BPOC documentat conform criteriilor de mai sus*

*3. Unul din (Tabel nr. 1):*

*a) Grup GOLD B*

*- pentru pacienţii cu dispnee persistentă la terapia cu un sigur bronhodilatator cu lungă durată de acţiune (LAMA sau LABA)*

*- terapie de primă intenţie la pacienţii cu dispnee severă (evaluată pe scala mMRC de >/= 2)*

*b) Grup GOLD C*

*- pacienţii cu profil exacerbator persistent sub monoterapia cu LAMA (conform recomandărilor GOLD studiile clinice au arătat un efect superior în reducerea ratei de exacerbări LAMA versus LABA).*

*- înaintea terapiei combinate LABA/ICS pentru pacienţii exacerbatori sub terapia cu LAMA din cauza riscului de pneumonie asociat terapiei ICS*

*c) Grup GOLD D*

*- tratament de primă intenţie la pacienţii din grupul D*

*- tratament alternativ după reevaluarea schemei terapeutice la pacienţii trataţi anterior cu combinaţia LABA/ICS şi/sau LAMA/LABA/ICS*

***IV. Criterii de excludere:***

*- Intoleranţă la Clorura de benzalconiu, Edetat disodic, Acid clorhidric 1M (pentru ajustarea nivelului de pH) sau la unul din medicamentele active.*

*- Refuzul pacientului.*

***V. Tratament:***

*Doze: Doza recomandată este de 5 mcg tiotropiu şi 5 mcg olodaterol, administrată sub forma a două pufuri eliberate din inhalatorul Respimat, o dată pe zi, la aceeaşi oră.*

*Durata: Tratamentul se administrează pe termen lung, în funcţie de eficacitate (stabilită în principal prin gradul de ameliorare al dispneei şi/sau reducerii numărului de exacerbări).*

***VI. Monitorizarea tratamentului:***

*Monitorizarea pacientului se face la 1 - 3 luni de la debutul medicaţiei pentru a evalua eficacitatea acesteia, dar şi tehnica inhalatorie adecvată, ulterior cel puţin anual.*

*Eficacitatea medicaţiei este evaluată pe baza evaluării subiective a pacientului şi a unor scale de dispnee (CAT sau mMRC) (Tabel nr. 2). Modificarea parametrilor spirometrici nu contribuie la evaluarea eficienţei tratamentului. Testul de mers de 6 minute ar putea constitui un element suplimentar de evaluare a eficacităţii.*

***VII. Întreruperea tratamentului:***

*a. Decizia pacientului de a întrerupe tratamentul.*

*b. Decizia medicului de întrerupere a tratamentului în cazul intoleranţei, reacţiilor adverse sau efectului insuficient*

***VIII. Contraindicaţii:***

*Hipersensibilitate la tiotropiu sau olodaterol sau la oricare dintre excipienţi*

***IX. Prescriptori:***

*Tratamentul se iniţiază de medicii în specialitatea pneumologie sau medicină internă şi poate fi continuat şi de către medicul de familie în dozele şi pe durata recomandată în scrisoarea medicală.*

***Tabel nr. 1***

***Clasificarea BPOC în grupuri GOLD***

*Grupul A: Dispnee minoră (scor mMRC 0 - 1 şi/sau CAT < 10), fără risc de exacerbări (cel mult 1 exacerbare fără spitalizare în ultimul an)*

*Grupul B: Dispnee semnificativă (scor mMRC >/= 2 şi/sau CAT > 10), fără risc de exacerbări (cel mult 1 exacerbare fără spitalizare în ultimul an)*

*Grupul C: Dispnee minoră (scor mMRC 0 - 1 şi/sau CAT < 10), cu risc de exacerbări (minim 1 sau 2 exacerbări cu spitalizare în ultimul an)*

*Grupul D: Dispnee semnificativă (scor mMRC >/= 2 şi/sau CAT > 10), cu risc de exacerbări (minim 1 sau 2 exacerbări cu spitalizare în ultimul an)*

*Note:*

*BronhoPneumonia Obstructivă Cronică (BPOC) este o boală obişnuită ce poate fi prevenită/tratată, caracterizată prin simptome respiratorii persistente, limitarea fluxului de aer, datorate anomaliilor de căi aeriene/alveolare, ca urmare a expunerii îndelungate la noxe particulate sau gaze.*

*VEMS (volumul expirator maxim în prima secundă) folosit pentru diagnostic, prognostic şi evaluarea spirometrică GOLD pe clasele 1 - 4 este cel măsurat postbronhodilatator (i.e. la 20 - 30 minute după administrarea a 400 µg salbutamol inhalator, de preferinţă printr-o cameră de inhalare).*

*Exacerbarea este definită ca o agravare acută a simptomatologiei respiratorii din BPOC care determină terapia adiţională specifică.*

*Exacerbare severă este definită prin una din:*

*- spitalizare continuă pentru exacerbare BPOC*

*- prezentare la camera de gardă/UPU pentru exacerbare BPOC*

*Terapia de întreţinere cu bronhodilatatoare de lungă durata trebuie iniţiată cât mai curând posibil, înainte de externarea din spital.*

*LAMA (Long Acting Muscarinic Antagonist) = Anticolinergic cu durata lungă de acţiune*

*LABA (Long Acting β2-agonist) = β2-agonist cu durata lungă de acţiune*

*ICS (Inhaled Corticosteroid) = Corticosteroid inhalator*

***Tabel nr. 2***

***Scala CAT pentru evaluarea simptomelor***

*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

*|* ***Pentru fiecare întrebare se marchează cu X cifra/celula care descrie cel mai*** *|*

*|* ***bine starea*** *|*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|*

*|* ***EXEMPLU:*** *| | |* ***SCOR*** *|*

*|* ***Mă simt foarte bine*** *| |* ***Mă simt foarte rău*** *| |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_|*

*| Nu tuşesc niciodată | \_ \_ \_ \_ \_ \_ | Pieptul meu este plin | |*

*| | (0)(1)(2)(3)(4)(5) | de mucus/secreţii | |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_|*

*| Nu am secreţii/mucus | \_ \_ \_ \_ \_ \_ | Îmi simt pieptul | |*

*| | (0)(1)(2)(3)(4)(5) | foarte încărcat | |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_|*

*| Nu îmi simt pieptul | \_ \_ \_ \_ \_ \_ | Obosesc atunci când urc| |*

*| încărcat deloc | (0)(1)(2)(3)(4)(5) | o pantă sau urc scările| |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_|*

*| Nu obosesc atunci când | \_ \_ \_ \_ \_ \_ | Mă simt foarte limitat | |*

*| urc o pantă sau urc | (0)(1)(2)(3)(4)(5) | în desfăşurarea | |*

*| scările | | activităţilor casnice | |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_|*

*| Nu sunt deloc limitat | \_ \_ \_ \_ \_ \_ | Nu mă simt încrezător | |*

*| în desfăşurarea | (0)(1)(2)(3)(4)(5) | să plec de acasă din | |*

*| activităţilor casnice | | cauza condiţiei mele | |*

*| | | pulmonare | |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_|*

*| Sunt încrezător să plec | \_ \_ \_ \_ \_ \_ | Nu pot dormi din cauza | |*

*| de acasă în ciuda | (0)(1)(2)(3)(4)(5) | condiţiei mele | |*

*| condiţiei mele pulmonare| | pulmonare | |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_|*

*| Am multă energie | \_ \_ \_ \_ \_ \_ | Nu am energie deloc | |*

*| | (0)(1)(2)(3)(4)(5) | | |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_|*

*|* ***Scorul Total*** *| |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_|*

***Scala mMRC pentru măsurarea dispneei***

*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

*| Grad | Descriere |*

*|\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|*

*| 0 | Am respiraţie grea doar la efort mare |*

*|\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|*

*| 1 | Am respiraţie grea când mă grăbesc pe teren plat sau când urc o pantă |*

*| | lină |*

*|\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|*

*| 2 | Merg mai încet decât alţi oameni de vârsta mea pe teren plat datorită |*

*| | respiraţiei grele, sau trebuie să mă opresc din cauza respiraţiei |*

*| | grele când merg pe teren plat în ritmul meu |*

*|\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|*

*| 3 | Mă opresc din cauza respiraţiei grele după ce merg aproximativ 100 de |*

*| | metri sau câteva minute pe teren plat |*

*|\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|*

*| 4 | Respiraţia grea nu îmi permite să ies din casă, sau am respiraţie |*

*| | grea când mă îmbrac sau mă dezbrac |*

*|\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|*

*Pacientul trebuie să aleagă varianta care se potriveşte cel mai bine situaţiei sale.*

*Unii pacienţi folosesc diferiţi termeni pentru respiraţie grea: respiraţie îngreunată, respiraţie dificilă, sufocare, oboseală etc.*

**#M15**

***DCI: FORMOTEROLUM***

***I. Indicaţie terapeutică:***

*Astmul Bronşic persistent, forme moderate şi severe, la pacienţi care necesită tratament cu bronhodilatatoare în combinaţie cu tratament de lungă durată cu medicamente antiinflamatorii (inhalatoare şi/sau glucocorticoizi).*

*BronhoPneumopatie Obstructivă Cronică (BPOC), unde este necesară terapia pe termen lung cu bronhodilatatoare.*

***II. Diagnostic:***

*A. Diagnostic de Astm Bronşic conform GINA, îndeplinind criteriile de mai jos:*

*- antecedente de simptome respiratorii variabile (apar variabil în timp şi variază în intensitate):*

*• wheezing (respiraţie şuierătoare întâlnită mai ales în cazul copiilor)*

*• dificultăţi de respiraţie*

*• constricţie toracică*

*• tuse*

*- şi minim unul dintre:*

*• spirometrie cu creşterea VEMS (volumul expirator maxim în prima secundă) postbronhodilatator (20 - 30 min. după 400 mcg de salbutamol inhalator) cu > 12% şi > 200 mL (ideal 400 mL);*

*• variabilitatea PEF de minimum 20% în minimum 3 zile din 7 pe o durată de minimum 2 săptămâni;*

*• hiperreactivitate bronşică la metacolină (PC 20 < 8 mg/ml);*

*B. Diagnostic de BPOC conform GOLD, îndeplinind toate criteriile de mai jos:*

*- spirometrie cu raport VEMS / CV < 0.70 post-bronhodilatator; la pacienţii cu comorbidităţi VEMS/CV sub limita inferioară a normalului*

*- istoric de expunere la factori de risc (fumat, inf. resp. recurente, expunere noxe/gaze)*

*- adult*

*- simptome respiratorii (evaluate şi cu chestionarul mMRC sau CAT)*

*• dispnee*

*• şi/sau tuse cronică*

*• şi/sau producţie de spută*

*• constricţie toracică*

*- absenţa criteriilor de astm*

***III. Criterii de includere:***

*1. Vârsta peste 12 ani (astm bronşic) şi peste 18 ani (BPOC)*

*2. Diagnostic de astm bronşic persistent, forme moderate şi severe, care necesită tratament cu bronhodilatatoare în combinaţie cu tratament de lungă durată cu medicamente antiinflamatorii (inhalatoare şi/sau glucocorticoizi).*

*3. BPOC unde este necesară terapia pe termen lung cu bronhodilatatoare*

***IV. Criterii de excludere:***

*- Tratament primar al astmului bronşic*

*- Exacerbări severe de astm bronşic*

*- Tulburări majore de ritm cardiac*

*- Vârstă sub 12 ani (copii)*

*- Refuzul pacientului*

***V. Tratament:***

*Doze: Dozele (prizele) recomandate, sub formă de soluţie de inhalat presurizată, se stabilesc în funcţie de tipul bolii şi gradul de severitate a bolii:*

*• Astm Bronşic.*

*Adulţi şi adolescenţi peste 12 ani: O priză dimineaţa şi una seara (24 micrograme formoterol fumarat pe zi). În cazuri severe, până la maxim două prize dimineaţa şi două seara (48 micrograme formoterol fumarat pe zi). Doza maximă zilnică este de 4 prize (48 micrograme formoterol fumarat pe zi).*

*• Bronhopneumopatie cronică obstructivă*

*Adulţi peste 18 ani: O priză dimineaţa şi una seara (24 micrograme formoterol fumarat pe zi).*

*Pacienţii nu trebuie să folosească inhalatorul mai mult de 3 luni de la data eliberării din farmacie!*

*Durata: Tratamentul se administrează pe termen lung, în funcţie de eficacitate (stabilită în principal prin gradul de ameliorare a simptomelor şi/sau reducerii numărului de exacerbări).*

***VI. Monitorizarea tratamentului:***

*Monitorizarea pacientului se face la 1 - 3 luni de la debutul medicaţiei pentru a evalua eficacitatea acesteia, dar şi tehnică inhalatorie adecvată, ulterior cel puţin anual.*

***VII. Întreruperea tratamentului:***

*a. Decizia pacientului de a întrerupe tratamentul.*

*b. Decizia medicului de întrerupere a tratamentului în cazul intoleranţei, reacţiilor adverse sau efectului insuficient.*

***VIII. Contraindicaţii:***

*Hipersensibilitate la fumarat de formoterol sau la oricare dintre excipienţi*

*Tulburări majore de ritm cardiac*

*Bronhospasm paradoxal*

*Hipokaliemie*

*Tratament cu IMAO, antidepresive triciclice sau blocanţii beta-adrenergici*

*În timpul sarcinii, în special în primele 3 luni.*

***IX. Prescriptori:***

*a) Pentru astmul bronşic: tratamentul se iniţiază de medicii în specialitatea pneumologie, alergologie, pediatrie sau medicină internă şi poate fi continuat şi de către medicul de familie în dozele şi pe durata recomandată în scrisoarea medicală,*

*b) Pentru BPOC: tratamentul se iniţiază de medicii în specialitatea pneumologie, medicină internă şi poate fi continuat şi de către medicul de familie în dozele şi pe durata recomandată în scrisoarea medicală.*

**#M15**

***DCI: COMBINAŢIE NAPROXENUM + ESOMEPRAZOLUM***

***I. Indicaţii:***

*Combinaţia naproxen + esomeprazol este indicată la adulţi în tratamentul simptomatic al pacienţilor cu osteoartrită, poliartrită reumatoidă şi spondilită anchilozantă cu risc de apariţie a ulcerului gastric şi/sau duodenal ca urmare a administrării medicamentelor antiinflamatoare nesteroidiene, în prezenţa a cel puţin unui factor de risc gastrointestinal.*

***II. Criterii de includere:***

*Factorii de risc pentru complicaţiile gastro-intestinale induse de antiinflamatoarele nonsteroidiene (AINS) sunt:*

*- antecedente de ulcer gastro-duodenal;*

*- vârsta > 65 ani;*

*- doza crescută de AINS;*

*- asocierea acidului acetilsalicilic (inclusiv în doză mică), a glucocorticoizilor sau a anticoagulantelor orale;*

*- infecţia cu Helicobacter Pylori.*

***III. Criterii de excludere***

*- Combinaţia naproxen + esomeprazol nu este adecvat pentru tratamentul durerii acute (de exemplu durere dentară, atac de gută).*

*- hipersensibilitate la substanţele active (naproxen, esomeprazol) sau la oricare dintre excipienţi sau la benzimidazol*

*- antecedente de astm bronşic, urticarie sau reacţii alergice induse de administrarea acidului acetilsalicilic sau a altor AINS*

*- gravide aflate în trimestrul al III-lea de sarcină*

*- insuficienţă hepatică severă (de exemplu Childs-Pugh C)*

*- insuficienţă renală severă (clearance creatinine < 30 ml/min)*

*- ulcer peptic activ*

*- hemoragii digestive, hemoragii cerebro-vasculare sau alte tulburări de coagulare*

*- tratamentul concomitent cu atazanavir şi nelfinavir*

***IV. Tratament***

*1 comprimat (500 mg/20 mg) administrat per os de 2 ori pe zi.*

***V. Monitorizare***

*Pacienţii trebuie strict monitorizaţi în scopul evaluării răspunsului terapeutic şi a eventualelor efecte adverse care pot apare în cursul tratamentului.*

***VI.*** *Prescriptori:*

*Iniţierea şi continuarea tratamentului se face de către medicii din specialităţile reumatologie, medicină internă, reabilitare medicală, ortopedie, geriatrie/gerontologie, medicina familiei.*

**#M16**

***DCI: VELAGLUCERASE ALFA***

***I. Indicaţii***

*Velaglucerase alfa este indicată pentru terapia specifică de substituţie enzimatică (TSE) pe termen lung, pentru pacienţii care prezintă boala Gaucher de tip 1.*

***II. Criterii de includere (prezenţa a cel puţin unuia dintre următoarele criterii):***

***a. Criteriile de includere în terapia pentru copiii sub 18 ani:***

*• Retard de creştere*

*• Hepatosplenomegalia simptomatică*

*• Hb < 10 g/dl*

*• trombocitopenia < 60.000/mm3*

*• neutrofile < 500/mm3 sau neutropenie simptomatică (asociată cu infecţii)*

*• boala osoasă simptomatică*

***b. Criteriile de includere în terapia pentru adulţi***

*• Hepatosplenomegalia masivă cu disconfort mecanic*

*• Pancitopenie acută*

*• Hb < 8,5 g/dl*

*• Trombocite < 60.000/mm3*

*• număr de neutrofile < 500/mm3 sau neutropenie simptomatică (asociată cu infecţii)*

*• Boala osoasă: fracturi patologice, crize osoase, necroză avasculară.*

***III. Criterii de excludere din terapie***

*• Lipsa de complianţă la tratament;*

*• Efecte secundare posibile ale terapiei: dureri osteoarticulare, abdominale, greaţă, cefalee, febră, tahicardie, urticarie, dispnee, dureri precordiale, angioedem, sinteză de anticorpi faţă de VPRIV.*

*• Absenţa unui răspuns terapeutic după o perioadă de 12 luni de tratament (60 U/kg la fiecare două săptămâni) constând în lipsa unei îmbunătăţiri sau înrăutăţirea semnelor clinice şi a parametrilor de laborator în baza cărora a fost indicat tratamentul:*

*a) splenomegalia;*

*b) hepatomegalia;*

*c) boala osoasă (clinic, DEXA, MRI, radiologic);*

*d) hemoglobina (g/dl);*

*e) numărul de trombocite (mii/mmc).*

***IV. Tratament***

*Doza recomandată este de 30 - 60 unităţi/kg (în funcţie de gradul de severitate a bolii), administrată la fiecare două săptămâni, în infuzie intravenoasă de 60 de minute, printr-un filtru de 0.22 µm.*

***Ajustările dozajului*** *pot fi făcute individual, în baza obţinerii şi menţinerii obiectivelor terapeutice de la 15 la 60 unităţi/kg la fiecare două săptămâni.*

*Pacienţii care au fost trataţi cu terapia de înlocuire cu enzima imiglucerază pentru boala Gaucher de tip 1 pot fi mutaţi pe tratamentul cu velaglucerase alfa (utilizând acelaşi dozaj şi aceeaşi frecvenţă), dacă opţiunea medicului pentru această decizie terapeutică este motivată de lipsa de răspuns la tratamentul cu Imiglucerasum conform criteriilor din protocolul pentru acest medicament.*

***V. Monitorizarea pacienţilor afectaţi de boala Gaucher***

***Obiective terapeutice***

*1. Anemia\*:*

*- hemoglobina trebuie să crească după 1 - 2 ani de TSE la:*

*>/= 11 g/dl (la femei şi copii);*

*>/= 12 g/dl (la bărbaţi)*

*2. Trombocitopenia\*:*

*- fără sindrom hemoragipar spontan;*

*- trombocitele trebuie să crească după 1 an de TSE:*

*de cel puţin 1,5 ori (la pacienţii nesplenectomizaţi);*

*la valori normale (la pacienţii splenectomizaţi)*

*3. Hepatomegalia\**

*- obţinerea unui volum hepatic = 1 - 1,5 x N 1)*

*- reducerea volumului hepatic cu: 20 - 30% (după 1 - 2 ani de TSE)*

*30 - 40% (după 3 - 5 ani de TSE)*

*4. Splenomegalia\**

*- obţinerea unui volum splenic </= 2 - 8 x N 2)*

*- reducerea volumului splenic cu: 30 - 50% (după primul an de TSE)*

*50 - 60% (după 2 - 5 ani de TSE)*

*5. Dureri osoase\**

*- absente după 1 - 2 ani de tratament*

*6. Crize osoase\**

*- absente*

*7. Ameliorare netă a calităţii vieţii*

*8. La copil/adolescent: - normalizarea ritmului de creştere*

*- pubertate normală*

*------------*

*\* International Collaborative Gaucher Group (ICGG): Gaucher Registry Annual Report 26.06.2014*

***Recomandări pentru monitorizarea pacienţilor cu boală Gaucher***

*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

*| |****Pacienţi fără*** *|****Pacienţi cu terapie de substituţie*** *|*

*| |****terapie de*** *|****enzimatică*** *|*

*| |****substituţie*** *|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|*

*| |****enzimatică*** *|Care NU au |Care au |În momentul |*

*| | |atins ţinta |atins ţinta|schimbării |*

*| | |terapeutică |terapeutică|dozei sau în |*

*| |\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_|prezenţa unei|*

*| |La |La |La |La |La |complicaţii |*

*| |fiecare|fiecare|fiecare|fiecare|fiecare |clinice |*

*| |12 luni|12 - 24|3 luni |12 - 24|12 - 24 |semnificative|*

*| | |luni | |luni |luni | |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_|*

*|****Hemoleucograma*** *| |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|*

*|****Hb*** *| X | | X | | X | X |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_|*

*|****Nr. trombocite*** *| X | | X | | X | X |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_|*

*|****Markeri biochimici*** *| X | | X | | X | X |*

*|****Chitotriozidaza****, sau| | | | | | |*

*|alţi markeri | | | | | | |*

*|disponibili | | | | | | |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_|*

*|****Evaluarea*** *| |*

*|****organomegaliei\**** *| |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|*

*|Volumul Splenic | | X | | X | X | X |*

*|(IRM/CT volumetric) | | | | | | |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_|*

*|Volumul Hepatic | | X | | X | X | X |*

*|(IRM/CT volumetric) | | | | | | |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_|*

*|****Evaluarea bolii*** *| |*

*|****osoase*** *| |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|*

*|1. IRM\*\* (secţiuni | | X | | X | X | X |*

*|coronale; T1 şi T2) | | | | | | |*

*|a întregului femur | | | | | | |*

*|(bilateral) | | | | | | |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_|*

*|2. Rgr.: - femur | | X | | X | X | X |*

*|(AP-bilateral) | | | | | | |*

*|- coloana vertebrală| | X | | X | X | X |*

*|(LL) | | | | | | |*

*|- pumn şi mână | X | | | X | X | X |*

*|(pentru pacienţi cu | | | | | | |*

*|vârsta egală sau | | | | | | |*

*|sub 14 ani) | | | | | | |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_|*

*|3. DEXA (de coloană | | X | | X | X | X |*

*|lombară şi de col | | | | | | |*

*|femural) | | | | | | |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_|*

*|5.* ***Ecocardiografie*** *| | X | | X | X | |*

*|****inclusiv măsurarea*** *| | | | | | |*

*|****PSDV*** *| | | | | | |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_|*

*|Teste bio-umorale\*\*\*| X | | | X | X | X |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_|*

*|****Calitatea vieţii*** *| |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|*

*|SF-36 Health Survey | X | | | X | X | X |*

*|(sănătate la nivel | | | | | | |*

*|funcţional şi stare | | | | | | |*

*|de bine) | | | | | | |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_|*

*\* organomegalia se va exprima atât în cmc cât şi în multiplu faţă de* ***valoarea normală*** *corespunzătoare pacientului: pentru* ***ficat*** *= [Gr. pacientului (gr) x 2,5]/100; pentru* ***splină*** *= [Gr. pacientului (gr) x 0,2]/100*

*\*\* IRM osos va preciza prezenţa şi localizarea următoarelor modificări: infiltrare medulară; infarcte osoase; necroza avasculară; leziuni litice. Este recomandat ca această examinare să fie făcută de acelaşi medic specializat în această direcţie, cu încadrare în grade de severitate Terk şi stadii Dusseldorf*

*\*\*\* TGP, TGO, colinesterază, G-GT, glicemie, colesterol (total, HDL, LDL), calciu, fosfor, fosfataza alcalină*

*NOTĂ:*

*Monitorizarea copiilor şi adulţilor cu boală Gaucher se face semestrial în centrele judeţene nominalizate şi anual în Centrul Naţional de Expertiză pentru Boli Lizozomale de la Spitalul de Urgenţă pentru Copii Cluj-Napoca.*

***VI. Prescriptori:*** *medicul din specialitatea gastroenterologie, hematologie, şi pediatrie.*

**#M16**

***DCI: ATALUREN***

***I. INDICAŢII TERAPEUTICE***

*Ataluren este indicat în tratamentul pacienţilor ambulatorii cu vârsta de 5 ani şi peste cu distrofie musculară Duchenne determinată de o mutaţie de tip nonsens la nivelul genei distrofinei. Tratamentul cu Ataluren se va adăuga tratamentului preexistent, incluzând tratamentul cu corticosteroizi, terapia fizică.*

*Pacienţii cu DMD, fără mutaţie nonsens, NU trebuie să primească ataluren.*

***Pacienţilor, părinţilor sau tutorilor legali (în funcţie de vârsta pacientului) trebuie să li se prezinte criteriile de includere şi excludere din tratamentul cu Ataluren, înainte de începerea tratamentului!***

***II. CRITERII DE INCLUDERE\****

*- VÂRSTA: pacienţi cu vârsta de 5 ani şi peste*

*- DIAGNOSTIC: distrofie musculară Duchenne, cauzată de o mutaţie nonsens la nivelul genei distrofinei (nmDMD) (Prezenţa unei mutaţii nonsens în gena distrofinei trebuie determinată prin testare genetică)*

*- ETAPA EVOLUTIVĂ: pacientul trebuie să aibă capacitate de deplasare păstrată (merge 10 paşi fără sprijin)*

*- CONSIMŢĂMÂNT INFORMAT: tratamentul va fi început numai după ce pacienţii/părinţii sau tutorii au semnat consimţământul informat privind administrarea medicamentului şi criteriile de includere, excludere şi oprire a tratamentului, precum şi acceptul de a se prezenta periodic la evaluările standardizate, înainte de începerea tratamentului*

*------------*

*\* Pentru includerea în programul de tratament, medicul Neurolog Pediatru sau Neurolog (pentru pacienţii peste 18 ani) din unul dintre Centrele de referinţă nominalizate în Protocol va întocmi dosarul pacientului, care va fi transmis medicului neurolog pediatru (inclusiv neuropsihiatri infantili) sau neurolog din teritoriu în vederea iniţierii tratamentului.*

***III. CRITERII DE EXCLUDERE***

*- VÂRSTA: sub 5 ani*

*- DIAGNOSTIC: pacienţii cu distrofie musculară Duchenne care nu prezintă o mutaţie nonsens nu trebuie să primească ataluren*

*- Pacienţi cu hipersensibilitate la substanţa activă sau la oricare dintre excipienţi*

*- ETAPA EVOLUTIVĂ: Pacienţi cu distrofie Musculară Duchenne care şi-au pierdut capacitatea de deplasare (nu merg 10 paşi fără sprijin)*

*- CONSIMŢĂMÂNT INFORMAT: refuzul semnării de către pacienţi/părinţi, tutori a consimţământului informat privind administrarea medicamentului şi criteriile de includere, excludere şi oprire a tratamentului, precum şi a acceptării de a se prezenta periodic la evaluările standardizate, înainte de începerea tratamentului*

***IV. CRITERII DE OPRIRE A TRATAMENTULUI***

*- Pacient necompliant la evaluările periodice (mai puţin de 2 prezentări în 14 luni)*

*- Dacă un pacient pierde ambulaţia (de ex. nu mai poate sta în picioare cu susţinere şi devine complet dependent de scaunul rulant) pentru toate activităţile din casă sau din afara casei (cauza pierderii ambulaţiei nefiind accident sau boală intercurentă), pentru o durată de timp mai mare de 6 luni, medicul trebuie să discute cu familia oprirea tratamentului cu ataluren. Tratamentul trebuie oprit nu mai târziu* ***de 6 luni*** *după ce a devenit non-ambulator. Urmărirea pacienţilor se va face în continuare conform standardelor de îngrijire europene. Pacienţii trebuie să vină în continuare la cel puţin 2 vizite de monitorizare în 14 luni.*

*- Renunţare a pacientului*

*- Întrerupere din cauza reacţiilor adverse.*

*Utilizarea concomitentă a aminoglicozidelor administrate intravenos este contraindicată.*

*Dacă este necesar tratamentul intravenos cu aminoglicozide, trebuie întrerupt tratamentul cu ataluren. Tratamentul se poate relua la 2 zile după administrarea aminoglicozidelor.*

***V. DOZE ŞI MOD DE ADMINISTRARE***

*Ataluren trebuie administrat pe cale orală în 3 doze, în fiecare zi.*

*Prima doză trebuie luată dimineaţa, a doua la prânz şi a treia seara. Intervalele recomandate dintre doze sunt de 6 ore între doza de dimineaţă şi cea de prânz, de 6 ore între doza de prânz şi cea de seară şi de 12 ore între doza de seară şi prima doză din ziua următoare.*

*Doza recomandată este de 10 mg/kg greutate corporală dimineaţa, de 10 mg/kg greutate corporală la prânz şi de 20 mg/kg greutate corporală seara (pentru obţinerea unei* ***doze totale zilnice de 40 mg/kg greutate corporală****).*

*Ataluren este disponibil sub formă de plicuri a câte 125 mg, 250 mg sau 1000 mg. În tabelul de mai jos sunt informaţiile privind concentraţia (concentraţiile) de substanţă din plic care trebuie utilizată (utilizate) pentru obţinerea dozei recomandate în raport cu intervalul de greutate corporală/zi.*

*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

*|Interval | Număr de plicuri |*

*|de |\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|*

*|greutate | Dimineaţa | Prânz | Seara |*

*|corporală|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|*

*|(kg) |Plicuri|Plicuri|Plicuri|Plicuri|Plicuri|Plicuri|Plicuri|Plicuri|Plicuri|*

*| |de |de |de |de |de |de |de |de |de |*

*| |125 mg |250 mg |1000 mg|125 mg |250 mg |1000 mg|125 mg |250 mg |1000 mg|*

*|\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|*

*| 12 | 14 | 1 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 |*

*|\_\_\_\_|\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|*

*| 15 | 16 | 1 | 0 | 0 | 1 | 0 | 0 | 1 | 1 | 0 |*

*|\_\_\_\_|\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|*

*| 17 | 20 | 0 | 1 | 0 | 0 | 1 | 0 | 0 | 1 | 0 |*

*|\_\_\_\_|\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|*

*| 21 | 23 | 0 | 1 | 0 | 0 | 1 | 0 | 1 | 1 | 0 |*

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*| 24 | 26 | 0 | 1 | 0 | 0 | 1 | 0 | 0 | 2 | 0 |*

*|\_\_\_\_|\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|*

*| 27 | 31 | 0 | 1 | 0 | 0 | 1 | 0 | 1 | 2 | 0 |*

*|\_\_\_\_|\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|*

*| 32 | 35 | 1 | 1 | 0 | 1 | 1 | 0 | 1 | 2 | 0 |*

*|\_\_\_\_|\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|*

*| 36 | 39 | 1 | 1 | 0 | 1 | 1 | 0 | 0 | 3 | 0 |*

*|\_\_\_\_|\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|*

*| 40 | 44 | 1 | 1 | 0 | 1 | 1 | 0 | 1 | 3 | 0 |*

*|\_\_\_\_|\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|*

*| 45 | 46 | 0 | 2 | 0 | 0 | 2 | 0 | 1 | 3 | 0 |*

*|\_\_\_\_|\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|*

*| 47 | 55 | 0 | 2 | 0 | 0 | 2 | 0 | 0 | 0 | 1 |*

*|\_\_\_\_|\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|*

*| 56 | 62 | 0 | 2 | 0 | 0 | 2 | 0 | 0 | 1 | 1 |*

*|\_\_\_\_|\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|*

*| 63 | 69 | 0 | 3 | 0 | 0 | 3 | 0 | 0 | 1 | 1 |*

*|\_\_\_\_|\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|*

*| 70 | 78 | 0 | 3 | 0 | 0 | 3 | 0 | 0 | 2 | 1 |*

*|\_\_\_\_|\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|*

*| 79 | 86 | 0 | 3 | 0 | 0 | 3 | 0 | 0 | 3 | 1 |*

*|\_\_\_\_|\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|*

*| 87 | 93 | 0 | 0 | 1 | 0 | 0 | 1 | 0 | 3 | 1 |*

*|\_\_\_\_|\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|*

*| 94 | 105| 0 | 0 | 1 | 0 | 0 | 1 | 0 | 0 | 2 |*

*|\_\_\_\_|\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|*

*|106 | 111| 0 | 0 | 1 | 0 | 0 | 1 | 0 | 1 | 2 |*

*|\_\_\_\_|\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|*

*|112 | 118| 0 | 1 | 1 | 0 | 1 | 1 | 0 | 1 | 2 |*

*|\_\_\_\_|\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|*

*|119 | 125| 0 | 1 | 1 | 0 | 1 | 1 | 0 | 2 | 2 |*

*|\_\_\_\_|\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|*

***Mod de administrare:***

*Ataluren trebuie administrat pe cale orală după amestecarea medicamentului, pentru a se obţine o suspensie, într-un lichid sau în alimente semi-solide. Plicurile trebuie deschise numai în momentul pregătirii dozei. Întregul conţinut din fiecare plic trebuie amestecat cu cel puţin 30 ml de lichid (apă, lapte, suc de fructe) sau cu 3 linguri de aliment semi-solid (iaurt sau sos de mere). Doza pregătită trebuie omogenizată bine înainte de administrare. Cantitatea de lichid sau de aliment semi-solid poate fi crescută după preferinţa pacientului. Pacienţii trebuie să ia doza în întregime.*

***VI. MONITORIZAREA PACIENŢILOR ÎN CADRUL PROGRAMULUI DE TRATAMENT CU ATALUREN***

***La includerea în Programul de tratament cu ataluren se documentează următoarele:***

*- Rezultatul analizei genetice care confirmă mutaţia nonsens la nivelul genei distrofinei*

*- Creatinina serică, azot ureic sanguin şi monitorizarea cistatinei C*

*- Colesterolul total, LDL, HDL şi trigliceridele*

*- Evaluare clinică conform Fişei de evaluare clinică iniţială*

***Monitorizarea pacientului pe parcursul tratamentului cu ataluren:***

*- În luna a 3-a şi luna a 9-a a fiecărui an de tratament de către medicul curant*

*- În luna a 6-a şi luna a 12-a a fiecărui an de tratament într-unul din Centrele de referinţă pentru boli neuro-musculare*

*Evaluarea va cuprinde:*

*- Evaluare clinică conform fişei clinice de monitorizare (Fişa de evaluare clinică follow-up) la fiecare 3 luni, conform standardului de îngrijire*

*- la interval de la 6 luni:*

*- creatinina serică, azot ureic sanguin şi monitorizarea cistatinei C*

*- tensiunea arterială sistolică şi distolică în stare de repaus la bolnavii cu nmDMD care primesc Ataluren concomitent cu corticosteroizi*

*- la interval de 12 luni: colesterolul total, LDL; HDL; trigliceride*

***VII. PRESCRIPTORI:***

*Medici din specialitatea neurologie şi neurologie pediatrică (inclusiv neuropsihiatrii infantili) cu experienţă în diagnosticul şi controlul terapeutic al distrofiei musculare Duchenne la copii şi adulţi.*

*1. Dosarul pacientului pentru iniţierea tratamentului este realizat în Centrul de referinţă. Acesta se trimite împreună cu pacientul în centrele de referinţă de boli neuro-musculare.*  ***Se completează fişa clinică de evaluare iniţială.***

*2. Recomandarea pentru iniţierea tratamentului se face de către medicii din centrele de referinţă de boli neuromusculare după evaluarea pacientului, întocmirea dosarului de iniţiere* ***pentru confirmarea diagnosticului de certitudine****. Se menţionează perioada pentru care va fi prescris tratamentul şi care nu va fi mai mare de 6 luni.*

*3. Dosarul pacientului se transmite în copie medicului din teritoriu în vederea iniţierii tratamentului - completarea Formularului specific în conformitate cu prevederile legale în vigoare şi emiterea prescripţiei medicale electronice pe perioade de maxim 30/31 de zile.*

*4. Eliberarea medicamentului se face prin furnizorii de medicamente, respectiv farmaciile cu circuit deschis.*

*5. În luna a 6-a şi luna a 12-a a fiecărui an de tratament se face evaluare multidisciplinară în centrul de referinţă conform standard of care. Medicul curant va transmite centrului de referinţă o copie după evaluarea la 3 luni, respectiv după evaluarea la 9 luni. Centrul de referinţă transmite medicului curant recomandarea de continuare a medicaţiei pentru 6 luni sau recomandarea de întrerupere a tratamentului.*

*MENŢIUNE - medicul curant din teritoriu va monitoriza pacientul şi va păstra legătura cu familia; dacă apare un eveniment (de exemplu pierderea ambulaţiei pe o perioadă de 0 - 6 luni sau eveniment advers major sau reacţie alergică la medicamente - a se vedea criteriile de excludere sau de oprire a medicaţiei - va semnala acest lucru şi va trimite pacientul la Centrul de referinţă pentru reevaluare. În caz de deces al pacientului - medicul curant va anunţa imediat centrul de referinţă.*

***Centre de referinţă pentru boli neuromusculare***

*• Spitalul Clinic de Psihiatrie "Prof. dr. Al. Obregia" Bucureşti - Secţia clinică de neurologie pediatrică*

*• Spitalul Clinic de Copii "Dr. V. Gomoiu" Bucureşti - Secţia clinică de neurologie pediatrică*

*• Spitalul Universitar de Urgenţă Bucureşti - Clinica Neurologie (pentru pacienţii ajunşi la vârsta adultă)*

***DOSARUL DE INIŢIERE A TRATAMENTULUI VA CONŢINE URMĂTOARELE DOCUMENTE:***

*• datele de identificare (copii după certificat de naştere, carte de identitate)*

*• Fişa clinică de evaluare iniţială*

*• Consimţământul informat al părintelui (tutorelui legal) al copilului sau al pacientului (dacă are vârsta peste 18 ani)*

*• buletin de testare genetică care să ateste distrofiei musculare Duchenne\*) cu mutaţie genetică nonsens, semnată şi parafată de un medic specialist genetician*

*• buletinele investigaţiilor paraclinice şi a explorărilor funcţionale prevăzute în Fişa clinică de evaluare iniţială*

**#CIN**

***\*)*** *Sintagma "care să ateste distrofiei musculare Duchenne" nu este corectă din punct de vedere gramatical, însă ea este reprodusă exact în forma în care a fost publicată la pagina 132 din Monitorul Oficial al României, Partea I, nr. 409 bis din 31 mai 2017.*

**#M16**

ANEXA 1

*Centrul de referinţă pentru boli neuromusculare ...............................*

***Fişa clinică de evaluare iniţială în vederea includerii în tratament cu Ataluren a pacienţilor cu Distrofie musculară progresivă tip Duchenne/Becker***

***Nume***

***Prenume***

***Data evaluării***

***Diagnostic***

***Data naşterii***

***Adresa***

***Telefon***

***Nume mama***

***Nume tata***

***Fraţi (nume, vârsta)***

***Surori (nume, vârsta)***

***Arbore genealogic***

***Antecedente heredocolaterale de boală musculară***

***Antecedente fiziologice***

***DPM***

***Vârsta la care a fost diagnosticat***

***Instituţia unde a fost diagnosticat***

***ISTORIC***

*- motivul prezentării la medic*

*- Elementele de debut pot fi:*

*• deficit muscular*

*• hipertrofie musculară*

*• mers pe vârfuri*

*• mialgii/crampe*

*• mioglobinuria*

*• disfuncţie cognitive*

*• întârziere în dezvoltarea psihomotorie*

*• CK crescute asimptomatic*

*• Complicaţii la anestezie*

*• Diagnostic prenatal*

***EXAMEN CLINIC:***

***• Greutate***

***• Înălţime***

***• Perimetru cranian***

***• evaluarea forţei musculare:*** *se va folosi scala de evaluare de la 0 - 5*

*(Medical Research Council of Great Britain)*

*0 - nu se detectează activitate musculară*

*1 - o contracţie foarte greu detectabilă*

*2 - mişcările se pot efectua doar în planul gravitaţional*

*3 - mişcări antigravitaţionale posibile, dar nu împotriva rezistenţei*

*4 - mişcări împotriva rezistenţei dar cu forţă mai mică decât normal*

*5 - forţă normală*

*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

*|* ***Mers*** *| |*

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*|* ***Manevra Gowers*** *| |*

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*|* ***Forţa musculară segmentară*** *|* ***Stânga*** *|* ***Dreapta*** *|*

*|* ***Centura pelvină*** *|\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_|*

*| |* ***Poziţie şezândă*** *|*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|*

*|* ***Flexia coapsei*** *| | |*

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*|* ***Extensia gambei*** *| | |*

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*|* ***Flexia dorsală*** *| | |*

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*|* ***Eversia plantei*** *| | |*

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*|* ***Inversia plantei*** *| | |*

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*| |* ***Decubit ventral*** *|*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|*

*|* ***Extensia coapsei*** *| | |*

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*|* ***Flexia gambe*** *| | |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_|*

*|* ***Flexia plantară a piciorului*** *| |*

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*|* ***Decubit lateral*** *|*

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*|* ***Abducţia coapsei*** *| |*

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*|* ***Forţa musculară centura scapulară*** *|* ***Poziţie şezândă*** *|*

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*|* ***Abducţia umăr*** *| | |*

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*|* ***Flexia cot (antebraţ)*** *| | |*

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*|* ***Flexia mâinii*** *| | |*

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*|* ***Extensia mâinii*** *| | |*

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*|* ***Abducţia policelui*** *| | |*

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*| |* ***Decubit ventral*** *|*

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*|* ***Rotaţia externă umăr*** *| | |*

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*| |* ***Decubit dorsal*** *|*

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*|* ***Extensia antebraţ*** *| | |*

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*| |* ***Decubit ventral*** *|*

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*|* ***Extensia gât*** *| | |*

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*| |* ***Decubit dorsal*** *|*

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*|* ***Flexia gât*** *| | |*

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*|* ***ROT membre superioare*** *| | |*

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*|* ***ROT membre inferioare*** *| | |*

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*|* ***Hipertrofie muşchi*** *| |*

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*|* ***Atrofii*** *| |*

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*|* ***Tulburări trofice (contracturi)*** *| |*

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*|* ***Scolioza*** *| |*

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***• Evaluare funcţională:***

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*|* ***Umeri şi membre superioare*** *| |*

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*| 1. Plecând de la postura de ortostatism cu braţele pe lângă corp, | |*

*| pacientul poate face abducţia braţelor în formă de cerc, ca să se | |*

*| atingă deasupra capului | |*

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*| 2. Poate ridica braţele deasupra capului doar cu coatele în flexie | |*

*| sau folosind muşchii accesori | |*

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*| 3. Nu poate ridica mâinile deasupra capului dar poate duce la gură | |*

*| un pahar cu apă de 250 ml (folosind ambele mâini dacă este necesar)| |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_|*

*| 4. Poate duce mâinile la gură dar nu poate duce la gură un pahar cu| |*

*| apă de 250 ml | |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_|*

*| 5. Nu poate ridica mâinile la nivelul gurii dar le poate folosi | |*

*| pentru a ţine un stilou sau pentru a-l ridica de pe masă | |*

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*| 6. Nu poate duce mâinile la gură şi nici nu le poate folosi în | |*

*| scopuri funcţionale | |*

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*|* ***Şolduri şi membre inferioare*** *| |*

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*| 1. Merge şi urcă scările fără ajutor | |*

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*| 2. Merge şi urcă scările cu ajutorul braţelor | |*

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*| 3. Merge şi urcă scările încet cu ajutorul braţelor | |*

*| Urcă patru trepte în mai mult de 4 secunde | |*

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*| 4. Merge fără ajutor şi se poate ridica de pe scaun dar nu poate | |*

*| urca scările | |*

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*| 5. Merge fără ajutor dar nu se poate ridica de pe scaun şi nu poate| |*

*| urca scările | |*

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*| 6. Merge doar cu ajutor | |*

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*| 7. Este imobilizat în scaunul cu rotile | |*

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*| 8. Este imobilizat la pat | |*

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***• Evaluare funcţională (timp în sec.)***

*- se ridică din decubit ventral*

*- aleargă 9 m*

*- urcă 4 trepte (cu ajutorul balustradei sau nu)*

***• Test mers timp de 6 minute (în metri)***

***• Evaluarea funcţională va fi completată cu Scala de evaluare a funcţiei motorii North Star Ambulatory Assessment (pentru comparaţie cu studii europene în desfăşurare) - existentă în anexă***

***• Examen psihologic:***

*- QI*

*- Tulburări de vorbire*

*- Tulburări de comportament*

*- ADHD*

*- Autism*

*- Tulburare pervazivă de dezvoltare*

*- Tulburare depresivă*

*- Tulburare de învăţare*

*- Întârziere mintală*

***• Tulburări de somn***

***EXAMENE PARACLINICE***

***- Teste genetice***

*• ca prim test diagnostic*

*• al doilea test diagnostic*

*• ce metodă s-a folosit*

*• Rezultatul analizei genetice care confirmă mutaţia nonsens la nivelul genei distrofinei*

***- Uzuale (pentru statusul biologic)***

***- Transaminaze***

***- Enzime musculare***

***- Creatinina serică, azot ureic sanguin şi monitorizarea cistatinei C***

***- Colesterolul total, LDL, HDL şi trigliceridele***

***- Biopsie musculară***

*• ca prim test diagnostic (înaintea testării genetice)*

*• ca al doilea test diagnostic (după testarea genetică)*

*• muşchiul unde s-a efectuat (deltoid, biceps, cvadriceps, gastrocnemian, alt muşchi)*

*• data biopsiei (vârsta la care s-a efectuat)*

*• nu s-a efectuat*

***- Rezultat biopsie musculară (dacă s-a efectuat)***

*• Imunohistochimie*

*• Testare prin metoda Imunnoblot (western blot)*

*• Cantitate de distrofină - Normală/scăzută/nu s-a efectuat*

*• Mărimea distrofinei -*

*• Dacă avem un raport în % -*

*• Utrofina - prezentă/absentă/modificată cantitativ*

***- Evaluare cardiacă***

*• EKG*

*• Ecografie cardiacă: Fracţia de ejecţie a VS*

***- Evaluarea funcţiei respiratorii*** *(după vârsta de 6 ani în funcţie de intelect şi cooperare)*

*• Spirometrie: capacitate vitală, volumul expirator forţat*

***ALTE PROBLEME MEDICALE (FRACTURI ETC.)***

***Evaluare frate***

***- clinică***

***- CK***

***- genetică***

***Evaluare soră***

***Evaluare mamă***

***- clinică***

***- CK***

***- Genetică***

***Consimţământul de la părinţi şi/sau pacient de a înregistra datele în registrul naţional***

***TRATAMENT CORTICOTERAPIC:***

***• Tip corticoterapie, doza, de când ia tratament ..................***

***• Reacţii adverse ....................***

***• Alte tratamente .....................***

***SE RECOMANDĂ:***

***ATALUREN - doza ............***

*Medic centru de referinţă,*

*Semnătura, parafa*

*Data completării Fişei de iniţiere,*

**#M16**

ANEXA 2

*[ ] Unitatea sanitară ..................*

*[ ] Centrul de referinţă pentru boli neuromusculare ..........................*

***Fişa clinică de monitorizare a pacientului cu Distrofie musculară progresivă tip Duchenne/Becker în tratament cu Ataluren***

***Tip evaluare***

*Medic curant: [ ] 3 luni [ ] 9 luni anul tratamentului cu Ataluren (1, 2, ...) ....*

*Centrul de referinţă [ ] 6 luni [ ] 12 luni anul tratamentului cu Ataluren (1, 2, ...) ....*

***Nume***

***Prenume***

***Data evaluării***

***Data naşterii***

***Adresa***

***Telefon***

***Nume mama***

***Nume tata***

***Vârsta la care a fost diagnosticat***

***EXAMEN CLINIC\*1***

***• Greutate***

***• Înălţime***

***• Perimetru cranian***

***• evaluarea forţei musculare:*** *se va folosi scala de evaluare de la 0 - 5*

*(Medical Research Council of Great Britain)*

*0 - nu se detectează activitate musculară*

*1 - o contracţie foarte greu detectabilă*

*2 - mişcările se pot efectua doar în planul gravitaţional*

*3 - mişcări antigravitaţionale posibile, dar nu împotriva rezistenţei*

*4 - mişcări împotriva rezistenţei dar cu forţă mai mică decât normal*

*5 - forţă normală*

*------------*

*\*1 Se completează la evaluările de 3, 6, 9 şi 12 luni ale fiecărui an de tratament cu Ataluren*

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*|* ***Mers*** *| |*

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*|* ***Manevra Gowers*** *| |*

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*| Forţa musculară segmentară | Stânga | Dreapta |*

*| Centura pelvină |\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_|*

*| | Poziţie şezândă |*

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*| Flexia coapsei | | |*

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*| Extensia gambei | | |*

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*| Flexia dorsală | | |*

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*| Eversia plantei | | |*

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*| Inversia plantei | | |*

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*| | Decubit ventral |*

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*| Extensia coapsei | | |*

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*| Flexia gambe | | |*

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*| Flexia plantară a piciorului | |*

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*| Decubit lateral |*

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*| Abducţia coapsei | |*

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*| Forţa musculară centura scapulară | Poziţie şezândă |*

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*| Abducţia umăr | | |*

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*| Flexia cot (antebraţ) | | |*

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*| Flexia mâinii | | |*

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*| Extensia mâinii | | |*

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*| Abducţia policelui | | |*

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*| | Decubit ventral |*

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*| Rotaţia externă umăr | | |*

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*| | Decubit dorsal |*

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*| Extensia antebraţ | | |*

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*| | Decubit ventral |*

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*| Extensia gât | | |*

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*| | Decubit dorsal |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|*

*| Flexia gât | | |*

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*| ROT membre superioare | | |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_|*

*| ROT membre inferioare | | |*

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*| Hipertrofie muşchi | |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|*

*| Atrofii | |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_| |*

*| Tulburări trofice (contracturi) | |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_| |*

*| Scolioza | |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|*

***• Evaluare funcţională:***

*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

*|* ***Umeri şi membre superioare*** *| |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_|*

*| 1. Plecând de la postura de ortostatism cu braţele pe lângă corp, | |*

*| pacientul poate face abducţia braţelor în formă de cerc, ca să se | |*

*| atingă deasupra capului | |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_|*

*| 2. Poate ridica braţele deasupra capului doar cu coatele în flexie | |*

*| sau folosind muşchii accesori | |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_|*

*| 3. Nu poate ridica mâinile deasupra capului dar poate duce la gură | |*

*| un pahar cu apă de 250 ml (folosind ambele mâini dacă este necesar)| |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_|*

*| 4. Poate duce mâinile la gură dar nu poate duce la gură un pahar cu| |*

*| apă de 250 ml | |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_|*

*| 5. Nu poate ridica mâinile la nivelul gurii dar le poate folosi | |*

*| pentru a ţine un stilou sau pentru a-l ridica de pe masă | |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_|*

*| 6. Nu poate duce mâinile la gură şi nici nu le poate folosi în | |*

*| scopuri funcţionale | |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_|*

*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

*|* ***Şolduri şi membre inferioare*** *| |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_|*

*| 1. Merge şi urcă scările fără ajutor | |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_|*

*| 2. Merge şi urcă scările cu ajutorul braţelor | |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_|*

*| 3. Merge şi urcă scările încet cu ajutorul braţelor | |*

*| Urcă patru trepte în mai mult de 4 secunde | |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_|*

*| 4. Merge fără ajutor şi se poate ridica de pe scaun dar nu poate | |*

*| urca scările | |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_|*

*| 5. Merge fără ajutor dar nu se poate ridica de pe scaun şi nu poate| |*

*| urca scările | |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_|*

*| 6. Merge doar cu ajutor | |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_|*

*| 7. Este imobilizat în scaunul cu rotile | |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_|*

*| 8. Este imobilizat la pat | |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_|*

***• Evaluare funcţională (timp în sec.)***

*- se ridică din decubit ventral*

*- aleargă 9 m*

*- urcă 4 trepte (cu ajutorul balustradei sau nu)*

***• Test mers timp de 6 minute (în metri)***

***• Evaluarea funcţională va fi completată cu Scala de evaluare a funcţiei motorii North Star Ambulatory Assessment (pentru comparaţie cu studii europene în desfăşurare) - existentă în anexă***

***• Examen psihologic***

*- QI*

*- Tulburări de vorbire*

*- Tulburări de comportament*

*- ADHD*

*- Autism*

*- Tulburare pervazivă de dezvoltare*

*- Tulburare depresivă*

*- Tulburare de învăţare*

*- Întârziere mintală*

***• Tulburări de somn***

***• Tensiunea arterială sistolică şi distolică*** *în stare de repaus (la bolnavii cu nmDMD care primesc Ataluren concomitent cu corticosteroizi) .......*

***• Alte probleme medicale (fracturi etc.)***

***EXAMENE PARACLINICE\*2:***

***• la evaluările de 6 şi 12 luni***

*- Uzuale (pentru statusul biologic)*

*- creatinina serică, azot ureic sanguin şi monitorizarea cistatinei C*

*- Transaminaze*

*- Enzime musculare*

***• la evaluarea de 12 luni:*** *colesterolul total, LDL; HDL; trigliceride*

***• Evaluare cardiacă*** *- la evaluarea de 12 luni*

***- EKG***

***- Ecografie cardiacă:*** *Fracţia de ejecţie a VS*

***Notă:***

*- evaluarea cardiacă la 2 ani sub vârsta de 10 ani*

*- după vârsta de 10 ani evaluare cardiacă completă o dată pe an*

*- evaluare cardiacă completă la apariţia semnelor cardiace (acestea pot fi discrete şi nespecifice: scădere în greutate, tuse, vărsături, ortopnee) de către un specialist cardiolog pentru tratament de specialitate*

*- pacienţii care au tratament cu prednison necesită o supraveghere mai atentă cardiacă datorită creşterii în greutate şi HTA*

*- trebuie făcută înainte de orice intervenţie chirurgicală majoră şi intraoperator*

***• Evaluarea funcţiei respiratorii*** *- după vârsta de 11 ani -* ***periodicitate anuală, la evaluarea de 12 luni***

*- Spirometrie: capacitate vitală, volumul expirator forţat*

*------------*

*\*2 Se completează la evaluările de 6 şi 12 luni ale fiecărui an de tratament cu Ataluren*

***TRATAMENT CORTICOTERAPIC:***

***• Tip corticoterapie, doza, de când ia tratament ...................***

***• Reacţii adverse .................***

***• Alte tratamente ...................***

***SE RECOMANDĂ\*3:***

***[ ] continuarea tratamentului cu ATALUREN - doza ...............***

***[ ] întreruperea tratamentului cu Ataluren***

*------------*

*\*3 Se completează doar la evaluările de 6 şi 12 luni, efectuate în Centrul de referinţă*

*Medic curant/medic Centru de referinţă,*

*Semnătura, parafa*

*Data completării Fişei de monitorizare,*

**#M16**

ANEXA 3

***FORMULAR PENTRU CONSIMŢĂMÂNTUL PACIENTULUI CU DISTROFIE MUSCULARĂ DUCHENNE, CAUZATĂ DE O MUTAŢIE NONSENS LA NIVELUL GENEI DISTROFINEI (nmDMD)***

***Privind tratamentul cu Ataluren (TRANSLARNA)***

*Subsemnatul(a) ................................................, cu CI/BI ......................., părinte/tutore legal al copilului ................................., cu* ***CNP*** *......................................... diagnosticat cu* ***distrofie musculară Duchenne, cauzată de o mutaţie nonsens la nivelul genei distrofinei (nmDMD)*** *am fost informat de către ......................................... privind tratamentul medical al distrofiei musculare Duchenne cu ataluren (TRANSLARNA).*

*Translarna este un medicament care conţine substanţa activă ataluren. Translarna este disponibil în 3 concentraţii, fiecare conţinând 125 mg, 250 mg şi 1000 mg de substanţă activă, denumită ataluren. Celelalte componente sunt: polidextroză (E1200), macrogol, poloxamer, manitol (E421), crospovidonă, hidroxietil celuloză, aromă artificială de vanilie (maltodextrină, arome artificiale şi propilen glicol), dioxid de siliciu coloidal anhidru (E551), stearat de magneziu.*

*Translarna se utilizează în tratamentul distrofiei musculare Duchenne care este determinată de un defect genetic specific care afectează funcţia musculară normală.*

*Translarna se utilizează pentru tratarea pacienţilor cu vârste de 5 ani şi peste, care au capacitatea de a se deplasa.*

*Distrofia musculară Duchenne este cauzată de modificări genetice, care conduc la apariţia unei anomalii a unei proteine din muşchi, denumită distrofină, care este necesară pentru funcţionarea adecvată a muşchilor. Translarna activează producerea distrofinei funcţionale şi ajută la funcţionarea corespunzătoare a muşchilor. Acest efect a fost demonstrat în cadrul unor studii clinice care au stat la baza aprobării de către Agenţia Europeană a Medicamentului, a primei şi singurei terapii medicamentoase pentru distrofie musculară Duchenne, cauzată de o mutaţie nonsens la nivelul genei distrofinei.*

*Ca toate medicamentele, acest medicament poate provoca reacţii adverse, cu toate că nu apar la toate persoanele. Copilul este posibil să manifeste una sau mai multe dintre următoarele reacţii adverse după ce ia Translarna:*

*Reacţii adverse foarte frecvente (pot afecta mai mult de 1 persoană din 10) cefalee, greaţă, vărsături. Reacţii adverse frecvente (pot afecta mai puţin de 1 persoană din 10) apetit alimentar scăzut, pierdere în greutate, ameţeli, tensiune arterială crescută, tuse, sângerări nazale, constipaţie, diaree, flatulenţă, regurgitaţie, disconfort stomacal, dureri stomacale, erupţii cutanate, dureri de braţe sau picioare, chist renal, urinare cu frecvenţă anormală, urinare involuntară, culoare anormală a urinei, febră, oboseală.*

*Reacţii adverse cu frecvenţă necunoscută (frecvenţa nu poate fi estimată din datele disponibile) creşteri ale concentraţiilor de lipide din sânge, creşteri ale rezultatelor testelor funcţiei renale.*

*Tratamentul cu ataluren (Translarna) nu este indicat la copii cu vârsta sub 5 ani, deoarece nu a fost testat la acest grup de pacienţi.*

*Tratamentul cu ataluren (Translarna) nu trebuie luat dacă copilul e alergic la ataluren sau la oricare dintre celelalte componente ale acestui medicament sau dacă copilul primeşte tratament cu anumite antibiotice, cum ar fi gentamicină, tobramicină sau streptomicină prin injecţie intravenoasă.*

*Ataluren (Translarna) poate afecta modul de acţiune al altor medicamente. Spuneţi medicului dumneavoastră dacă copilul a luat sau s-ar putea să ia alte medicamente. În special, nu se administrează Translarna cu antibioticele gentamicină, tobramicină sau streptomicină administrate prin injecţie. Acestea pot afecta funcţia renală a copilului.*

*Spuneţi medicului dacă copilul se află în tratament cu oricare dintre următoarele medicamente:*

*- aciclovir prescris pentru tratamentul vărsatului de vânt [varicelă]*

*- adefovir prescris pentru tratamentul hepatitei B cronice şi/sau al infecţiei cu HIV*

*- atorvastatină prescris pentru scăderea lipidelor*

*- benzilpenicilină prescris pentru infecţii severe*

*- bumetanidă prescris pentru tratamentul sau prevenirea insuficienţei cardiace congestive*

*- captopril prescris pentru tratamentul sau prevenirea insuficienţei cardiace congestive*

*- ciclosporină prescris pentru prevenirea respingerii organului în urma transplantului de organ*

*- famotidină prescris pentru tratamentul ulcerului duodenal activ, tratamentul bolii de reflux gastroesofagian*

*- furosemid prescris pentru tratamentul sau prevenirea insuficienţei cardiace congestive*

*- metotrexat prescris pentru poliartrită reumatoidă, psoriazis*

*- micofenolat mofetil prescris pentru prevenirea respingerii organului în urma transplantului*

*- olmesartan prescris pentru hipertensiune arterială esenţială la adulţi*

*- oseltamivir prescris pentru prevenirea gripei*

*- fenobarbital prescris pentru inducerea somnului, prevenirea convulsiilor*

*- pitavastatină prescris pentru scăderea lipidelor*

*- pravastatină prescris pentru scăderea lipidelor*

*- rifampicină prescris pentru tratamentul tuberculozei*

*- rosuvastatină prescris pentru scăderea lipidelor*

*- sitagliptină prescris pentru diabet zaharat de tip 2*

*- telmisartan prescris pentru tratamentul sau prevenirea insuficienţei cardiace congestive*

*- valsartan prescris pentru tratamentul sau prevenirea insuficienţei cardiace congestive*

*Aceste medicamente nu au fost testate în asociere cu Translarna şi medicul poate decide să monitorizeze îndeaproape pacientul.*

*Se recomandă a se efectua analize ale sângelui înainte de tratamentul cu Translarna şi periodic în timpul tratamentului. Dacă copilul are orice afecţiune hepatică sau renală, medicul trebuie să verifice periodic funcţiile hepatice şi renale. Medicul va analiza concentraţiile lipidelor din sânge (grăsimi, precum colesterolul şi trigliceridele) şi funcţia renală o dată la 6 sau la 12 luni, conform protocolului. Medicul va monitoriza tensiunea arterială o dată la 6 luni, în cazul în care copilul ia un medicament corticosteroid.*

*Pentru o supraveghere atentă a stării de sănătate a copilului aflat în tratament, a eficienţei şi a posibilelor reacţii adverse ale terapiei cu Translarna, am obligaţia de a mă prezenta lunar la medicul curant, la evaluările de bilanţ clinic ale medicului curant din luna a 3-a şi luna a 9-a a fiecărui an de tratament, la evaluările multidisciplinare din Centrul de referinţă unde s-a confirmat diagnosticul din luna a 6-a şi luna a 12-a a fiecărui an de tratament sau ori de câte ori apar modificări în evoluţia stării de sănătate a copilului meu, sau la solicitarea medicului curant sau a medicului din Centrul de referinţă.*

*În situaţia în care în mod nejustificat nu voi respecta obligaţiile asumate, inclusiv de a mă prezenta sistematic cu copilul meu la controalele periodice stabilite prin protocolul terapeutic şi care mi-au fost comunicate de către medicul curant pentru distrofia musculară Duchenne, medicul din Centrul de referinţă are dreptul de a exclude copilul meu din tratament - aşa cum este stipulat în PROTOCOLUL TERAPEUTIC AL BOLNAVILOR CU DISTROFIE MUSCULARĂ DUCHENNE.*

*În cazul în care evoluţia clinică este nefavorabilă (pierderea totală a capacităţii de deplasare - menţinută mai mult de 6 luni) medicul curant, împreună cu medicul din Centrul de referinţă pot opta pentru întreruperea tratamentului cu ataluren.*

***Sunt de acord să respect condiţiile de includere în Sub-Programul Naţional de Tratament al distrofiei musculare Duchenne în vederea iniţierii tratamentului cu: ATALUREN (TRANSLARNA)***

***Înainte de a începe tratamentul, mă voi prezenta împreună cu copilul meu la medicul curant în vederea instructajului efectuat de medic şi asistenta medicală privind modul de administrare.***

***Data: Pacient:***

***Semnătura***

***Părinte/Tutore legal:***

***Semnătura***

***Medic Centru de referinţă:***

***Semnătura***

**#M16**

ANEXA 4

***Scala de evaluare a funcţiei motorii North Star Ambulatory Assessment***

*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

*|* ***Activitate*** *|* ***Instrucţiuni pt.****|* ***Poziţie de start/*** *|* ***Comentarii*** *|*

*| |* ***pacient*** *|* ***detalii test*** *| |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|*

*| 1. | Poţi sta în | Picioarele | Cel mai bine pe podea, |*

*| Ortostaţiune | picioare? | apropiate, | nu pe covor |*

*| | Pt. cât mai mult| călcâiele pe | (suprafaţa aleasă |*

*| | timp şi cât mai | podea, braţele pe | trebuie păstrată pe |*

*| | liniştit | lângă corp; | parcursul întregii |*

*| | | Fără pantofi | testări) |*

*| | | | Minim 3 sec. pt. |*

*| | | | 2 puncte |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|*

*| 2. Mers | Poţi merge de la| Merge fără | O evaluare corectă este|*

*| | punctul A la B? | ciorapi/pantofi, | necesară pt. scoring; |*

*| | | distanţa | Dacă pacientul merge de|*

*| | | suficientă pentru | obicei pe vârfuri, dar |*

*| | | a observa "mersul | ocazional/la cerere |*

*| | | normal" pt. | poate pune întreaga |*

*| | | pacient | plantă pe sol - va |*

*| | | | primi 1 punct. |*

*| | | |* ***Se notează dacă merge*** *|*

*| | | |* ***10 m.*** *|*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|*

*| 3. Ridicarea | Poţi să te | Din poziţia şezând| Se foloseşte un scaun/ |*

*| de pe scaun | ridici de pe | cu genunchii | un suport ajustabil |*

*| | scaun, cu | flectaţi la 90°, | înălţimii; braţele |*

*| | braţele | cu plantele pe | trebuie menţinute pe |*

*| | flectate? | podea/suport | lângă corp pt. 2 puncte|*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|*

*| 4. Stat | Poţi sta într-un| Minim 3 sec. pt. | Cel mai bine pe podea, |*

*| într-un | picior (drept)? | 2 puncte | nu pe covor (suprafaţa |*

*| picior: drept | Cât timp? | Fără pantofi | aleasă trebuie păstrată|*

*| | | | pe parcursul întregii |*

*| | | | testări) |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|*

*| 5. Stat | Poţi sta într-un| Minim 3 sec. pt. | Cel mai bine pe podea, |*

*| într-un | picior (stâng)? | 2 puncte | nu pe covor (suprafaţa |*

*| picior: stâng | Cât timp? | Fără pantofi | aleasă trebuie păstrată|*

*| | | | pe parcursul întregii |*

*| | | | testări) |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|*

*| 6. Urcarea cu | Poţi să urci pe | Poziţionare cu | Putem folosi un suport |*

*| un picior pe | cutie folosind | faţa spre cutie | cu înălţime ajustabilă/|*

*| suport: drept | piciorul drept | (~ 15 cm înălţime)| "improvizăm" |*

*| | primul? | | |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|*

*| 7. Urcarea cu | Poţi să urci pe | Poziţionare cu | Putem folosi un suport |*

*| un picior pe | cutie folosind | faţa spre cutie | cu înălţime ajustabilă/|*

*| suport: stâng | piciorul stâng | (~ 15 cm înălţime)| "improvizăm" |*

*| | primul? | | |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|*

*| 8. Coborârea | Poţi să cobori | Stând pe cutie | Putem folosi un suport |*

*| de pe suport: | de pe cutie | păşeşte în faţă. | cu înălţime ajustabilă/|*

*| cu piciorul | folosind | Înălţimea | "improvizăm" |*

*| drept | piciorul drept | suportului ~ 15 cm| |*

*| | primul? | | |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|*

*| 9. Coborârea | Poţi să cobori | Stând pe cutie | Putem folosi un suport |*

*| de pe suport: | de pe cutie | păşeşte în faţă. | cu înălţime ajustabilă/|*

*| cu piciorul | folosind | Înălţimea | "improvizăm" |*

*| stâng | piciorul stâng | suportului ~ 15 cm| |*

*| | primul? | | |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|*

*| 10. Ridicarea | Te poţi ridica | Întins pe spate, | Dacă se întoarce în |*

*| în şezut | în şezut din | fără pernă | pronaţie/cu faţa spre |*

*| | poziţia întins? | | podea în timpul |*

*| | | | ridicării - va primi 1 |*

*| | | | punct |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|*

*| 11. Ridicarea | Te poţi ridica | Întins pe spate, | Se încearcă iniţial |*

*| de pe podea | de pe podea, din| cu braţele pe | fără obiecte |*

*| | poziţia întins, | lângă corp, | ajutătoare; dacă se |*

*| | cu un ajutor cât| picioarele | foloseşte un scaun - nu|*

*| | mai mic? cât de | întinse, fără | se mai cronometrează |*

*| | repede? | pernă | |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|*

*| 12. Ridicarea | Poţi ridica | Întins pe spate, | Manevra "bărbia în |*

*| capului | capul pentru aţi| pe covor, fără | piept" - Pacientul va |*

*| | privi degetele, | pernă | menţine braţele |*

*| | păstrând braţele| | încrucişate pe piept |*

*| | flectate | | (evităm să se ajute) - |*

*| | | | trebuie să îşi |*

*| | | | privească degetele (ne |*

*| | | | asigurăm că flectează |*

*| | | | capul) |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|*

*| 13. Statul pe | Poţi sta pe | Ortostatism pe | Privim inversia: dacă |*

*| călcâie | călcâie? | podea; fără | inversia este |*

*| | | pantofi | importantă, dar |*

*| | | | picioarele rămân |*

*| | | | ridicate - 1 punct; |*

*| | | | dacă realizează doar |*

*| | | | inversia, cu sprijin pe|*

*| | | | marginea laterală a |*

*| | | | piciorului - 0 puncte |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|*

*| 14. Săritura | Cât de sus poţi | Ortostatism pe | Săritura înaltă, nu în |*

*| | să sari? | podea, fără | faţă; |*

*| | | pantofi cu | Mici mişcări înainte- |*

*| | | picioarele cât mai| înapoi sunt acceptate |*

*| | | apropiate | |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|*

*| 15. Săritura | Poţi sări | Poziţie de | Trebuie desprins clar |*

*| într-un picior| într-un picior? | ortostatism pe | piciorul de pe podea |*

*| (drept) | (dreptul) | podea, pe piciorul| pt. 2 puncte |*

*| | | drept; fără | |*

*| | | pantofi | |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|*

*| 16. Săritura | Poţi sări | Poziţie de | Trebuie desprins clar |*

*| într-un picior| într-un picior? | ortostatism pe | piciorul de pe podea |*

*| (stâng) | (stângul) | podea, pe piciorul| pt. 2 puncte |*

*| | | drept; fără | |*

*| | | pantofi | |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|*

*| 17. Alergare | Aleargă cât de | Stabilim strict | "Duchenne jog" - nu |*

*| (10 m) | repede poţi până| distanţa de 10 m | este o alergare |*

*| | la ... (stabilim| pe un coridor; | adevărată, dar este mai|*

*| | un punct) | utilizăm un | mult decât un mers. |*

*| | | cronometru; | Tipic: utilizarea |*

*| | | stabilim dacă | excesivă a braţelor, |*

*| | | poartă pantofi/nu;| rotaţia trunchiului, |*

*| | | | legănare |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|*

*SCOR*

*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

*| Activitate | 2 | 1 | 0 |Comentarii|*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_|*

*| 1. | Stă drept, | Reuşeşte să stea | Nu poate sta| |*

*| Ortostaţiune | liniştit şi | cu o compensare | liniştit/ | |*

*| | simetric, fără | (pe vârfuri/cu | independent;| |*

*| | mişcări | membrele în | necesită | |*

*| | compensatorii (cu| abducţie/cu fundul| suport | |*

*| | călcâiele pe sol)| înapoi) - min 3 | (chiar | |*

*| | - min 3 sec. | sec. | minim) | |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_|*

*| 2. Mers | Merge cu pattern | Mers digitigrad | Pierderea | |*

*| | călcâi-degete/ | persistent/din | mersului | |*

*| | "flat-footed" | obişnuinţă; | independent | |*

*| | | incapabil să | - poate | |*

*| | | meargă în modul | folosi | |*

*| | | călcâi-degete | mijloace | |*

*| | | | ajutătoare/ | |*

*| | | | merge pe | |*

*| | | | distanţe | |*

*| | | | scurte cu | |*

*| | | | ajutor | |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_|*

*| 3. Ridicarea | Păstrează braţele| Cu ajutor pe | Nu se poate | |*

*| de pe scaun | flectate. Pleacă | coapse/împingerea | ridica | |*

*| | din poziţia cu | pe scaun/ | | |*

*| | genunchii | întoarcerea în | | |*

*| | flectaţi la 90°; | pronaţie | | |*

*| | picioarele pe | | | |*

*| | podea/suport | | | |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_|*

*| 4. Stat | Poate sta, | Poate sta, dar pt.| Nu poate sta| |*

*| într-un | relaxat - 3 sec. | timp foarte scurt/| într-un | |*

*| picior: drept| | necesită o fixare | picior | |*

*| | | mai bună | | |*

*| | | (genunchiul uşor | | |*

*| | | adus/alt ajutor) | | |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_|*

*| 5. Stat | Poate sta, | Poate sta, dar pt.| Nu poate sta| |*

*| într-un | relaxat - 3 sec. | timp foarte scurt/| într-un | |*

*| picior: stâng| | necesită o fixare | picior | |*

*| | | mai bună | | |*

*| | | (genunchiul uşor | | |*

*| | | adus/alt ajutor) | | |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_|*

*| 6. Urcarea cu| Un pas în faţă, | Se urcă dintr-o | Nu poate | |*

*| un picior pe | fără ajutor | parte/cu ajutor | urca pe | |*

*| suport: drept| | | suport | |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_|*

*| 7. Urcarea cu| Un pas în faţă, | Se urcă dintr-o | Nu poate | |*

*| un picior pe | fără ajutor | parte/cu ajutor | urca pe | |*

*| suport: stâng| | | suport | |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_|*

*| 8. Coborârea | Cu faţa înainte, | Cu faţa înainte, | Nu poate | |*

*| de pe suport:| coboară, | coboară, | efectua | |*

*| cu piciorul | controlând | controlând | mişcarea | |*

*| drept | greutatea cu | greutatea cu | | |*

*| | piciorul drept; | piciorul drept; | | |*

*| | fără ajutor | fără ajutor | | |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_|*

*| 9. Coborârea | Cu faţa înainte, | Cu faţa înainte, | Nu poate | |*

*| de pe suport:| coboară, | coboară, | efectua | |*

*| cu piciorul | controlând | controlând | mişcarea | |*

*| stâng | greutatea cu | greutatea cu | | |*

*| | piciorul drept; | piciorul drept; | | |*

*| | fără ajutor | fără ajutor | | |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_|*

*| 10. Ridicarea| Din poziţia | Se ajută singur: | Nu poate | |*

*| în şezut | întins cu faţa în| se împinge cu un | efectua | |*

*| | sus se ridică - | picior/se ridică | mişcarea | |*

*| | se poate ajuta cu| în "capul | | |*

*| | o mână | mâinilor"/flexia | | |*

*| | | capului spre podea| | |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_|*

*| 11. Ridicarea| Din poziţia | Gowers pozitiv | Se ajută cu | Timp: |*

*| de pe podea | decubit dorsal - | | un | (00.0 |*

*| | manevra Gowers | | obiect (ex.:| sec.) |*

*| | absentă | | scaun)/nu | |*

*| | | | poate | |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_|*

*| 12. Ridicarea| Din poziţia | Capul este | Nu poate | |*

*| capului | decubit dorsal | ridicat, dar prin | efectua | |*

*| | capul trebuie | flexia într-o | mişcarea | |*

*| | ridicat pe linia | parte/fără flexia | | |*

*| | mediană. Bărbia | gâtului | | |*

*| | trebuie pusă în | | | |*

*| | piept | | | |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_|*

*| 13. Statul pe| Ambele picioare | Fixează coapsele | Nu poate | |*

*| călcâie | trebuie să stea | şi ridică doar | efectua | |*

*| | numai pe călcâie,| antepiciorul | mişcarea | |*

*| | simultan. Se | | | |*

*| | acceptă mici paşi| | | |*

*| | pentru a menţine | | | |*

*| | echilibru, timp | | | |*

*| | de 3 sec. | | | |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_|*

*| 14. Săritura | Ridicarea de pe | Sare cu câte un | Nu poate | |*

*| | podea cu ambele | picior alternativ | efectua | |*

*| | picioare | | mişcarea | |*

*| | simultan; | | | |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_|*

*| 15. Săritura | Ridicarea de pe | Poate îndoi | Nu poate | |*

*| într-un | podea cu întreaga| genunchiul şi să | efectua | |*

*| picior | talpă | ridice călcâiul, | mişcarea | |*

*| (drept) | | dar nu ridică în | | |*

*| | | totalitate | | |*

*| | | piciorul | | |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_|*

*| 16. Săritura | Ridicarea de pe | Poate îndoi | Nu poate | |*

*| într-un | podea cu întreaga| genunchiul şi să | efectua | |*

*| picior | talpă | ridice călcâiul, | mişcarea | |*

*| (stâng) | | dar nu ridică în | | |*

*| | | totalitate | | |*

*| | | piciorul | | |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_|*

*| 17. Alergare | Ambele picioare | "Duchenne jog" | Merge | Timp: |*

*| (10 m) | părăsesc solul | | | (00.0 |*

*| | (nu există o | | | sec.) |*

*| | etapă, în timpul | | | |*

*| | alergării, în | | | |*

*| | care ambele | | | |*

*| | picioare să fie | | | |*

*| | pe sol) | | | |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_|*

**#M17**

***DCI: TRASTUZUMAB EMTASINUM***

***I. Indicaţii:***

*Trastuzumab emtasinum ca monoterapie este indicat pentru tratamentul pacienţilor adulţi cu neoplasm mamar HER2-pozitiv metastatic sau local avansat inoperabil, care au urmat anterior tratament cu trastuzumab şi un taxan\*), separat sau în asociere. Pacienţii trebuie:*

*• să fi urmat anterior tratament pentru boală metastatică sau local avansată; sau*

*• să fi dezvoltat o recurenţă a bolii în timpul tratamentului adjuvant sau în intervalul de şase luni de la terminarea tratamentului adjuvant.*

*------------*

*\*) Sau orice alt chimioterapic, conform practicii clinice din România.*

***II. Criterii de includere:***

*a) vârstă peste 18 ani;*

*b) ECOG 0 - 2;*

*c) FEVS >/= 50%;*

*d) pacienţi cu rezultat IHC 3+ sau test FISH/CISH/SISH pozitiv pentru Her2, determinat în laboratoarele acreditate (cel puţin o testare pentru stadiul metastatic), care îndeplinesc una dintre următoarele condiţii:*

*• stadiu metastatic, linia a doua de tratament, pentru pacienţii care au progresat în urma primei linii bazate pe trastuzumab;*

*• stadiu metastatic, linia a treia sau ulterioară, pentru pacienţii care nu au primit trastuzumab emtasinum în liniile anterioare;*

*• local avansat inoperabil care a dezvoltat o recurenţă a bolii în timpul tratamentului adjuvant sau în intervalul de şase luni de la terminarea tratamentului adjuvant bazat pe trastuzumab.*

***III. Criterii de excludere/întrerupere definitivă/temporară (la latitudinea medicului curant):***

*a) pacienţi la care a fost întreruptă definitiv administrarea trastuzumab din cauza apariţiei reacţiilor adverse legate de perfuzie (IRR);*

*b) afecţiuni cardiace importante [pacienţii cu antecedente de infarct miocardic, angină pectorală care a necesitat tratament medical, cei care au avut sau au ICC (clasa II - IV NYHA), alte cardiomiopatii, aritmie cardiacă care necesită tratament medical, boală valvulară cardiacă semnificativă clinic, hipertensiune arterială slab controlată şi esudat pericardic semnificativ din punct de vedere hemodinamic];*

*c) pacienţii care prezintă dispnee de repaus determinată de comorbidităţi;*

*d) sarcină/alăptare;*

*e) hipersensibilitate la substanţa activă sau la oricare dintre excipienţi;*

*f) pacienţi diagnosticaţi cu BPI sau pneumonită;*

*g) pacienţi diagnosticaţi cu hiperplazie regenerativă nodulară a ficatului.*

*IV.* ***Durata tratamentului:*** *până la progresie sau apariţia unor efecte secundare care depăşesc beneficiul terapeutic.*

***V. Schema terapeutică***

*Doza recomandată de trastuzumab emtasinum este de 3,6 mg/kg greutate corporală, administrată sub formă de perfuzie intravenoasă la fiecare 3 săptămâni (ciclu de tratament la 21 de zile), conform instrucţiunilor din RCP produsului.*

*Modificarea dozei*

*Tratarea reacţiilor adverse simptomatice poate necesita întreruperea temporară, reducerea dozei sau întreruperea definitivă a tratamentului cu trastuzumab emtasinum, conform instrucţiunilor din RCP produsului.*

*După ce s-a efectuat o reducere de doză nu se poate relua creşterea dozei de trastuzumab emtasinum.*

*Scheme de reducere a dozei:*

*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

*| Schema de reducere a dozei | Doza care va trebui|*

*| (doza iniţială este de 3,6 mg/kg)| administrată |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|*

*| Prima reducere a dozei | 3 mg/kg |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|*

*| A doua reducere a dozei | 2,4 mg/kg |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|*

*| Necesitatea reducerii în | Întreruperea |*

*| continuare a dozei | tratamentului |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|*

*Instrucţiuni de modificare a dozei în cazul transaminazelor crescute (AST/ALT)*

*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

*| Gradul 2 | Gradul 3 | Gradul 4 |*

*|(< 2,5 până la </= 5 x LSN)| (< 5 până la </= 20 x LSN) | (< 20 x LSN) |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|*

*| Nu este necesară | Nu se va administra trastuzumab | Se va întrerupe|*

*| modificarea dozei. | emtasinum până când AST/ALT | administrarea |*

*| | revine la grad </= 2 (> 2,5 până| trastuzumab |*

*| | la < 5 x LSN); apoi se va | emtasinum. |*

*| | reduce doza. | |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|*

*Instrucţiuni de modificare a dozei în cazul hiperbilirubinemiei:*

*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

*| Gradul 2 | Gradul 3 | Gradul 4 |*

*|(< 1,5 până la </= 3 x LSN)| (< 3 până la </= 10 x LSN) | (< 10 x LSN) |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|*

*| Nu se va administra | Nu se va administra trastuzumab | Se va întrerupe|*

*| trastuzumab emtasinum până| emtasinum până când valoarea | administrarea |*

*| când valoarea bilirubinei | bilirubinei totale revine la | trastuzumab |*

*| totale revine la grad | grad </= 1 (> LSN până la 1,5 x | emtasinum. |*

*| </= 1 (> LSN până la 1,5 x| LSN); apoi se va reduce doza. | |*

*| LSN). Nu este necesară | | |*

*| modificarea dozei. | | |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|*

*Instrucţiuni de modificare a dozei în cazul trombocitopeniei:*

*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

*| Gradul 3 | Gradul 4 |*

*| (Numărul trombocitelor: 25000 | (Numărul trombocitelor: |*

*| până la < 50000/mm3) | < 25000/mm3) |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|*

*| Nu se va administra trastuzumab emtasinum | Nu se va administra trastuzumab |*

*| până când numărul trombocitelor revine la | emtasinum până când numărul |*

*| grad </= 1 (de exemplu, numărul | trombocitelor revine la grad < 1 |*

*| trombocitelor >/= 75.000/mm3). Nu este | (de exemplu, numărul |*

*| necesară modificarea dozei. | trombocitelor >/= 75.000/mm3); |*

*| | şi apoi se va reduce doza. |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|*

*Instrucţiuni de modificare a dozei în cazul disfuncţiei ventriculare stângi*

*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

*| FEVS < 40% | FEVS > 45% | FEVS 40% până | FEVS 40% până | ICC |*

*| | | la </= 45% şi | la </= 45% şi | simptomatică |*

*| | | scăderea este | scăderea este | |*

*| | | < 10% puncte | >/= 10% puncte| |*

*| | | sub valoarea | sub valoarea | |*

*| | | iniţială | iniţială | |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_|*

*| Nu se va | Se va continua| Se va continua| Nu se va | Se va |*

*| administra | tratamentul cu| tratamentul cu| administra | întrerupe |*

*| trastuzumab | trastuzumab | trastuzumab | trastuzumab | administrarea|*

*| emtasinum. Se | emtasinum. | emtasinum. Se | emtasinum. Se | trastuzumab |*

*| va repeta | | va repeta | va repeta | emtasinum. |*

*| evaluarea FEVS| | evaluarea FEVS| evaluarea FEVS| |*

*| într-un | | într-un | într-un | |*

*| interval de 3 | | interval de 3 | interval de 3 | |*

*| săptămâni. | | săptămâni. | săptămâni. | |*

*| Dacă se | | | Dacă valoarea | |*

*| confirmă | | | FEVS nu a | |*

*| valoarea FEVS | | | revenit cu 10%| |*

*| < 40%, se va | | | puncte din | |*

*| întrerupe | | | valoarea | |*

*| administrarea | | | iniţială, se | |*

*| trastuzumab | | | va întrerupe | |*

*| emtasinum. | | | administrarea | |*

*| | | | trastuzumab | |*

*| | | | emtasinum. | |*

*|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_|*

*Neuropatie periferică*

*Administrarea trastuzumab emtasinum trebuie întreruptă temporar la pacienţii care prezintă neuropatie periferică de grad 3 sau 4 până la revenirea la </= gradul 2. La reluarea administrării se poate lua în considerare o reducere a dozei conform schemei de reducere a dozei.*

*Pacienţi vârstnici*

*Nu este necesară ajustarea dozei la pacienţii cu vârsta >/= 65 de ani. Nu sunt date suficiente pentru a stabili siguranţa şi eficacitatea la pacienţii cu vârsta >/= 75 de ani, deoarece datele provenite de la acest subgrup sunt limitate. Analizele farmacocinetice populaţionale indică faptul că vârsta nu are un efect clinic semnificativ asupra farmacocineticii trastuzumab emtasinum.*

*Pacienţii cu insuficienţă renală*

*Nu este necesară ajustarea dozei iniţiale la pacienţii cu insuficienţă renală uşoară sau moderată. O potenţială necesitate de ajustare a dozei la pacienţii cu insuficienţă renală severă nu poate fi determinată din cauza datelor insuficiente şi de aceea pacienţii cu insuficienţă renală severă trebuie monitorizaţi cu atenţie.*

*Pacienţii cu insuficienţă hepatică*

*Siguranţa şi eficacitatea la pacienţii cu insuficienţă hepatică nu au fost studiate. Nu se pot face recomandări specifice privind dozele.*

***VI. Întreruperea tratamentului***

*În cazul progresiei bolii (răspunsul terapeutic se va evalua prin metode imagistice periodic). Se recomandă întreruperea tratamentului conform schemelor de modificare a dozei din RCP produsului, precum şi în următoarele situaţii:*

*- sarcină/alăptare;*

*- pacienţii care prezintă dispnee de repaus determinată de complicaţiile malignităţii avansate sau comorbidităţilor;*

*- decizia medicului oncolog curant;*

*- decesul pacientului.*

***VII. Monitorizare:***

*- funcţia cardiacă trebuie evaluată la iniţierea tratamentului şi monitorizată pe parcursul acestuia, ori de câte ori este nevoie, inclusiv după încheierea tratamentului;*

*- evaluare imagistică periodică.*

***VIII. Prescriptori: medici specialişti oncologie medicală***

**#M17**

***DCI: OSIMERTINIB***

*Definiţia afecţiunii - tratamentul cancerului pulmonar nonmicrocelular*

***I. Indicaţii:*** *osimertinib este indicat pentru tratamentul pacienţilor adulţi cu cancer bronhopulmonar, altul decât cu celule mici (NSCLC), local avansat sau metastazat, cu mutaţie pozitivă T790M a receptorului pentru factorul de creştere epidermal (EGFR).*

***II. Criterii de includere:***

*a) vârstă peste 18 ani;*

*b) status de performanţă ECOG 0 - 2;*

*c) pacienţi cu cancer bronhopulmonar, altul decât cu celule mici, local avansat sau metastazat şi cu mutaţie pozitivă T790M a EGFR;*

*d) prezenţa mutaţiei pozitive T790M a receptorului pentru factorul de creştere epidermal (EGFR) - din ADN tumoral extras dintr-o probă de ţesut sau ADN tumoral circulant (ADNtc) obţinut din plasmă. Dacă se utilizează testarea ADNtc, cu o probă din plasmă şi rezultatul este negativ, se recomandă ori de câte ori este posibil repetarea cu un test tisular, deoarece există posibilitatea apariţiei rezultatelor fals negative la testele cu probă din plasmă.*

***III. Criterii de excludere/întrerupere:***

*a) insuficienţa hepatică severă: siguranţa şi eficacitatea acestui medicament nu au fost stabilite la pacienţi cu insuficienţă hepatică severă. Până când vor fi disponibile date suplimentare, utilizarea la pacienţii cu insuficienţă hepatică severă nu este recomandată;*

*b) boală interstiţială pulmonară/pneumonită;*

*c) interval QTc mai mare de 500 msec pe cel puţin 2 trasee ECG diferite: întreruperea tratamentului cu Osimertinib până când intervalul QTc este mai mic de 481 msec sau până la revenirea la valoarea iniţială, dacă aceasta este mai mare sau egală cu 481 msec, apoi reluare cu o doză mai mică (40 mg);*

*d) prelungirea intervalului QTc cu semne/simptome de aritmie gravă;*

*e) pacienţii care prezintă interval QTc prelungit în asociere cu oricare dintre următoarele: torsada vârfurilor, tahicardie ventriculară polimorfă, semne/simptome de aritmie gravă;*

*f) pacienţi cu sindrom congenital de QT prelungit;*

*g) sarcina/alăptarea;*

*h) hipersensibilitate la substanţa activă sau la oricare din excipienţi.*

***IV. Durata tratamentului:*** *până la progresia bolii sau până la apariţia unei toxicităţi inacceptabile.*

***V. Tratament***

*Doza recomandată este de 80 mg osimertinib o dată pe zi.*

*Dacă este omisă o doză de osimertinib, doza trebuie administrată cât mai curând, numai dacă următoarea doză nu va fi administrată în următoarele 12 ore.*

*Osimertinib poate fi administrat cu sau fără alimente la aceeaşi oră în fiecare zi.*

*Acest medicament este pentru administrare orală. Comprimatele trebuie înghiţite întregi, cu apă, şi nu trebuie sfărâmate, divizate sau mestecate.*

***Ajustarea dozelor***

*Întreruperea administrării şi/sau reducerea dozelor ar putea fi necesare în funcţie de parametrii individuali de siguranţă şi tolerabilitate. Dacă este necesară reducerea dozei, atunci doza trebuie redusă la 40 mg o dată pe zi.*

***Grupe speciale de pacienţi***

*Nu este necesară ajustarea dozei în funcţie de vârstă, greutate corporală, sex, rasă şi statutul de fumător.*

***VI. Monitorizare***

*Răspunsul terapeutic se va evalua prin metode clinice, imagistice (CT sau RMN sau PET).*

***VII. Prescriptori***

*Iniţierea se face de către medicii din specialitatea oncologie medicală. Continuarea tratamentului se face de către medicul oncolog sau pe baza scrisorii medicale de către medicii de familie desemnaţi.*

**#B**

ANEXA 2

**SUBLISTA A - MEDICAMENTE CU NIVEL DE COMPENSARE 90% DIN PREŢUL DE REFERINŢĂ**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

| **1** |**A02BA02**| **RANITIDINUM** | |

|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|

NOTĂ:

**Terapia de eradicare a infecţiei cu Helicobacter pylori trebuie avută în vedere înaintea iniţierii tratamentului ulcerului peptic cu acest medicament. Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A02BA02 RANITIDINUM CAPS. 150 mg

ULCORAN 150 mg EUROPHARM SA

A02BA02 RANITIDINUM COMPR. 150 mg

RANITIDIN 150 mg ARENA GROUP SA

RANITIDINA 150 mg 150 mg MAGISTRA C&C

A02BA02 RANITIDINUM COMPR. EFF. 150 mg

DIGENEFF 150 mg 150 mg OZONE LABORATORIES LTD.

A02BA02 RANITIDINUM COMPR. FILM. 150 mg

GERTOCALM 150 mg FARAN LABORATORIES SA.

RANITIDIN 150 mg 150 mg AC HELCOR SRL

RANITIDINA 150 mg 150 mg FILDAS TRADING SRL

RANITIDINA ANTIBIOTICE 150 mg 150 mg ANTIBIOTICE SA

RANITIDINA LPH 150 mg 150 mg LABORMED PHARMA SA

ZANTAC 150 mg 150 mg GLAXO WELLCOME UK LTD.

A02BA02 RANITIDINUM SOL. INJ. 25 mg/ml

ARNETIN 25 mg/ml MEDOCHEMIE LTD.

ZANTAC SOLUŢIE INJECTABILĂ 25 mg/ml GLAXO WELLCOME UK LTD.

A02BA02 RANITIDINUM COMPR. FILM. 300 mg

RANITIDIN 300 mg 300 mg AC HELCOR SRL

RANITIDINA 300 mg 300 mg FILDAS TRADING SRL

RANITIDINA LPH 300 mg 300 mg LABORMED PHARMA SA

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| **2** |**A02BA03**| **FAMOTIDINUM** | |

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NOTĂ:

**Terapia de eradicare a infecţiei cu Helicobacter pylori trebuie avută în vedere înaintea iniţierii tratamentului ulcerului peptic cu acest medicament. Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A02BA03 FAMOTIDINUM COMPR. FILM. 10 mg

FAMODAR ABR 10 mg DAR AL DAWA PHARMA S.R.L.

A02BA03 FAMOTIDINUM COMPR. FILM. 20 mg

FAMODAR 20 20 mg DAR AL DAWA PHARMA S.R.L.

FAMODIN 20 20 mg AC HELCOR PHARMA SRL

FAMOTAK 20 mg SEDICO IMPEX S.R.L.

QUAMATEL(R) 20 mg 20 mg GEDEON RICHTER PLC

A02BA03 FAMOTIDINUM COMPR. FILM. 20 mg

FAMODAR 20 20 mg DAR AL DAWA PHARMA S.R.L

FAMODIN 20 20 mg AC HELCOR PHARMA SRL

FAMOTAK 20 mg SEDICO IMPEX S.R.L.

QUAMATEL(R) 20 mg 20 mg GEDEON RICHTER PLC

A02BA03 FAMOTIDINUM LIOF. + SOLV. PT.

SOL. INJ. 20 mg

QUAMATEL(R) 20 mg 20 mg GEDEON RICHTER PLC

A02BA03 FAMOTIDINUM COMPR. FILM. 40 mg

FAMODAR 40 40 mg DAR AL DAWA PHARMA SRL

FAMODIN 40 40 mg AC HELCOR PHARMA SRL

FAMOTAK 40 mg SEDICO IMPEX S.R.L.

FAMOTIDINA ZENTIVA 40 mg 40 mg ZENTIVA S.A.

GASTROSIDIN 40 mg ECZACIBASI

PHARMACEUTICALS S.R.L.

QUAMATEL(R) 40 mg 40 mg GEDEON RICHTER PLC

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| **3** |**A02BA04**| **NIZATIDINUM** | |

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NOTĂ:

**Terapia de eradicare a infecţiei cu Helicobacter pylori trebuie avută în vedere înaintea iniţierii tratamentului ulcerului peptic cu acest medicament. Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A02BA04 NIZATIDINUM CAPS. 150 mg

NIZATIDIN 150 mg 150 mg VIM SPECTRUM SRL

NIZATIDIN ALAROPHARM 150 mg 150 mg LAROPHARM S.R.L.

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| **4** |**A02BC01**| **OMEPRAZOLUM** | |

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NOTĂ:

**Terapia de eradicare a infecţiei cu Helicobacter pylori trebuie avută în vedere înaintea iniţierii tratamentului ulcerului peptic cu acest medicament. Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A02BC01 OMEPRAZOLUM CAPS. GASTROREZ. 10 mg

ORTANOL(R) S 10 mg LEK PHARMACEUTICALS D.D.

Prescriere limitată: **Boala de reflux gastro-esofagian.**

**Se aplică pentru toate denumirile comerciale şi formele farmaceutice ale concentraţiei de 10 mg.**

A02BC01 OMEPRAZOLUM COMPR. FILM. GASTROREZ. 10 mg

LOSEC MUPS 10 mg 10 mg ASTRAZENECA AB

A02BC01 OMEPRAZOLUM CAPS. GASTROREZ. 20 mg

HELICID 20 20 mg ZENTIVA AS

OMEPRAZOL 20 mg 20 mg GEDEON RICHTER ROMANIA SA

OMEPRAZOL BIOFARM 20 mg 20 mg BIOFARM S.A.

OMEPRAZOL LPH 20 mg 20 mg LABORMED PHARMA SA

OMEPRAZOL TERAPIA 20 mg 20 mg TERAPIA S.A.

OMERAN 20 20 mg EUROPHARM SA

OMEZ 20 mg DR. REDDY'S LABORATORIES

ORTANOL(R) 20 mg 20 mg LEK PHARMACEUTICALS D.D.

ULTOP 20 mg KRKA D.D.

Prescriere limitată: **Boala de reflux gastro-esofagian**

Prescriere limitată: **Sclerodermia esofagului.**

Prescriere limitată: **Sindromul Zollinger - Ellison**

Prescriere limitată: **Tratamentul ulcerului gastric şi duodenal.**

Prescriere limitată: **Profilaxia ulcerului gastro - duodenal la pacienţii în tratament cu AINS pe termen lung şi care prezintă factori de risc gastrointestinal.**

NOTĂ:

**Se aplică pentru toate denumirile comerciale şi formele farmaceutice corespunzătoare concentraţiilor de 20 mg.**

A02BC01 OMEPRAZOLUM CAPS. ENTER. 20 mg

RISEK 20 mg GULF PHARMACEUTICAL

INDUSTRIES S.R.L.

A02BC01 OMEPRAZOLUM COMPR. FILM. GASTROREZ. 20 mg

LOSEC MUPS 20 mg 20 mg ASTRAZENECA AB

OMEDAR(R) 20 mg DAR AL DAWA PHARMA S.R.L.

A02BC01 OMEPRAZOLUM CAPS. GASTROREZ. 40 mg

OMERAN 40 40 mg EUROPHARM SA

ORTANOL(R) 40 mg LEK PHARMACEUTICALS D.D.

ULTOP 40 mg KRKA D.D. NOVO MESTO

Prescriere limitată: **Boala de reflux gastro-esofagian**

Prescriere limitată: **Sclerodermia esofagului.**

Prescriere limitată: **Sindromul Zollinger-Ellison**

Prescriere limitată: **Tratamentul ulcerului gastric şi duodenal.**

NOTĂ:

**Se aplică pentru toate denumirile comerciale şi formele farmaceutice corespunzătoare concentraţiilor de 40 mg.**

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| **5** |**A02BC03**| **LANSOPRAZOLUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A02BC03 LANSOPRAZOLUM CAPS. GASTROREZ. 15 mg

LEVANT 15 mg 15 mg RANBAXY UK LTD.

Prescriere limitată: **Boala de reflux gastro-esofagian**

A02BC03 LANSOPRAZOLUM CAPS. GASTROREZ. 30 mg

LANZAP 30 mg 30 mg DR. REDDY'S LABORATORIES

LANZUL 30 mg KRKA D.D. NOVO MESTO

LEVANT 30 mg 30 mg RANBAXY UK LTD.

Prescriere limitată: **Boala de reflux gastro-esofagian**

Prescriere limitată: **Sindromul Zollinger-Ellison.**

Prescriere limitată: **Tratamentul ulcerului gastric şi duodenal.**

Prescriere limitată: **Profilaxia ulcerului gastro-duodenal la pacienţii în tratament cu AINS pe termen lung şi care prezintă factori de risc gastrointestinal.**

NOTĂ:

**Se aplică pentru toate denumirile comerciale şi formele farmaceutice corespunzătoare concentraţiei de 30 mg.**

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| **6** |**A03AA04**| **MEBEVERINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A03AA04 MEBEVERINUM CAPS. ELIB. PREL. 200 mg

DUSPATALIN(R) 200 mg 200 mg SOLVAY PHARMACEUTICALS BV

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| **7** |**A03AA05**| **TRIMEBUTINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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A03AA05 TRIMEBUTINUM COMPR. 100 mg

COLOBUTINE(R) 100 mg LAB. FOURNIER SA

COLPERIN 100 mg 100 mg GEDEON RICHTER

ROMANIA S.A.

PROMEBUTIN(R) 100 mg 100 mg TERAPIA SA

TRIMEBUTIN 100 100 mg MAGISTRA C & C

A03AA05 TRIMEBUTINUM COMPR. FILM. 100 mg

DEBRIDAT 100 mg 100 mg PFIZER EUROPE MA EEIG

A03AA05 TRIMEBUTINUM GRAN. PT. SUSP. ORALĂ 24 mg/5 ml

DEBRIDAT 24 mg/5 ml PFIZER EUROPE MA EEIG

A03AA05 TRIMEBUTINUM COMPR. FILM. ELIB. 300 mg

PREL.

IBUTIN(R) 300 mg 300 mg ZENTIVA SA

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| **8** |**A03AD01**| **PAPAVERINI HYDROCHLORIDUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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A03AD01 PAPAVERINI COMPR. 100 mg

HYDROCHLORIDUM

PAPAVERINA 100 mg 100 mg SINTOFARM SA

A03AD01 PAPAVERINI COMPR. 200 mg

HYDROCHLORIDUM

PAPAVERINA 200 mg FARMACOM SA

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| **9** |**A03FA01**| **METOCLOPRAMIDUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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A03FA01 METOCLOPRAMIDUM COMPR. 10 mg

METOCLOPRAMID 10 mg SLAVIA PHARM SRL

METOCLOPRAMID 10 mg 10 mg TERAPIA SA

N-METOCLOPRAMID 10 mg MEDUMAN SA

A03FA01 METOCLOPRAMIDUM SIROP 1 mg/5 ml

METOCLOPRAMID BIOFARM 1 mg/5 ml BIOFARM S.A.

1 mg/5 ml

A03FA01 METOCLOPRAMIDUM SOL. INJ. 5 mg/ml

METOCLOPRAMID 10 mg 5 mg/ml TERAPIA SA

A03FA01 METOCLOPRAMIDUM PIC. ORALE - SOL. 7 mg/ml

METOCLOPRAMID 7 mg/ml BIOFARM SA

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| **10** |**A03FA03**| **DOMPERIDONUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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A03FA03 DOMPERIDONUM COMPR. FILM. 10 mg

MOTILIUM 10 mg JANSSEN PHARMACEUTICA NV

MOTILIUM 10 mg 10 mg TERAPIA SA

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| **11** |**A05AA02**| **ACIDUM URSODEOXYCHOLICUM\*** | |

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NOTĂ:

**Nu se va prescrie în regim compensat pentru tratamentul litiazei biliare.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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A05AA02 ACIDUM CAPS. 250 mg

URSODEOXYCHOLICUM

URSOFALK(R) 250 mg DR. FALK PHARMA GMBH

URSOSAN 250 mg PRO. MED. CS PRAHA AS

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| **12** |**A06AD11**| **LACTULOSUM** | |

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Prescriere limitată: **Tratamentul encefalopatiei cronice porto-sistemice**

**Tratamentul constipaţiei la pacienţii neoplazici.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A06AD11 LACTULOSUM LICHID ORAL 66.7%

DUPHALAC(R) 66.7% SOLVAY PHARMACEUTICALS BV

A06AD11 LACTULOSUM SIROP 66.7%

LACTULOSE AL SIROP 66.7% ALIUD PHARMA GMBH & CO.KG

A06AD11 LACTULOSUM SOL. ORALĂ 670 mg/ml

LAEVOLAC 670 mg/ml 670 mg/ml FRESENIUS KABI AUSTRIA

GMBH

A06AD11 LACTULOSUM SIROP 66.7%

LACTULOSE AL SIROP 66.7% ALIUD PHARMA GMBH & CO.KG

A06AD11 LACTULOSUM SOL. ORALĂ 670 mg/ml

LAEVOLAC 670 mg/ml 670 mg/ml FRESENIUS KABI AUSTRIA

GMBH

A06AD11 LACTULOSUM SIROP 66.7%

LACTULOSE AL SIROP 66.7% ALIUD PHARMA GMBH & CO.KG

A06AD11 LACTULOSUM SOL. ORALĂ 670 mg/ml

LAEVOLAC 670 mg/ml 670 mg/ml FRESENIUS KABI AUSTRIA

GMBH

A06AD11 LACTULOSUM LICHID ORAL 66.7%

DUPHALAC(R) 66.7% SOLVAY PHARMACEUTICALS BV

A06AD11 LACTULOSUM SIROP 65%

LACTULOSE 65% E.I.P.I.CO. MED S.R.L.

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| **13** |**A07AA02**| **NYSTATINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A07AA02 NYSTATINUM COMPR. FILM. 500.000 ui

NISTATINA 500.000 ui ANTIBIOTICE SA

A07AA02 NYSTATINUM COMPR. FILM. 500.000 ui

STAMICIN(R) 500.000 U.I. 500.000 ui ZENTIVA SA

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| **14** |**A07EC01**| **SULFASALAZINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A07EC01 SULFASALAZINUM COMPR. FILM. 500 mg

SALAZIDIN 500 mg AC HELCOR SRL

A07EC01 SULFASALAZINUM COMPR. FILM. GASTROREZ. 500 mg

SULFASALAZIN EN 500 mg KRKA D.D. NOVO MESTO

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| **15** |**A07EC02**| **MESALAZINUM\*\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A07EC02 MESALAZINUM SUPOZ. 1 g

PENTASA 1 g FERRING A/S

Prescriere limitată: **Episod acut de proctită ulcerativă forma moderată.**

NOTĂ:

**A nu se administra în tratamentul bolii Crohn.**

A07EC02 MESALAZINUM COMPR. GASTROREZ. 250 mg

SALOFALK 250 mg COMPRIMATE 250 mg DR. FALK PHARMA GMBH

GASTROREZISTENTE

Cod restricţie 1708: **Colită ulcerativă asociată cu hipersensibilitate la sulfonamide**

Cod restricţie 1709: **Colită ulcerativă asociată cu intoleranţă la sulfasalazinum**

Cod restricţie 2268: **Boala Crohn în cazul în care există hipersensibilitate la sulfonamide**

Cod restricţie 2269: **Boala Crohn în cazul în care există intoleranţă la sulfasalazinum**

A07EC02 MESALAZINUM SUPOZ. 250 mg

SALOFALK(R) 250 mg 250 mg DR. FALK PHARMA GMBH

Prescriere limitată: **Episod acut de proctită ulcerativă forma moderată**

A07EC02 MESALAZINUM SUSP. RECTALĂ 4 g/60 ml

SALOFALK 4 g/60 ml 4 g/60 ml DR. FALK PHARMA GMBH

Cod restricţie 1707: **Episod acut de colită ulcerativă forma moderată**

A07EC02 MESALAZINUM COMPR. ELIB. PREL. 500 mg

PENTASA 500 mg FERRING A/S

Cod restricţie 1708: **Colită ulcerativă asociată cu hipersensibilitate la sulfonamide**

Cod restricţie 1709: **Colită ulcerativă asociată cu intoleranţă la sulfasalazinum**

Cod restricţie 2268: **Boala Crohn în cazul în care există hipersensibilitate la sulfonamide**

Cod restricţie 2269: **Boala Crohn în cazul în care există intoleranţă la sulfasalazinum**

A07EC02 MESALAZINUM COMPR. GASTROREZ. 500 mg

SALOFALK 500 mg COMPRIMATE 500 mg DR. FALK PHARMA GMBH

GASTROREZISTENTE

Cod restricţie 1708: **Colită ulcerativă asociată cu hipersensibilitate la sulfonamide**

Cod restricţie 1709: **Colită ulcerativă asociată cu intoleranţă la sulfasalazinum**

Cod restricţie 2268: **Boala Crohn în cazul în care există hipersensibilitate la sulfonamide**

Cod restricţie 2269: **Boala Crohn în cazul în care există intoleranţă la sulfasalazinum**

A07EC02 MESALAZINUM SUPOZ. 500 mg

SALOFALK(R) 500 mg 500 mg DR. FALK PHARMA GMBH

Prescriere limitată: **Episod acut de proctită ulcerativă forma moderată**

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| **16** |**B01AA07**| **ACENOCUMAROLUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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B01AA07 ACENOCUMAROLUM COMPR. 2 mg

TROMBOSTOP 2 mg 2 mg TERAPIA SA

B01AA07 ACENOCUMAROLUM COMPR. 4 mg

SINTROM(R) 4 mg NOVARTIS PHARMA GMBH

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| **17** |**B01AC05**| **TICLOPIDINUM (1)** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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B01AC05 TICLOPIDINUM COMPR. FILM. 250 mg

IPATON 250 mg EGIS PHARMACEUTICALS PLC

TICLID(R) 250 mg 250 mg SANOFI-SYNTHELABO FRANCE

TICLODIN 250 mg AC HELCOR SRL

TICLOPIDIN SANDOZ 250 mg HEXAL AG

Cod restricţie 1719: **Prevenţia recurentei accidentului vascular ischiemic sau a accidentului ischemic tranzitor la pacienţii cu istoric de episoade ischiemice cerebrovasculare în timpul terapiei cu doze reduse de aspirină**

Cod restricţie 1720: **Prevenţia recurenţei accidentului vascular ischiemic sau a accidentului ischemic tranzitor la pacienţii la care terapia cu doze reduse de aspirină prezintă un risc major (inacceptabil) de sângerare gastrointestinală;**

Cod restricţie 1721: **Prevenţia recurenţei accidentului vascular ischiemic sau a accidentului ischemic tranzitor la pacienţii cu istoric de reacţie anafilactică, urticarie sau astm bronşic în decurs de 4 ore de la administrarea de aspirină, alţi salicilaţi sau AINS**

Neutropenia severă este un efect advers comun în primele luni de terapie. Monitorizarea hematologică se impune la începutul tratamentului şi apoi la fiecare două săptămâni în primele patru luni de tratament.

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| **18** |**B02BA01**| **PHYTOMENADIONUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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B02BA01 PHYTOMENADIONUM SOL. INJ. 10 mg/ml

FITOMENADION 10 mg/ml 10 mg/ml TERAPIA SA

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| **19** |**B03AA07**| **FERROSI SULFAS** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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B03AA07 FERROSI SULFAS COMPR. ELIB. PREL. 105 mg

FERROGRADUMET(R) 105 mg TEOFARMA SRL

B03AA07 FERROSI SULFAS DRAJ. ELIB. PREL. 80 mg

TARDYFERON 80 mg 80 mg LAB. PIERRE FABRE

B03AA07 FERROSI SULFAS COMPR. FILM. ELIB.

PREL.

FERRO-GRADUMET POLIPHARMA

INDUSTRIES S.R.L.

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| **20** |**B03AB05**| **COMPLEX DE HIDROXID DE FER (III)** | |

| | | **POLIMALTOZAT** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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B03AB05 COMPLEX DE HIDROXID COMPR. MAST. 100 mg

DE FER (III)

POLIMALTOZAT

MALTOFER 100 mg VIFOR FRANCE SA

B03AB05 COMPLEX DE HIDROXID SIROP 10 mg/ml

DE FER (III)

POLIMALTOZAT

FERRUM HAUSMANN(R) 10 mg/ml VIFOR FRANCE SA

B03AB05 COMPLEX DE HIDROXID SIROP 50 mg/5 ml

DE FER (III)

POLIMALTOZAT

FERGLUROM 50 mg/5 ml 50 mg/5 ml BIOFARM S.A.

B03AB05 COMPLEX DE HIDROXID PICĂTURI ORALE - SOL. 5%

DE FER (III)

POLIMALTOZAT

PHARMA-FERRUM(R) 5% TERAPIA SA

B03AB05 COMPLEX DE HIDROXID PICĂTURI ORALE - SOL. 50 mg/ml

DE FER (III)

POLIMALTOZAT

FERRUM HAUSMANN(R) 50 mg/ml VIFOR FRANCE SA

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| **21** |**B03AEN1**| **COMBINAŢII (FERROSI SULFAS + ACIDUM** | |

| | | **ASCORBICUM)** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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B03AEN1 COMBINAŢII (FERROSI COMPR. FILM.

SULFAS + ACIDUM

ASCORBICUM)

SORBIFER DURULES EGIS PHARMACEUTICALS LTD.

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| **22** |**B03BB01**| **ACIDUM FOLICUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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B03BB01 ACIDUM FOLICUM COMPR. FILM. 5 mg

ACIFOL 5 mg 5 mg ZENTIVA SA

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| **23** |**C01AA05**| **DIGOXINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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C01AA05 DIGOXINUM SOL. ORALĂ 0.05 mg/ml

LANOXIN SOLUŢIE ORALĂ 0.05 mg/ml THE WELLCOME

FOUNDATION LTD.

C01AA05 DIGOXINUM COMPR. 0.25 mg

DIGOXIN 0,25 mg 0,25 mg ZENTIVA SA

C01AA05 DIGOXINUM SOL. INJ. 0.5 mg/ml

DIGOXIN 0,5 mg/2 ml 0,5 mg/ml ZENTIVA SA

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| **24** |**C01BA01**| **CHINIDINI SULFAS** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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C01BA01 CHINIDINI SULFAS COMPR. 200 mg

CHINIDINA LAROPHARM 200 mg 200 mg LAROPHARM SRL

CHINIDINA SULFAT 200 mg 200 mg ARENA GROUP SA

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| **25** |**C01BC03**| **PROPAFENONUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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C01BC03 PROPAFENONUM COMPR. 150 mg

PROPAFENONA 150 mg 150 mg ARENA GROUP SA

C01BC03 PROPAFENONUM COMPR. FILM. 150 mg

PROPAFENON AL 150 150 mg ALIUD(R) PHARMA GMBH &

CO.KG

PROPAFENON SANDOZ 150 mg 150 mg HEXAL AG

RYTMONORM(R) 150 mg ABBOTT GMBH & CO.KG

C01BC03 PROPAFENONUM SOL. INJ. 70 mg/20 ml

RYTMONORM 70 mg/20 ml ABBOTT GMBH & CO.KG

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| **26** |**C01BD01**| **AMIODARONUM** | |

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Prescriere limitată: **Tratamentul tulburărilor de ritm severe care nu răspund**

**la alte terapii sau când alte antiaritmice nu pot fi**

**folosite: a) tahiaritmii asociate sindromului Wolff -**

**Parkinson - White; b) flutter/fibrilaţie atrială,**

**atunci când alte antiaritmice nu pot fi folosite; c)**

**toate tahiaritmiile paroxistice, incluzând tahicardii**

**supraventriculare, tahicardii ventriculare şi nodale,**

**fibrilaţie ventriculară, atunci când alte antiaritmice**

**nu pot fi folosite.**

Există dovezi că amiodarona poate produce toxicitate frecventă şi potenţial severă. Se recomandă monitorizarea periodică a funcţiilor hepatice şi tiroidiene.

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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C01BD01 AMIODARONUM COMPR. 200 mg

AMIODARONA 200 mg 200 mg ARENA GROUP SA

AMIODARONA LPH 200 mg 200 mg LABORMED PHARMA SA

DARITMIN(R) 200 mg 200 mg GEDEON RICHTER ROMANIA SA

SEDACORON(R) 200 mg EBEWE PHARMA GMBH NFG. KG

C01BD01 AMIODARONUM COMPR. DIVIZ. 200 mg

CORDARONE 200 mg 200 mg SANOFI-AVENTIS FRANCE

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| **27** |**C01DA02**| **NITROGLYCERINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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C01DA02 NITROGLYCERINUM SPRAY SUBLINGUAL 0.4 mg/doza

NITROMINT 0.4 mg/doza EGIS PHARMACEUTICALS

P.L.C.

NOTĂ:

**Sprayul nu trebuie inhalat.**

C01DA02 NITROGLYCERINUM COMPR. SUBLING. 0.5 mg

NITROGLICERINA 0,5 mg 0.5 mg ZENTIVA SA

C01DA02 NITROGLYCERINUM COMPR. ELIB. PREL. 2.6 mg

NITROMINT 2,6 mg 2.6 mg EGIS PHARMACEUTICALS LTD.

C01DA02 NITROGLYCERINUM SIST. TERAP. TRANSDERM. 25 mg

NITRODERM(R) TTS 5 25 mg NOVARTIS PHARMA GMBH

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| **28** |**C01DA08**| **ISOSORBIDI DINITRAS** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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C01DA08 ISOSORBIDI DINITRAS COMPR. 10 mg

ISOSORBIDE DINITRATE 10 mg 10 mg E.I.P.I.CO. MED S.R.L.

C01DA08 ISOSORBIDI DINITRAS CAPS. ELIB. PREL. 20 mg

DINITER SR 20 mg 20 mg TERAPIA SA

C01DA08 ISOSORBIDI DINITRAS COMPR. ELIB. PREL. 20 mg

ISODINIT(R) RETARD 20 mg BALKAN PHARMA DUPNITZA AD

C01DA08 ISOSORBIDI DINITRAS CAPS. ELIB. PREL. 40 mg

DINITER SR 40 mg 40 mg TERAPIA SA

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| **29** |**C01DA14**| **ISOSORBIDI MONONITRAS** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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C01DA14 ISOSORBIDI MONONITRAS CAPS. ELIB. PREL. 40 mg

OLICARD 40 mg RETARD 40 mg SOLVAY PHARMACEUTICALS

GMBH

C01DA14 ISOSORBIDI MONONITRAS CAPS. ELIB. PREL. 60 mg

OLICARD 60 mg RETARD 60 mg SOLVAY PHARMACEUTICALS

GMBH

C01DA14 ISOSORBIDI MONONITRAS COMPR. FILM. ELIB. 60 mg

PREL.

MONONITRON(R) EP 60 mg 60 mg ZENTIVA S.A.

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| **30** |**C01EA01**| **ALPROSTADILUM\*\*\*** | **Protocol: C002I** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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C01EA01 ALPROSTADILUM CONC. PT. SOL. PERF. 20 µg

ALPROSTADIL "PINT" 20 µg PINT-PHARMA GMBH

20 µg

C01EA01 ALPROSTADILUM LIOF. PT. SOL. PERF. 20 µg

VASAPROSTAN 20 20 µg SCHWARZ PHARMA AG

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| **31** |**C01EB15**| **TRIMETAZIDINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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C01EB15 TRIMETAZIDINUM CAPS. 20 mg

TRIMETAZIDIN 20 mg 20 mg VIM SPECTRUM SRL

C01EB15 TRIMETAZIDINUM COMPR. FILM. 20 mg

DILATAN 20 mg 20 mg TERAPIA SA

MODUXIN(R) 20 mg 20 mg GEDEON RICHTER ROMÂNIA SA

PREDOZONE 20 mg 20 mg OZONE LABORATORIES LTD.

PREDUCTAL(R) 20 mg LES LAB. SERVIER IND.

TRIMETAZIDINA LPH(R) 20 mg 20 mg LABORMED PHARMA SA

TRIVEDON 20 20 mg CIPLA (UK) LIMITED

C01EB15 TRIMETAZIDINUM DRAJ. 20 mg

TRIMETAZIDINA 20 mg 20 mg TERAPIA SA

C01EB15 TRIMETAZIDINUM COMPR. FILM. ELIB. 35 mg

MODIF.

DILATAN MR 35 mg 35 mg TERAPIA SA

PREDUCTAL MR 35 mg 35 mg LES LAB. SERVIER IND.

TRIMETAZIDINA LPH(R) 35 mg 35 mg LABORMED PHARMA SA

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| **32** |**C02AB01**| **METHYLDOPUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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C02AB01 METHYLDOPUM COMPR. 250 mg

DOPEGYT 250 mg EGIS PHARMACEUTICALS PLC

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| **33** |**C02AC01**| **CLONIDINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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C02AC01 CLONIDINUM COMPR. 0.15 mg

CLONIDINA 0,15 mg 0.15 mg ARENA GROUP SA

CLONIDINA SINTOFARM 0,15 mg 0.15 mg SINTOFARM SA

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| **34** |**C02CA04**| **DOXAZOSINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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C02CA04 DOXAZOSINUM COMPR. 1 mg

DOXAZOSIN 1 MEDOCHEMIE 1 mg MEDOCHEMIE ROMANIA SRL

DOXAZOSIN AL 1 1 mg ALIUD(R) PHARMA GMBH &

CO.KG

KAMIREN 1 mg KRKA D.D. NOVO MESTO

MAGUROL 1 mg MEDOCHEMIE LTD.

C02CA04 DOXAZOSINUM COMPR. 2 mg

DOXAZOSIN 2 MEDOCHEMIE 2 mg MEDOCHEMIE ROMANIA SRL

DOXAZOSIN AL 2 2 mg ALIUD(R) PHARMA GMBH &

CO.KG

DOXAZOSIN SANDOZ 2 mg 2 mg HEXAL AG

KAMIREN 2 mg KRKA, D.D. NOVO MESTO

MAGUROL 2 mg MEDOCHEMIE LTD.

C02CA04 DOXAZOSINUM COMPR. 4 mg

DOXAZOSIN 4 MEDOCHEMIE 4 mg MEDOCHEMIE ROMANIA SRL

DOXAZOSIN AL 4 4 mg ALIUD(R) PHARMA GMBH &

CO.KG

KAMIREN 4 mg KRKA D.D. NOVO MESTO

MAGUROL 4 mg MEDOCHEMIE LTD.

C02CA04 DOXAZOSINUM COMPR. ELIB. MODIF. 4 mg

CARDURA XL 4 mg 4 mg PFIZER H.C.P. CORPORATION

C02CA04 DOXAZOSINUM COMPR. FILM. ELIB. 4 mg

PREL.

KAMIREN XL 4 mg 4 mg KRKA D.D. NOVO MESTO

C02CA04 DOXAZOSINUM COMPR. 1 mg

DOXAZOSIN 1 MEDOCHEMIE 1 mg MEDOCHEMIE ROMANIA SRL

DOXAZOSIN AL 1 1 mg ALIUD(R) PHARMA GMBH &

CO.KG

KAMIREN 1 mg KRKA D.D. NOVO MESTO

MAGUROL 1 mg MEDOCHEMIE LTD.

C02CA04 DOXAZOSINUM COMPR. 2 mg

DOXAZOSIN 2 MEDOCHEMIE 2 mg MEDOCHEMIE ROMANIA SRL

DOXAZOSIN AL 2 2 mg ALIUD(R) PHARMA GMBH &

CO.KG

DOXAZOSIN SANDOZ 2 mg 2 mg HEXAL AG

KAMIREN 2 mg KRKA D.D. NOVO MESTO

MAGUROL 2 mg MEDOCHEMIE LTD.

C02CA04 DOXAZOSINUM COMPR. 4 mg

DOXAZOSIN 4 MEDOCHEMIE 4 mg MEDOCHEMIE ROMANIA SRL

DOXAZOSIN AL 4 4 mg ALIUD(R) PHARMA GMBH &

CO.KG

KAMIREN 4 mg KRKA D.D. NOVO MESTO

MAGUROL 4 mg MEDOCHEMIE LTD.

C02CA04 DOXAZOSINUM COMPR. ELIB. MODIF. 4 mg

CARDURA XL 4 mg 4 mg PFIZER H.C.P. CORPORATION

C02CA04 DOXAZOSINUM COMPR. FILM. ELIB. 4 mg

PREL.

KAMIREN XL 4 mg 4 mg KRKA D.D. NOVO MESTO

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| **35** |**C03AA03**| **HYDROCHLOROTHIAZIDUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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C03AA03 HYDROCHLOROTHIAZIDUM COMPR. 25 mg

NEFRIX 25 mg 25 mg ZENTIVA SA

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| **36** |**C03BA11**| **INDAPAMIDUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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C03BA11 INDAPAMIDUM COMPR. FILM. ELIB. 1,5 mg

PREL.

IMPAMID SR 1,5 mg 1,5 mg GEDEON RICHTER

ROMANIA S.A.

INDATER SR 1,5 mg 1,5 mg TERAPIA SA

C03BA11 INDAPAMIDUM COMPR. FILM. ELIB. 1.5 mg

PREL.

INDAPAMID SR 1,5 mg LAROPHARM 1.5 mg LAROPHARM SRL

C03BA11 INDAPAMIDUM COMPR. ELIB. PREL. 1.5 mg

INDAPAMID MCC 1,5 mg 1.5 mg MAGISTRA C & C SRL

C03BA11 INDAPAMIDUM COMPR. FILM. ELIB. 1.5 mg

PREL.

INDAPAMID LPH(R) 1,5 mg 1.5 mg LABORMED PHARMA SA

RAWEL SR 1,5 mg 1.5 mg KRKA D.D. NOVO MESTO

TERTENSIF(R) SR 1.5 mg LES LAB. SERVIER IND.

C03BA11 INDAPAMIDUM COMPR. 2.5 mg

IMPAMID(R) 2,5 mg 2.5 mg GEDEON RICHTER ROMANIA SA

C03BA11 INDAPAMIDUM COMPR. FILM. 2.5 mg

INDAPAMID LPH (R) 2,5 mg 2.5 mg LABORMED PHARMA SA

INDAPAMIDE 2,5 mg 2.5 mg HEMOFARM S.R.L.

INDATER(R) 2,5 mg 2.5 mg TERAPIA SA

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| **37** |**C03CA01**| **FUROSEMIDUM** | |

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Electroliţii serici trebuie să fie verificaţi periodic.

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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C03CA01 FUROSEMIDUM SOL. INJ. 10 mg/ml

FUROSEMID 20 mg/2 ml 10 mg/ml ZENTIVA SA

C03CA01 FUROSEMIDUM COMPR. 40 mg

FUROSEMID ARENA 40 mg 40 mg ARENA GROUP S.A.

FUROSEMID EEL 40 mg BIO EEL SRL

FUROSEMID LPH 40 mg 40 mg LABORMED PHARMA SA

FUROSEMID MCC 40 mg 40 mg MAGISTRA C & C SRL

FUROSEMID SLAVIA 40 mg SLAVIA PHARM SRL

FUROSEMID ZENTIVA 40 mg ZENTIVA SA

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| **38** |**C03DA01**| **SPIRONOLACTONUM** | |

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Electroliţii serici trebuie să fie verificaţi periodic.

Femeile la vârsta fertilă la care s-a iniţiat tratament cu spironolactona trebuie să ia măsuri adecvate de contracepţie.

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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C03DA01 SPIRONOLACTONUM CAPS. 100 mg

VEROSPIRON 100 mg GEDEON RICHTER LTD.

C03DA01 SPIRONOLACTONUM COMPR. 25 mg

SPIRONOLACTONA 25 mg 25 mg BIO EEL SRL

C03DA01 SPIRONOLACTONUM COMPR. FILM. 25 mg

ALSPIRON 25 mg 25 mg AC HELCOR PHARMA SRL

SPIRONOLACTONA 25 mg 25 mg TERAPIA SA

C03DA01 SPIRONOLACTONUM CAPS. 50 mg

VEROSPIRON 50 mg GEDEON RICHTER LTD.

C03DA01 SPIRONOLACTONUM COMPR. FILM. 50 mg

ALSPIRON 50 mg 50 mg AC HELCOR PHARMA SRL

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| **39** |**C03EB01**| **COMBINAŢII (SPIRONOLACTONUM + FUROSEMIDUM)** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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C03EB01 COMBINAŢII CAPS.

(SPIRONOLACTONUM +

FUROSEMIDUM)

DIUREX 50 TERAPIA SA

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| **40** |**C04AD03**| **PENTOXIFYLLINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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C04AD03 PENTOXIFYLLINUM COMPR. FILM. ELIB. 400 mg

PREL.

ANGIOPENT 400 mg 400 mg AC HELCOR PHARMA SRL

PENTOXI RETARD 400 mg 400 mg TERAPIA SA

C04AD03 PENTOXIFYLLINUM DRAJ. ELIB. PREL. 400 mg

TRENTAL(R) 400 mg AVENTIS PHARMA DEUTSCHLAND

GMBH

C04AD03 PENTOXIFYLLINUM COMPR. FILM. ELIB. 600 mg

PREL.

ANGIOPENT 600 mg 600 mg AC HELCOR PHARMA SRL

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| **41** |**C07AA05**| **PROPRANOLOLUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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C07AA05 PROPRANOLOLUM COMPR. 10 mg

N-PROPRANOLOL 10 mg 10 mg SC MEDUMAN SA

PROPRANOLOL 10 mg BIO EEL SRL

PROPRANOLOL 10 mg 10 mg SINTOFARM SA

C07AA05 PROPRANOLOLUM COMPR. 40 mg

PROPRANOLOL 40 mg 40 mg SINTOFARM SA

PROPRANOLOL EEL 40 mg 40 mg BIO EEL SRL

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| **42** |**C07AA07**| **SOTALOLUM** | |

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Prescriere limitată: **Tratamentul aritmiilor ventriculare severe.**

**Tratamentul aritmiilor supraventriculare.**

**Se aplică pentru toate denumirile comerciale şi formele farmaceutice corespunzătoare denumirii comune internaţionale.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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C07AA07 SOTALOLUM COMPR. 160 mg

ALS-SOTALOL 160 mg 160 mg ALSIFCOM INTERMED SRL

DAROB(R) 160 mg 160 mg ABBOTT GMBH & CO.KG

SOTAGAMMA 160 160 mg WORWAG PHARMA GMBH & CO.KG

SOTALOL AL 160 160 mg ALIUD PHARMA GMBH & CO.KG

C07AA07 SOTALOLUM COMPR. 80 mg

ALS-SOTALOL 80 mg 80 mg ALSIFCOM INTERMED SRL

DAROB(R) 80 mg 80 mg ABBOTT GMBH & CO.KG

SOTAGAMMA 80 80 mg WORWAG PHARMA GMBH & CO.KG

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| **43** |**C07AB02**| **METOPROLOLUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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C07AB02 METOPROLOLUM COMPR. 100 mg

BETAPROL 100 mg 100 mg AC HELCOR PHARMA SRL

BLOXAN 100 mg KRKA D.D. NOVO MESTO

EGILOK 100 mg 100 mg EGIS PHARMACEUTICALS

P.L.C.

METOPRO TAD 100 100 mg TAD PHARMA GMBH

METOPROLOL 100 mg 100 mg MAGISTRA C & C SRL

METOPROLOL AL 100 100 mg ALIUD(R) PHARMA GMBH &

CO.KG

METOPROLOL LPH 100 mg 100 mg LABORMED PHARMA SA

METOPROLOL MEDICO UNO 100 mg 100 mg MEDICO UNO PHARMACEUTICAL

S.R.L.

METOPROLOL TERAPIA 100 mg 100 mg TERAPIA SA

VASOCARDIN(R) 100 100 mg SLOVAKOFARMA

C07AB02 METOPROLOLUM COMPR. ELIB. PREL. 100 mg

METOPROLOL RETARD 100 mg 100 mg TERAPIA S.A.

C07AB02 METOPROLOLUM COMPR. FILM. ELIB. 100 mg

PREL.

BETALOCR ZOC 100 mg 100 mg ASTRAZENECA AB

C07AB02 METOPROLOLUM COMPR. FILM. ELIB. MOD. 190 mg

METOSUCCINAT SANDOZ 190 mg 190 mg HEXAL AG

C07AB02 METOPROLOLUM COMPR. ELIB. PREL. 200 mg

VASOCARDIN(R) SR 200 200 mg ZENTIVA AS

C07AB02 METOPROLOLUM COMPR. 25 mg

EGILOK 25 mg 25 mg EGIS PHARMACEUTICALS

P.L.C.

METOPROLOL 25 mg 25 mg ARENA GROUP SA

METOPROLOL LPH 25 mg 25 mg LABORMED PHARMA SA

METOPROLOL MEDICO UNO 25 mg 25 mg MEDICO UNO PHARMACEUTICAL

S.R.L.

C07AB02 METOPROLOLUM COMPR. FILM. ELIB. MOD. 47.5 mg

METOSUCCINAT SANDOZ 47,5 mg 47.5 mg HEXAL AG

C07AB02 METOPROLOLUM COMPR. 50 mg

BETAPROL 50 mg 50 mg AC HELCOR PHARMA SRL

EGILOK 50 mg 50 mg EGIS PHARMACEUTICALS

P.L.C.

METOPRO TAD 50 50 mg TAD PHARMA GMBH

METOPROLOL 50 mg 50 mg MAGISTRA C & C SRL

METOPROLOL AL 50 50 mg ALIUD PHARMA GMBH & CO.KG

METOPROLOL LPH 50 mg 50 mg LABORMED PHARMA SA

METOPROLOL MEDICO UNO 50 mg 50 mg MEDICO UNO PHARMACEUTICAL

S.R.L.

METOPROLOL TERAPIA 50 mg 50 mg TERAPIA SA

C07AB02 METOPROLOLUM COMPR. FILM. ELIB. 50 mg

PREL.

BETALOCR ZOC 50 mg 50 mg ASTRAZENECA AB

C07AB02 METOPROLOLUM COMPR. FILM. ELIB. MOD. 95 mg

METOSUCCINAT SANDOZ 95 mg 95 mg HEXAL AG

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| **44** |**C07AB03**| **ATENOLOLUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA FIRMA

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C07AB03 ATENOLOLUM COMPR. 100 mg

ATECOR 100 mg WIN - MEDICARE LTD.

ATENOCOR 100 mg 100 mg AC HELCOR SRL

ATENOLOL 100 mg 100 mg ARENA GROUP SA

ATENOLOL LPH 100 mg 100 mg LABORMED PHARMA SA

C07AB03 ATENOLOLUM COMPR. FILM. 100 mg

ATENOLOL 100 mg 100 mg TERAPIA SA

ATENOLOL 100 mg MEDO 100 mg MEDOCHEMIE ROMANIA SRL

VASCOTEN 100 mg MEDOCHEMIE LTD.

C07AB03 ATENOLOLUM COMPR. 50 mg

ATENOCOR 50 mg 50 mg AC HELCOR SRL

ATENOLOL 50 mg 50 mg SLAVIA PHARM SRL

ATENOLOL LPH 50 mg 50 mg LABORMED PHARMA SA

C07AB03 ATENOLOLUM COMPR. FILM. 50 mg

ATENOLOL 50 mg 50 mg TERAPIA SA

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| **45** |**C07AB05**| **BETAXOLOLUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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C07AB05 BETAXOLOLUM COMPR. FILM. 20 mg

BETAC 20 mg MEDOCHEMIE LTD.

LOKREN 20 mg 20 mg SANOFI-AVENTIS FRANCE

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| **46** |**C07AB07**| **BISOPROLOLUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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C07AB07 BISOPROLOLUM COMPR. 10 mg

BISOBLOCK 10 mg 10 mg KERI PHARMA GENERICS LTD.

C07AB07 BISOPROLOLUM COMPR. FILM. 10 mg

BISOGAMMA(R) 10 10 mg WORWAG PHARMA GMBH & CO.KG

BISOTENS 10 mg 10 mg ANTIBIOTICE SA

CONCOR 10 mg 10 mg MERCK KGAA

C07AB07 BISOPROLOLUM COMPR. FILM. 2.5 mg

CONCOR COR 2,5 mg 2.5 mg MERCK KGAA

C07AB07 BISOPROLOLUM COMPR. 5 mg

BISOBLOCK 5 mg 5 mg KERI PHARMA GENERICS LTD.

C07AB07 BISOPROLOLUM COMPR. FILM. 5 mg

BISOGAMMA(R) 5 5 mg WORWAG PHARMA GMBH & CO.KG

BISOTENS 5 mg 5 mg ANTIBIOTICE SA

CONCOR 5 mg 5 mg MERCK KGAA

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| **47** |**C07AG02**| **CARVEDILOLUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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C07AG02 CARVEDILOLUM COMPR. 12,5 mg

CARVEDILOL SANDOZ 12,5 mg HEXAL AG

C07AG02 CARVEDILOLUM COMPR. 12.5 mg

ATRAM 12.5 12.5 mg ZENTIVA AS

CARVEDILOL 12,5 mg 12.5 mg VIM SPECTRUM SRL

CARVEDILOL HELCOR 12,5 mg 12.5 mg AC HELCOR PHARMA SRL

CARVEDILOL LPH 12,5 mg 12.5 mg LABORMED PHARMA SA

CARVEDILOL TEVA 12,5 mg 12.5 mg TEVA PHARMACEUTICAL S.R.L.

CORYOL(R) 12.5 mg KRKA D.D.

DILATREND(R) 12,5 mg 12.5 mg ROCHE ROMANIA S.R.L.

TALLITON(R) 12,5 mg 12.5 mg EGIS PHARMACEUTICALS LTD.

C07AG02 CARVEDILOLUM COMPR. FILM. 12.5 mg

CARVEDIGAMMA 12,5 mg 12.5 mg WORWAG PHARMA GMBH & CO.KG

C07AG02 CARVEDILOLUM COMPR. 25 mg

ATRAM 25 25 mg ZENTIVA AS

CARVEDILOL HELCOR 25 mg 25 mg AC HELCOR PHARMA SRL

CARVEDILOL LPH 25 mg 25 mg LABORMED PHARMA SA

CARVEDILOL SANDOZ 25 mg HEXAL AG

CARVEDILOL TEVA 25 mg 25 mg TEVA PHARMACEUTICAL S.R.L.

CORYOL(R) 25 mg KRKA D.D.

DILATREND(R) 25 mg 25 mg ROCHE ROMANIA S.R.L.

TALLITON(R) 25 mg 25 mg EGIS PHARMACEUTICALS LTD.

C07AG02 CARVEDILOLUM COMPR. FILM. 25 mg

CARVEDIGAMMA 25 mg 25 mg WORWAG PHARMA GMBH & CO.KG

C07AG02 CARVEDILOLUM COMPR. 3.125 mg

CORYOL(R) 3,125 mg 3.125 mg KRKA D.D.

C07AG02 CARVEDILOLUM COMPR. 6.25 mg

ATRAM 6.25 6.25 mg ZENTIVA AS

CARVEDILOL 6,25 mg 6.25 mg VIM SPECTRUM SRL

CARVEDILOL LPH 6,25 mg 6.25 mg LABORMED PHARMA SA

CARVEDILOL SANDOZ 6.25 mg HEXAL AG

CARVEDILOL TEVA 6,25 mg 6.25 mg TEVA PHARMACEUTICAL S.R.L.

CORYOL(R) 6.25 mg KRKA D.D.

DILATREND(R) 6,25 mg 6.25 mg ROCHE ROMANIA S.R.L.

TALLITON 6,25 mg 6.25 mg EGIS PHARMACEUTICALS LTD.

C07AG02 CARVEDILOLUM COMPR. FILM. 6.25 mg

CARVEDIGAMMA 6,25 mg 6.25 mg WORWAG PHARMA GMBH & CO.KG

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| **48** |**C08CA01**| **AMLODIPINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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C08CA01 AMLODIPINUM COMPR. 10 mg

ALOZUR 10 mg 10 mg OZONE LABORATORIES BV

AMLO TAD 10 mg 10 mg TAD PHARMA GMBH

AMLODIPIN 10 mg 10 mg VIM SPECTRUM SRL

AMLODIPINE-TEVA 10 mg 10 mg TEVA PHARMACEUTICAL S.R.L.

AMLOHEXAL 10 mg 10 mg HEXAL AG

NORVASC 10 mg 10 mg PFIZER EUROPE MA EEIG

STAMLO M 10 mg 10 mg DR. REDDY'S LABORATORIES

TENOX(R) 10 10 mg KRKA D.D.

VASOREX 10 mg 10 mg LABORMED PHARMA S.A.

C08CA01 AMLODIPINUM COMPR. 5 mg

ALOZUR 5 mg 5 mg OZONE LABORATORIES BV

AMLO TAD 5 mg 5 mg TAD PHARMA GMBH

AMLODIPIN 5 mg 5 mg VIM SPECTRUM SRL

AMLODIPINE-TEVA 5 mg 5 mg TEVA PHARMACEUTICAL S.R.L.

AMLOHEXAL 5 mg 5 mg HEXAL AG

NORVASC 5 mg 5 mg PFIZER EUROPE MA EEIG

STAMLO M 5 mg 5 mg DR. REDDY'S LABORATORIES

TENOX(R) 5 5 mg KRKA D.D.

VASOREX 5 mg 5 mg LABORMED PHARMA S.A.

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| **49** |**C08CA02**| **FELODIPINUM** | |

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C08CA02 FELODIPINUM COMPR. ELIB. MODIF. 10 mg

FELODIPIN AL 10 RETARD 10 mg ALIUD(R) PHARMA GMBH &

CO.KG

C08CA02 FELODIPINUM COMPR. ELIB. PREL. 10 mg

PLENDIL 10 mg ASTRAZENECA AB

C08CA02 FELODIPINUM COMPR. FILM. ELIB. 10 mg

MODIF.

SISTAR 10 mg 10 mg GEDEON RICHTER ROMANIA SA

C08CA02 FELODIPINUM COMPR. FILM. ELIB. 10 mg

PREL.

AURONAL 10 mg 10 mg EGIS PHARMACEUTICALS PLC

MIVARA 10 mg 10 mg STADA ARZNEIMITTEL AG

PRESID(R) 10 mg 10 mg IVAX-PHARMACEUTICALS

S.R.O.

C08CA02 FELODIPINUM COMPR. ELIB. MODIF. 2.5 mg

FELODIPIN AL 2,5 RETARD 2.5 mg ALIUD(R) PHARMA GMBH &

CO.KG

C08CA02 FELODIPINUM COMPR. ELIB. PREL. 2.5 mg

PLENDIL 2.5 mg ASTRAZENECA AB

C08CA02 FELODIPINUM COMPR. FILM. ELIB. 2.5 mg

MODIF.

SISTAR 2,5 mg 2.5 mg GEDEON RICHTER ROMANIA SA

C08CA02 FELODIPINUM COMPR. FILM. ELIB. 2.5 mg

PREL.

AURONAL 2,5 mg 2.5 mg EGIS PHARMACEUTICALS PLC

PRESID(R) 2,5 mg 2.5 mg IVAX-PHARMACEUTICALS

S.R.O.

C08CA02 FELODIPINUM COMPR. ELIB. MODIF. 5 mg

FELODIPIN AL 5 RETARD 5 mg ALIUD(R) PHARMA GMBH &

CO.KG

C08CA02 FELODIPINUM COMPR. ELIB. PREL. 5 mg

PLENDIL 5 mg ASTRAZENECA AB

C08CA02 FELODIPINUM COMPR. FILM. ELIB. 5 mg

MODIF.

SISTAR 5 mg 5 mg GEDEON RICHTER ROMANIA SA

C08CA02 FELODIPINUM COMPR. FILM. ELIB. 5 mg

PREL.

AURONAL 5 mg 5 mg EGIS PHARMACEUTICALS PLC

MIVARA 5 mg 5 mg STADA ARZNEIMITTEL AG

PRESID(R) 5 mg 5 mg IVAX-PHARMACEUTICALS

S.R.O.

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| **50** |**C08CA05**| **NIFEDIPINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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C08CA05 NIFEDIPINUM COMPR. ELIB. MODIF. 20 mg

ADALAT CR 20 20 mg BAYER HEALTHCARE AG

C08CA05 NIFEDIPINUM COMPR. FILM. ELIB. 20 mg

PREL.

ADALAT(R) RETARD 20 mg BAYER HEALTHCARE AG

NIFEDIPIN RETARD TERAPIA 20 mg TERAPIA SA

20 mg

C08CA05 NIFEDIPINUM DRAJ. 20 mg

EPILAT RETARD 20 mg E.I.P.I.CO. MED S.R.L.

C08CA05 NIFEDIPINUM COMPR. ELIB. MODIF. 30 mg

ADALAT CR 30 30 mg BAYER HEALTHCARE AG

C08CA05 NIFEDIPINUM COMPR. ELIB. MODIF. 20 mg

ADALAT CR 20 20 mg BAYER HEALTHCARE AG

C08CA05 NIFEDIPINUM COMPR. FILM. ELIB. 20 mg

PREL.

ADALAT(R) RETARD 20 mg BAYER HEALTHCARE AG

NIFEDIPIN RETARD TERAPIA 20 mg TERAPIA SA

20 mg

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| **51** |**C08DA01**| **VERAPAMILUM** | |

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Efectele de inhibare a funcţiei miocardice ale acestui medicament se cumulează cu cele ale beta-blocantelor.

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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C08DA01 VERAPAMILUM COMPR. FILM. ELIB. 240 mg

PREL.

ISOPTIN RR 240 mg ABBOTT GMBH & CO.KG

VEROGALID(R) ER 240 mg 240 mg IVAX-PHARMACEUTICALS

S.R.O.

C08DA01 VERAPAMILUM COMPR. FILM. 40 mg

ISOPTIN(R) 40 mg 40 mg ABBOTT GMBH & CO.KG

VERAPAMIL AL 40 40 mg ALIUD(R) PHARMA GMBH &

CO.KG

C08DA01 VERAPAMILUM COMPR. FILM. 80 mg

ISOPTIN(R) 80 mg 80 mg ABBOTT GMBH & CO.KG

VERAPAMIL AL 80 80 mg ALIUD(R) PHARMA GMBH &

CO.KG

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| **52** |**C08DB01**| **DILTIAZEMUM** | |

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Efectele de inhibare a funcţiei miocardice ale acestui medicament se cumulează cu cele ale beta-blocantelor.

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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C08DB01 DILTIAZEMUM COMPR. 60 mg

DILTIAZEM ALKALOID 60 mg 60 mg ALKALOID DOO

DILTIAZEM EIPICO 60 mg 60 mg E.I.P.I.CO. MED S.R.L.

DILTIAZEM LPH 60 mg 60 mg LABORMED PHARMA SA

DILZEM 60 mg 60 mg PFIZER EUROPE MA EEIG

C08DB01 DILTIAZEMUM COMPR. 90 mg

DILTIAZEM ALKALOID 90 mg 90 mg ALKALOID DOO

C08DB01 DILTIAZEMUM COMPR. FILM. ELIB. 90 mg

PREL.

DILZEM 90 mg RETARD 90 mg PFIZER EUROPE MA EEIG

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| **53** |**C09AA01**| **CAPTOPRILUM** | |

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Utilizarea inhibitorilor enzimelor de conversie a angiotensinei în timpul sarcinii este contraindicată deoarece medicamentele din această categorie au fost asociate cu moartea fătului in utero.

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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C09AA01 CAPTOPRILUM COMPR. 12,5 mg

CAPTOPRIL MCC 12,5 mg 12,5 mg MAGISTRA C & C

C09AA01 CAPTOPRILUM COMPR. 12.5 mg

CAPTOPRIL 12,5 mg 12.5 mg EGIS PHARMACEUTICALS LTD.

C09AA01 CAPTOPRILUM COMPR. 25 mg

CAPTOPRIL-AC 25 mg 25 mg AC HELCOR PHARMA SRL

CAPTOPRIL SINTOFARM 25 mg 25 mg SINTOFARM SA

CAPTOPRIL 25 EEL 25 mg BIO EEL SRL

CAPTOPRIL 25 mg 25 mg EGIS PHARMACEUTICALS LTD.

CAPTOPRIL LPH 25 mg 25 mg LABORMED PHARMA SA

CAPTOPRIL MCC 25 mg 25 mg MAGISTRA C & C

C09AA01 CAPTOPRILUM COMPR. 50 mg

CAPTOPRIL 50 mg 50 mg ARENA GROUP SA

C09AA01 CAPTOPRILUM COMPR. 50 mg

CAPTOPRIL-AC 50 mg 50 mg AC HELCOR PHARMA SRL

CAPTOPRIL 50 EEL 50 mg BIO EEL SRL

CAPTOPRIL 50 mg 50 mg EGIS PHARMACEUTICALS LTD.

CAPTOPRIL LPH 50 mg 50 mg LABORMED PHARMA SA

CAPTOPRIL MCC 50 mg 50 mg MAGISTRA C & C

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| **54** |**C09AA02**| **ENALAPRILUM** | |

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Utilizarea inhibitorilor enzimelor de conversie a angiotensinei în timpul sarcinii este contraindicată deoarece medicamentele din această categorie au fost asociate cu moartea fătului in utero.

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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C09AA02 ENALAPRILUM SOL. INJ. 1.25 mg/ml

ENAP(R) 1.25 mg/ml KRKA D.D.

C09AA02 ENALAPRILUM COMPR. 10 mg

EDNYT(R) 10 mg 10 mg GEDEON RICHTER LTD.

ENAHEXAL(R) 10 mg 10 mg HEXAL AG

ENALA TAD 10 10 mg TAD PHARMA GMBH

ENALAP 10 mg E.I.P.I.CO. MED S.R.L.

ENALAPRIL 10 mg 10 mg MAGISTRA C & C

ENALAPRIL AL 10 10 mg ALIUD(R) PHARMA GMBH &

CO.KG

ENALAPRIL FABIOL 10 mg 10 mg FABIOL SA

ENALAPRIL LPH 10 mg 10 mg LABORMED PHARMA SA

ENALAPRIL SANDOZ 10 mg 10 mg SANDOZ SRL

ENALAPRIL TERAPIA 10 mg 10 mg TERAPIA SA

ENAM 10 mg 10 mg REPREZENTANTA DR. REDDY'S

LABORATORIES LTD.

ENAP 10 mg 10 mg KRKA D.D. NOVO MESTO

RENITEC 10 mg 10 mg MERCK SHARP & DOHME

ROMANIA S.R.L.

C09AA02 ENALAPRILUM COMPR. 2.5 mg

EDNYT(R) 2,5 mg 2.5 mg GEDEON RICHTER LTD.

C09AA02 ENALAPRILUM COMPR. 20 mg

EDNYT(R) 20 mg 20 mg GEDEON RICHTER LTD.

ENAHEXAL(R) 20 mg 20 mg HEXAL AG

ENALA TAD 20 20 mg TAD PHARMA GMBH

ENALAPRIL 20 mg OZONE LABORATORIES LTD.

ENALAPRIL 20 mg 20 mg MAGISTRA C & C

ENALAPRIL AL 20 20 mg ALIUD(R) PHARMA GMBH &

CO.KG

ENALAPRIL FABIOL 20 mg 20 mg FABIOL SA

ENALAPRIL LPH 20 mg 20 mg LABORMED PHARMA SA

ENALAPRIL SANDOZ 20 mg 20 mg SANDOZ SRL

ENALAPRIL TERAPIA 20 mg 20 mg TERAPIA SA

ENAP 20 mg 20 mg KRKA D.D. NOVO MESTO

RENITEC 20 mg 20 mg MERCK SHARP & DOHME

ROMANIA S.R.L.

C09AA02 ENALAPRILUM COMPR. 5 mg

EDNYT(R) 5 mg 5 mg GEDEON RICHTER LTD.

ENAHEXAL(R) 5 mg 5 mg HEXAL AG

ENALA TAD 5 5 mg TAD PHARMA GMBH

ENALAPRIL 5 mg 5 mg OZONE LABORATORIES LTD.

ENALAPRIL AL 5 5 mg ALIUD(R) PHARMA GMBH &

CO.KG

ENALAPRIL LPH(R) 5 mg 5 mg LABORMED PHARMA SA

ENALAPRIL SANDOZ 5 mg 5 mg SANDOZ SRL

ENAP 5 mg 5 mg KRKA D.D. NOVO MESTO

RENITEC 5 mg 5 mg MERCK SHARP & DOHME

ROMANIA S.R.L.

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| **55** |**C09AA03**| **LISINOPRILUM** | |

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CONCENTRAŢIE FIRMA

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C09AA03 LISINOPRILUM COMPR. 10 mg

LISIGAMMA 10 mg 10 mg WORWAG PHARMA GMBH & CO.KG

LISINOPRIL 10 MEDO 10 mg MEDOCHEMIE ROMANIA SRL

LISINOPRIL ANTIBIOTICE 10 mg 10 mg ANTIBIOTICE SA

LISINOPRIL SANDOZ 10 mg 10 mg HEXAL AG

LISIREN 10 mg 10 mg AC HELCOR SRL

MEDAPRIL 10 10 mg MEDOCHEMIE LTD.

RANOLIP 10 mg RANBAXY U.K. LIMITED

SINOPRYL(R) 10 10 mg ECZACIBASI PHARMACEUTICALS

S.R.L.

TONOLYSIN 10 mg 10 mg GEDEON RICHTER LTD.

C09AA03 LISINOPRILUM COMPR. 2.5 mg

TONOLYSIN 2,5 mg 2.5 mg GEDEON RICHTER LTD.

C09AA03 LISINOPRILUM COMPR. 20 mg

USIGAMMA 20 mg 20 mg WORWAG PHARMA GMBH & CO.KG

LISINOPRIL 20 MEDO 20 mg MEDOCHEMIE ROMANIA SRL

LISINOPRIL ANTIBIOTICE 20 mg 20 mg ANTIBIOTICE SA

LISINOPRIL SANDOZ 20 mg 20 mg HEXAL AG

LISIREN 20 mg 20 mg AC HELCOR SRL

MEDAPRIL 20 20 mg MEDOCHEMIE LTD.

RANOLIP 20 mg RANBAXY U.K. LIMITED

TONOLYSIN 20 mg 20 mg GEDEON RICHTER LTD.

C09AA03 LISINOPRILUM COMPR. 40 mg

LISINOPRIL ANTIBIOTICE 40 mg 40 mg ANTIBIOTICE SA

C09AA03 LISINOPRILUM COMPR. 5 mg

LISIGAMMA 5 mg 5 mg WORWAG PHARMA GMBH & CO.KG

LISINOPRIL 5 MEDO 5 mg MEDOCHEMIE ROMANIA SRL

LISINOPRIL SANDOZ 5 mg 5 mg HEXAL AG

MEDAPRIL 5 5 mg MEDOCHEMIE LTD.

RANOLIP 5 mg RANBAXY U.K. LIMITED

TONOLYSIN 5 mg 5 mg GEDEON RICHTER LTD.

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| **56** |**C09AA05**| **RAMIPRILUM** | |

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Utilizarea inhibitorilor enzimelor de conversie a angiotensinei în timpul sarcinii este contraindicată deoarece medicamentele din această categorie au fost asociate cu moartea fătului in utero.

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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C09AA05 RAMIPRILUM COMPR. FILM. 1.25 mg

RAMIRAN 1,25 mg 1.25 mg RANBAXY U.K. LIMITED

C09AA05 RAMIPRILUM COMPR. 10 mg

EMREN 10 mg 10 mg GEDEON RICHTER ROMANIA

S.A.

VIVACE 10 mg 10 mg ACTAVIS GROUP HF

C09AA05 RAMIPRILUM COMPR. 10 mg

AMPRIL 10 mg 10 mg KRKA D.D. NOVO MESTO

PIRAMIL 10 mg 10 mg SANDOZ SRL

RAMIGAMMA 10 mg 10 mg WORWAG PHARMA GMBH & CO.KG

RAMIPRIL-AC 10 mg 10 mg AC HELCOR PHARMA SRL

TRITACE 10 10 mg SANOFI-AVENTIS DEUTSCHLAND

GMBH

ZENRA 10 10 mg ZENTIVA S.A.

C09AA05 RAMIPRILUM COMPR. FILM. 10 mg

RAMIRAN 10 mg 10 mg RANBAXY U.K. LIMITED

C09AA05 RAMIPRILUM COMPR. 2,5 mg

EMREN 2,5 mg 2,5 mg GEDEON RICHTER ROMANIA

S.A.

VIVACE 2,5 mg 2,5 mg ACTAVIS GROUP HF

C09AA05 RAMIPRILUM COMPR. 2.5 mg

AMPRIL 2,5 mg 2.5 mg KRKA D.D. NOVO MESTO

PIRAMIL 2,5 mg 2.5 mg SANDOZ SRL

RAMIPRIL-AC 2,5 mg 2.5 mg AC HELCOR PHARMA SRL

TRITACE(R) 2,5 2.5 mg AVENTIS PHARMA DEUTSCHLAND

GMBH

ZENRA 2,5 2.5 mg ZENTIVA S.A.

C09AA05 RAMIPRILUM COMPR. FILM. 2.5 mg

RAMIRAN 2,5 mg 2.5 mg RANBAXY U.K. LIMITED

C09AA05 RAMIPRILUM COMPR. 5 mg

EMREN 5 mg 5 mg GEDEON RICHTER ROMANIA

S.A.

VIVACE 5 mg 5 mg ACTAVIS GROUP HF

C09AA05 RAMIPRILUM COMPR. 5 mg

AMPRIL 5 mg 5 mg KRKA D.D. NOVO MESTO

PIRAMIL 5 mg 5 mg SANDOZ SRL

RAMIGAMMA 5 mg 5 mg WORWAG PHARMA GMBH & CO.KG

RAMIPRIL-AC 5 mg 5 mg AC HELCOR PHARMA SRL

TRITACE(R) 5 5 mg AVENTIS PHARMA DEUTSCHLAND

GMBH

ZENRA 5 5 mg ZENTIVA S.A.

C09AA05 RAMIPRILUM COMPR. FILM. 5 mg

RAMIRAN 5 mg 5 mg RANBAXY U.K. LIMITED

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| **57** |**C09AA06**| **QUINAPRILUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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C09AA06 QUINAPRILUM COMPR. FILM. 10 mg

QUINAPRIL SANDOZ 10 mg 10 mg HEXAL AG

C09AA06 QUINAPRILUM COMPR. FILM. 10 mg

ACCUPRO 10 mg 10 mg PFIZER EUROPE MA EEIG

AQUIRIL 10 mg 10 mg LABORMED PHARMA SA

QUINARAN 10 mg 10 mg RANBAXY UK LIMITED

C09AA06 QUINAPRILUM COMPR. FILM. 20 mg

QUINAPRIL SANDOZ 20 mg 20 mg HEXAL AG

C09AA06 QUINAPRILUM COMPR. FILM. 20 mg

ACCUPRO(R) 20 20 mg PFIZER EUROPE MA EEIG

QUINARAN 20 mg 20 mg RANBAXY UK LIMITED

C09AA06 QUINAPRILUM COMPR. FILM. 40 mg

QUINAPRIL SANDOZ 40 mg 40 mg HEXAL AG

C09AA06 QUINAPRILUM COMPR. FILM. 40 mg

QUINARAN 40 mg 40 mg RANBAXY UK LIMITED

C09AA06 QUINAPRILUM COMPR. FILM. 5 mg

QUINAPRIL SANDOZ 5 mg 5 mg HEXAL AG

C09AA06 QUINAPRILUM COMPR. FILM. 5 mg

ACCUPRO(R) 5 5 mg PFIZER EUROPE MA EEIG

QUINARAN 5 mg 5 mg RANBAXY UK LIMITED

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| **58** |**C09AA09**| **FOSINOPRILUM** | |

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Utilizarea inhibitorilor enzimelor de conversie a angiotensinei în timpul sarcinii este contraindicată deoarece medicamentele din această categorie au fost asociate cu moartea fătului in utero.

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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C09AA09 FOSINOPRILUM COMPR. 10 mg

FOSINOPRIL TERAPIA 10 mg 10 mg TERAPIA SA

FOSYPRIL 10 mg 10 mg TERAPIA S.A.

MONOPRIL 10 mg 10 mg BRISTOL MYERS SQUIBB KFT

C09AA09 FOSINOPRILUM COMPR. 20 mg

FOSINOPRIL TERAPIA 20 mg 20 mg TERAPIA SA

FOSINOPRIL TEVA 20 mg 20 mg TEVA PHARMACEUTICAL S.R.L.

FOSYPRIL 20 mg 20 mg TERAPIA SA.

MONOPRIL 20 mg 20 mg BRISTOL-MYERS SQUIBB KFT

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| **59** |**C09BA02**| **COMBINAŢII (ENALAPRILUM +** | |

| | | **HYDROCHLOROTHIAZIDUM)** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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C09BA02 COMBINAŢII COMPR. 10 mg/25 mg

(ENALAPRILUM + 10 mg/25 mg HEXAL AG

HYDROCHLOROTHIAZIDUM)

ENALAPRIL HCT SANDOZ

10 mg/25 mg

C09BA02 COMBINAŢII COMPR. 10 mg + 12.5 mg

(ENALAPRILUM +

HYDROCHLOROTHIAZIDUM)

ENAP HL 10 mg + 12.5 mg KRKA D.D. NOVO MESTO

C09BA02 COMBINAŢII COMPR. 10 mg + 25 mg

(ENALAPRILUM +

HYDROCHLOROTHIAZIDUM)

ENAP H 10 mg + 25 mg KRKA D.D. NOVO MESTO

C09BA02 COMBINAŢII COMPR. 20 mg/12.5 mg

(ENALAPRILUM +

HYDROCHLOROTHIAZIDUM)

ENAP(R) HL 20 mg/12,5 mg 20 mg/12.5 mg KRKA D.D. NOVO MESTO

C09BA02 COMBINAŢII COMPR. 20 mg/12.5 mg

(ENALAPRILUM + 20 mg/12.5 mg HEXAL AG

HYDROCHLOROTHIAZIDUM)

ENALAPRIL HCT SANDOZ

20 mg/12,5 mg

C09BA02 COMBINAŢII COMPR.

(ENALAPRILUM +

HYDROCHLOROTHIAZIDUM)

VIMAPRIL H VIM SPECTRUM SRL

VIMAPRIL HL VIM SPECTRUM SRL

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| **60** |**C09BA05**| **COMBINAŢII (RAMIPRILUM +** | |

| | | **HYDROCHLOROTHIAZIDUM)** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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C09BA05 COMBINAŢII COMPR. 2.5 mg/12.5 mg

(RAMIPRILUM +

HYDROCHLOROTHIAZIDUM)

HARTIL HCT 2,5 mg/12,5 mg 2.5 mg/12.5 mg EGIS PHARMACEUTICALS PLC

PIRAMIL HCT 2,5 mg/12,5 mg 2.5 mg/12.5 mg HEXAL AG

RAMIPRIL HCT-MEDOCHEMIE 2.5 mg/12.5 mg MEDOCHEMIE LTD.

C09BA05 COMBINAŢII COMPR. 2.5 mg + 12.5 mg

(RAMIPRILUM +

HYDROCHLOROTHIAZIDUM)

AMPRIL HL 2.5 mg + 12.5 mg KRKA D.D. NOVO MESTO

C09BA05 COMBINAŢII COMPR. 5 mg/25 mg

(RAMIPRILUM +

HYDROCHLOROTHIAZIDUM)

HARTIL HCT 5 mg/25 mg 5 mg/25 mg EGIS PHARMACEUTICALS PLC

PIRAMIL HCT 5 mg/25 mg 5 mg/25 mg HEXAL AG

RAMIPRIL HCT-MEDOCHEMIE 5 mg/25 mg MEDOCHEMIE LTD.

C09BA05 COMBINAŢII COMPR. 5 mg + 25 mg

(RAMIPRILUM +

HYDROCHLOROTHIAZIDUM)

AMPRIL HD 5 mg + 25 mg KRKA D.D. NOVO MESTO

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| **61** |**C09CA01**| **LOSARTANUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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C09CA01 LOSARTANUM COMPR. FILM. 50 mg

COZAAR 50 mg MERCK SHARP & DOHME

ROMANIA S.R.L.

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| **62** |**C10AA01**| **SIMVASTATINUM** | **Protocol: CE01E** |

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Prescriere limitată: Se utilizează pentru pacienţii care îndeplinesc criteriile de eligibilitate stabilite prin Protocolul de prescriere a medicamentelor hipolipemiante.

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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C10AA01 SIMVASTATINUM COMPR. FILM. 10 mg

SIMVASTATIN 10 mg 10 mg TERAPIA S.A.

C10AA01 SIMVASTATINUM COMPR. FILM. 10 mg

SIMGAL(R) 10 mg 10 mg IVAX-PHARMACEUTICALS

S.R.O.

SIMVA TAD 10 mg 10 mg TAD PHARMA GMBH

SIMVACARD(R) 10 10 mg ZENTIVA AS

SIMVAGAMMA 10 mg 10 mg WORWAG PHARMA GMBH & CO.KG

SIMVAHEXAL(R) 10 mg 10 mg HEXAL AG

SIMVASTATIN LPH 10 mg 10 mg LABORMED PHARMA SA

SIMVOR 10 mg 10 mg RANBAXY U.K. LIMITED

SINTENAL 10 mg 10 mg AC HELCOR PHARMA SRL

VABADIN 10 mg 10 mg MENARINI INTERNATIONAL

OPERATIONS LUXEMBURG S.A.

VASILIP 10 mg 10 mg KRKA D.D.

ZAREDIL 10 mg 10 mg OZONE LABORATORIES LTD.

ZEPLAN(R) 10 mg 10 mg GEDEON RICHTER ROMANIA SA

ZOCOR 10 mg 10 mg MERCK SHARP & DOHME

ROMANIA S.R.L.

C10AA01 SIMVASTATINUM COMPR. FILM. 20 mg

SIMVASTATIN 20 mg 20 mg TERAPIA S.A.

C10AA01 SIMVASTATINUM COMPR. FILM. 20 mg

SIMCOR 20 mg 20 mg ANTIBIOTICE SA

SIMGAL(R) 20 mg 20 mg IVAX-PHARMACEUTICALS

S.R.O.

SIMVA TAD 20 mg 20 mg TAD PHARMA GMBH

SIMVACARD(R) 20 20 mg ZENTIVA AS

SIMVAGAMMA 20 mg 20 mg WORWAG PHARMA GMBH & CO.KG

SIMVAHEXAL(R) 20 mg 20 mg HEXAL AG

SIMVASTATIN LPH 20 mg 20 mg LABORMED PHARMA SA

SIMVOR 20 mg 20 mg RANBAXY U.K. LIMITED

SINTENAL 20 mg 20 mg AC HELCOR PHARMA SRL

VABADIN 20 mg 20 mg MENARINI INTERNATIONAL

OPERATIONS LUXEMBURG S.A.

VASILIP 20 mg 20 mg KRKA D.D.

ZAREDIL 20 mg 20 mg OZONE LABORATORIES LTD.

ZEPLAN(R) 20 mg 20 mg GEDEON RICHTER ROMANIA SA

ZOCOR 20 mg 20 mg MERCK SHARP & DOHME

ROMANIA S.R.L.

C10AA01 SIMVASTATINUM COMPR. FILM. 30 mg

SIMVAHEXAL(R) 30 mg 30 mg HEXAL AG

C10AA01 SIMVASTATINUM COMPR. FILM. 40 mg

SIMVASTATIN 40 mg 40 mg TERAPIA S.A.

C10AA01 SIMVASTATINUM COMPR. FILM. 40 mg

SIMCOR 40 mg 40 mg ANTIBIOTICE S.A.

SIMGAL(R) 40 mg 40 mg IVAX-PHARMACEUTICALS

S.R.O.

SIMVA TAD 40 mg 40 mg TAD PHARMA GMBH

SIMVACARD(R) 40 40 mg ZENTIVA AS

SIMVAGAMMA 40 mg 40 mg WORWAG PHARMA GMBH & CO.KG

SIMVAHEXAL(R) 40 mg 40 mg HEXAL AG

SIMVASTATIN LPH 40 mg 40 mg LABORMED PHARMA S.A.

SIMVOR 40 mg 40 mg RANBAXY U.K. LIMITED

SINTENAL 40 mg 40 mg AC HELCOR PHARMA SRL

VABADIN 40 mg 40 mg MENARINI INTERNATIONAL

OPERATIONS LUXEMBURG S.A.

VASILIP(R) 40 mg 40 mg KRKA D.D.

ZAREDIL 40 mg 40 mg OZONE LABORATORIES LTD.

ZEPLAN(R) 40 mg 40 mg GEDEON RICHTER ROMANIA SA

ZOCOR FORTE 40 mg MERCK SHARP & DOHME

ROMANIA S.R.L.

C10AA01 SIMVASTATINUM COMPR. FILM. 5 mg

SIMVOR 5 mg 5 mg RANBAXY U.K. LIMITED

C10AA01 SIMVASTATINUM COMPR. FILM. 80 mg

SIMVASTATIN LPH 80 mg 80 mg LABORMED PHARMA S.A.

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| **63** |**C10AA02**| **LOVASTATINUM** | **Protocol: CE01E** |

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Prescriere limitată: Se utilizează pentru pacienţii care îndeplinesc criteriile de eligibilitate stabilite prin Protocolul de prescriere a medicamentelor hipolipemiante.

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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C10AA02 LOVASTATINUM COMPR. 20 mg

MEDOSTATIN 20 mg MEDOCHEMIE LTD.

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| **64** |**C10AA03**| **PRAVASTATINUM** | **Protocol: CE01E** |

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Prescriere limitată: Se utilizează pentru pacienţii care îndeplinesc criteriile de eligibilitate stabilite prin Protocolul de prescriere a medicamentelor hipolipemiante.

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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C10AA03 PRAVASTATINUM COMPR. 10 mg

PRALIP 10 mg 10 mg SANDOZ SRL

PRAVATOR 10 mg 10 mg RANBAXY U.K. LIMITED

C10AA03 PRAVASTATINUM COMPR. 20 mg

PRALIP 20 mg 20 mg SANDOZ SRL

PRAVATOR 20 mg 20 mg RANBAXY U.K. LIMITED

C10AA03 PRAVASTATINUM COMPR. 40 mg

PRALIP 40 mg 40 mg SANDOZ SRL

PRAVATOR 40 mg 40 mg RANBAXY U.K. LIMITED

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| **65** |**C10AB05**| **FENOFIBRATUM** | **Protocol: CE01E** |

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Prescriere limitată: **Se utilizează pentru pacienţii care îndeplinesc criteriile de eligibilitate stabilite prin Protocolul de prescriere a medicamentelor hipolipemiante.**

NOTĂ:

**Riscul de toxicitate musculară severă creşte dacă fenofibratum este utilizat simultan cu inhibitori de HMG CoA reductaza sau alţi fibraţi. Terapia combinată trebuie folosită cu precauţie la pacienţii cu dislipidemie mixtă severă combinată cu risc cardiovascular înalt, în absenţa antecedentelor de afecţiune musculară. Pacienţii vor fi monitorizaţi regulat pentru semne cronice de toxicitate musculară.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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C10AB05 FENOFIBRATUM CAPS. 100 mg

LIPANTHYL(R) 100 100 mg LAB. FOURNIER SA

C10AB05 FENOFIBRATUM CAPS. 160 mg

LIPOFIB 160 mg 160 mg TERAPIA S.A.

C10AB05 FENOFIBRATUM COMPR. FILM. ELIB. 160 mg

MODIF.

LIPANTHYL(R) SUPRA 160 mg 160 mg LAB. FOURNIER SA

C10AB05 FENOFIBRATUM CAPS. 200 mg

LIPOFIB 200 mg 200 mg TERAPIA S.A.

C10AB05 FENOFIBRATUM CAPS. PULB. MICRONIZATĂ 200 mg

FENOFIBRAT LPH 200 mg 200 mg LABORMED PHARMA SA

LIPANTHYL 200 M 200 mg LAB. FOURNIER SA

LIPIVIM 200 mg VIM SPECTRUM SRL

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| **66** |**D01AC02**| **MICONAZOLUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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D01AC02 MICONAZOLUM CREMĂ 20 mg/g

MICONAL ECOBI 20 mg/g FARMACEUTICI ECOBI S.A.S.

D01AC02 MICONAZOLUM CREMĂ 2%

MEDACTER 2% FARAN LABORATORIES S.A.

MICONAZOL NITRAT 2% 2% SLAVIA PHARM SRL

D01AC02 MICONAZOLUM GEL 2%

DERMOZOL 2% PHARCOIMPEX 93 S.R.L.

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| **67** |**D01AC10**| **BIFONAZOLUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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D01AC10 BIFONAZOLUM SOL. CUT. 0,01 g/ml

MYCOSPOR 0,01 g/ml BAYER HEALTHCARE AG

D01AC10 BIFONAZOLUM CREMĂ 100 g

MYCO-FLUSEMIDON 100 g ANFARM HELLAS S.A.

PHARMACEUTICALS

D01AC10 BIFONAZOLUM CREMĂ 10 mg/g

BIAZOL 10 mg/g 10 mg/g GEDEON RICHTER ROMANIA SA

D01AC10 BIFONAZOLUM CREMĂ 1%

MYCOSPOR 1% BAYER HEALTHCARE AG

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| **68** |**D06BB03**| **ACICLOVIRUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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D06BB03 ACICLOVIRUM CREMĂ 50 mg/g

ACICLOVIR HYPERION 50 mg/g HYPERION S.A.

ACIKLOVIR CREMĂ 50 mg/g A & G MED TRADING S.R.L.

D06BB03 ACICLOVIRUM CREMĂ 5%

ACICLOVIR 5% OZONE LABORATORIES LTD.

ACICLOVIR 5% 5% GEDEON RICHTER ROMANIA SA

CLOVIRAL(R) 5% 5% ANTIBIOTICE SA

ZOVIRAX 5% THE WELLCOME FOUNDATION

LTD.

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| **69** |**D07AA02**| **HYDROCORTISONUM** | **Protocol: D001L** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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D07AA02 HYDROCORTISONUM UNGUENT 1,00%

HIDROCORTIZON 1% 1% ANTIBIOTICE SA

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| **70** |**D07AC01**| **BETAMETHASONUM** | **Protocol: D001L** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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D07AC01 BETAMETHASONUM CREMĂ 0,5 mg/g

BELODERM CREMĂ 0,5 mg/g A & G MED TRADING S.R.L.

D07AC01 BETAMETHASONUM UNGUENT 0,5 mg/g

BELODERM UNGUENT 0,5 mg/g A & G MED TRADING S.R.L.

D07AC01 BETAMETHASONUM CREMĂ 0.1%

BETADERM 0.1% E.I.P.I.CO. MED S.R.L.

D07AC01 BETAMETHASONUM UNGUENT 0.1%

BETADERM 0.1% E.I.P.I.CO. MED S.R.L.

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| **71** |**G01AF04**| **MICONAZOLUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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G01AF04 MICONAZOLUM CAPS. MOI VAG. 1.2 g

MICONAL ECOBI 1.2 g FARMACEUTICI ECOBI S.A.S

G01AF04 MICONAZOLUM CREMĂ VAG. 20 mg/g

MICONALECOBI 20 mg/g FARMACEUTICI ECOBI S.A.S

G01AF04 MICONAZOLUM SOL. VAGINALĂ 2 mg/ml

MICONAL ECOBI 2 mg/ml FARMACEUTICI ECOBI S.A.S

G01AF04 MICONAZOLUM OVULE 50 mg

MICONALECOBI 50 mg FARMACEUTICI ECOBI S.A.S

G01AF04 MICONAZOLUM CREMĂ VAG. 2%

MEDACTER 2% FARAN LABORATORIES S.A.

MYCOHEAL 2% DAR AL DAWA PHARMA S.R.L.

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| **72** |**G02AB03**| **ERGOMETRINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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G02AB03 ERGOMETRINUM SOL. INJ. 0.2 mg/ml

MALEAT DE ERGOMETRINA 0.2 mg/ml ZENTIVA S.A.

0,2 mg/ml

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| **73** |**G03BA03**| **TESTOSTERONUM\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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G03BA03 TESTOSTERONUM SOL. INJ. 1000 mg/4 ml

NEBIDO 1000 mg/4 ml 1000 mg/4 ml SCHERING AG

G03BA03 TESTOSTERONUM CAPS. MOI 40 mg

UNDESTO(R) TESTOCAPS(R) 40 mg ORGANON NV

Prescriere limitată: **Deficit androgenic la bărbaţi de cauză primară testiculară sau secundară hipotalamo-hipofizară (confirmat prin nivel plasmatic al testosteronului la cel puţin 2 determinări în două dimineţi diferite mai mic sau egal cu limita inferioară a valorilor reactivului utilizat).**

Prescriere limitată: **Micropenis, inducerea pubertăţii sau întârzierea constituţională a creşterii sau a pubertăţii la băieţi sub 18 ani.**

G03BA03 TESTOSTERONUM GEL 50 mg

ANDROGEL 50 mg 50 mg LAB. BESINS INTERNATIONAL

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| **74** |**G03CA03**| **ESTRADIOLUM\*** | |

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Prescriere limitată: **Utilizat în simptomele caracteristice post-menopauzei, în cazul în care terapia estrogenică în doze reduse a demonstrat intoleranţa la administrarea orală cu estrogeni.**

**Această limitare este valabilă doar pentru formele farmaceutice Sistem terapeutic transdermic şi plasture transdermic.**

NOTĂ:

**Estradiol trebuie folosit împreună cu un progestativ oral la femeile nehisterectomizate.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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G03CA03 ESTRADIOLUM GEL 0.06%

OESTROGEL(R) 0.06% LAB. BESINS INTERNATIONAL

G03CA03 ESTRADIOLUM GEL 0.1%

ESTREVA(R) 0.1% LAB. THERAMEX

G03CA03 ESTRADIOLUM COMPR. FILM. 1 mg

ESTROFEM 1 mg 1 mg NOVO NORDISK A/S

G03CA03 ESTRADIOLUM COMPR. VAG. 25 µg

VAGIFEM 25 µg NOVO NORDISK A/S

G03CA03 ESTRADIOLUM IMPLANT 25 mg

RISELLE 25 mg 25 mg ORGANON NV

G03CA03 ESTRADIOLUM PLASTURE TRANSDERM. 50 µg/24 ore

CLIMARA 50 µg/24 ore SCHERING AG

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| **75** |**G04CAN1**| **DOXAZOSINUM** | |

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G04CAN1 DOXAZOSINUM COMPR. 1 mg

DOXAZOSIN 1 MEDOCHEMIE 1 mg MEDOCHEMIE ROMANIA SRL

DOXAZOSIN AL 1 1 mg ALIUD(R) PHARMA GMBH &

CO.KG

KAMIREN 1 mg KRKA D.D. NOVO MESTO

MAGUROL 1 mg MEDOCHEMIE LTD.

G04CAN1 DOXAZOSINUM COMPR. 2 mg

DOXAZOSIN 2 MEDOCHEMIE 2 mg MEDOCHEMIE ROMANIA SRL

DOXAZOSIN AL 2 2 mg ALIUD(R) PHARMA GMBH &

CO.KG

DOXAZOSIN SANDOZ 2 mg 2 mg HEXAL AG

KAMIREN 2 mg KRKA D.D. NOVO MESTO

MAGUROL 2 mg MEDOCHEMIE LTD.

G04CAN1 DOXAZOSINUM COMPR. 4 mg

DOXAZOSIN 4 MEDOCHEMIE 4 mg MEDOCHEMIE ROMANIA SRL

DOXAZOSIN AL 4 4 mg ALIUD(R) PHARMA GMBH &

CO.KG

KAMIREN 4 mg KRKA D.D. NOVO MESTO

MAGUROL 4 mg MEDOCHEMIE LTD.

G04CAN1 DOXAZOSINUM COMPR. ELIB. MODIF. 4 mg

CARDURA XL 4 mg 4 mg PFIZER H.C.P. CORPORATION

G04CAN1 DOXAZOSINUM COMPR. FILM. ELIB. 4 mg

PREL.

KAMIREN XL 4 mg 4 mg KRKA D.D. NOVO MESTO

G04CAN1 DOXAZOSINUM COMPR. 1 mg

DOXAZOSIN 1 MEDOCHEMIE 1 mg MEDOCHEMIE ROMANIA SRL

DOXAZOSIN AL 1 1 mg ALIUD(R) PHARMA GMBH &

CO.KG

KAMIREN 1 mg KRKA D.D. NOVO MESTO

MAGUROL 1 mg MEDOCHEMIE LTD.

G04CAN1 DOXAZOSINUM COMPR. 2 mg

DOXAZOSIN 2 MEDOCHEMIE 2 mg MEDOCHEMIE ROMANIA SRL

DOXAZOSIN AL 2 2 mg ALIUD(R) PHARMA GMBH &

CO.KG

DOXAZOSIN SANDOZ 2 mg 2 mg HEXAL AG

KAMIREN 2 mg KRKA D.D. NOVO MESTO

MAGUROL 2 mg MEDOCHEMIE LTD.

G04CAN1 DOXAZOSINUM COMPR. 4 mg

DOXAZOSIN 4 MEDOCHEMIE 4 mg MEDOCHEMIE ROMANIA SRL

DOXAZOSIN AL 4 4 mg ALIUD(R) PHARMA GMBH &

CO.KG

DOXAZOSIN SANDOZ 4 mg 4 mg HEXAL AG

KAMIREN 4 mg KRKA D.D. NOVO MESTO

MAGUROL 4 mg MEDOCHEMIE LTD.

G04CAN1 DOXAZOSINUM COMPR. ELIB. MODIF. 4 mg

CARDURA XL 4 mg 4 mg PFIZER H.C.P. CORPORATION

G04CAN1 DOXAZOSINUM COMPR. FILM. ELIB. 4 mg

PREL.

KAMIREN XL 4 mg 4 mg KRKA D.D. NOVO MESTO

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| **76** |**H02AB04**| **METHYLPREDNISOLONUM\*** | |

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CONCENTRAŢIE FIRMA

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H02AB04 METHYLPREDNISOLONUM LIOF. PT. SOL. INJ. 125 mg

LEMOD SOLU 125 mg 125 mg HEMOFARM S.R.L.

H02AB04 METHYLPREDNISOLONUM LIOF. ŞI SOLV. PT. SOL. 125 mg/2 ml

INJ.

SOLU-MEDROL ACT-O-VIAL 125 mg/2 ml PFIZER EUROPE MA EEIG

H02AB04 METHYLPREDNISOLONUM LIOF. PT. SOL. INJ. 20 mg

LEMOD SOLU 20 mg 20 mg HEMOFARM S.R.L.

H02AB04 METHYLPREDNISOLONUM LIOF. ŞI SOLV. PT. SOL. 250 mg/4 ml

INJ.

SOLU-MEDROL ACT-O-VIAL 250 mg/4 ml PFIZER EUROPE MA EEIG

H02AB04 METHYLPREDNISOLONUM LIOF. PT. SOL. INJ. 40 mg

LEMOD SOLU 40 mg 40 mg HEMOFARM S.R.L.

H02AB04 METHYLPREDNISOLONUM LIOF. ŞI SOLV. PT. SOL. 40 mg/1 ml

INJ.

SOLU-MEDROL ACT-O-VIAL 40 mg/1 ml PFIZER EUROPE MA EEIG

H02AB04 METHYLPREDNISOLONUM LIOF. PT. SOL. INJ. 500 mg

LEMOD SOLU 500 mg 500 mg HEMOFARM S.R.L.

H02AB04 METHYLPREDNISOLONUM LIOF. + SOLV. PT. SOL. 500 mg/7.8 ml

INJ.

SOLU-MEDROL 500 mg/7,8 ml 500 mg/7.8 ml PFIZER EUROPE MA EEIG

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| **77** |**H02AB07**| **PREDNISONUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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H02AB07 PREDNISONUM COMPR. 5 mg

N-PREDNISON 5 mg MEDUMAN SA

PREDNISON 5 mg 5 mg SINTOFARM SA

PREDNISON ARENA 5 mg 5 mg ARENA GROUP SA

PREDNISON GEDEON RICHTER 5 mg 5 mg GEDEON RICHTER ROMÂNIA SA

PREDNISON MAGISTRA 5 mg 5 mg MAGISTRA C & C

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| **78** |**H02AB09**| **HYDROCORTISONUM\*** | |

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H02AB09 HYDROCORTISONUM LIOF. + SOLV. PT. SOL. 100 mg

INJ.

HYDROCORTISONE 100 mg 100 mg HEMOFARM S.R.L.

HYDROCORTISONE SUCCINAT SODIC 100 mg E.I.P.I.CO. MED S.R.L.

H02AB09 HYDROCORTISONUM SOL. INJ. I.V. 25 mg/5 ml

HIDROCORTIZON HEMISUCCINAT 25 mg/5 ml ZENTIVA S.A.

H02AB09 HYDROCORTISONUM LIOF. PT. SOL. INJ. + 500 mg

SOLV.

HYDROCORTISONE 500 mg 500 mg HEMOFARM S.R.L.

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| **79** |**J01AA02**| **DOXYCYCLINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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J01AA02 DOXYCYCLINUM CAPS. 100 mg

DOXICICLINA 100 mg EUROPHARM SA

DOXICICLINA 100 mg 100 mg ANTIBIOTICE SA

DOXICICLINA SANDOZ 100 mg 100 mg SANDOZ SRL

J01AA02 DOXYCYCLINUM COMPR. DISP. 100 mg

UNIDOX SOLUTAB 100 mg ASTELLAS PHARMA EUROPE

B.V.

J01AA02 DOXYCYCLINUM CAPS. 100 mg

DOXICICLINA 100 mg ARENA GROUP SA

DOXICICLINA 100 mg 100 mg ANTIBIOTICE SA

DOXICICLINA SANDOZ 100 mg 100 mg SANDOZ SRL

J01AA02 DOXYCYCLINUM COMPR. DISP. 100 mg

UNIDOX SOLUTAB 100 mg ASTELLAS PHARMA EUROPE

B.V.

J01AA02 DOXYCYCLINUM CAPS. 100 mg

DOXICICLINA 100 mg ARENA GROUP SA

DOXICICLINA 100 mg 100 mg ANTIBIOTICE SA

DOXICICLINA SANDOZ 100 mg 100 mg SANDOZ SRL

J01AA02 DOXYCYCLINUM COMPR. DISP. 100 mg

UNIDOX SOLUTAB 100 mg ASTELLAS PHARMA EUROPE

B.V.

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| **80** |**J01CA04**| **AMOXICILLINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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J01CA04 AMOXICILLINUM COMPR. FILM. 1000 mg

OSPAMOX 1000 mg 1000 mg SANDOZ GMBH

J01CA04 AMOXICILLINUM PULB. PT. SUSP. ORALĂ 125 mg/5 ml

AMOXICILINA 125 mg/5 ml 125 mg/5 ml OZONE LABORATORIES LTD.

AMOXICILINA SANDOZ 125 mg/5 ml SANDOZ S.R.L.

125 mg/5 ml PULBERE PENTRU

SUSPENSIE ORALĂ

JULPHAMOX 125 mg/5 ml GULF PHARMACEUTICAL

INDUSTRIES S.R.L.

OSPAMOX(R) 125 mg/5 ml 125 mg/5 ml SANDOZ GMBH

J01CA04 AMOXICILLINUM PULB. SUSP. 125 mg/5 ml

MOXILEN 125 mg/5 ml MEDOCHEMIE LTD.

J01CA04 AMOXICILLINUM CAPS. 250 mg

AMOXICILINA 250 mg EUROPHARM SA

AMOXICILINA SANDOZ 250 mg 250 mg SANDOZ SRL

CAPSULE

AMOXICILINA 250 mg 250 mg OZONE LABORATORIES LTD.

AMOXICILINA ANTIBIOTICE 250 mg ANTIBIOTICE SA

250 mg

AMOXICILINA ARENA 250 mg 250 mg ARENA GROUP SA

AMOXICILINA MEDICO UNO 250 mg 250 mg MEDICO UNO PHARMACEUTICAL

S.R.L.

OSPAMOX 250 mg 250 mg SANDOZ GMBH

J01CA04 AMOXICILLINUM PULB. PT. SUSP. ORALĂ 250 mg/5 ml

AMOXICILINA SANDOZ 250 mg/5 ml SANDOZ S.R.L.

250 mg/5 ml PULBERE PENTRU

SUSPENSIE ORALĂ

AMOXICILINA 250 mg/5 ml 250 mg/5 ml OZONE LABORATORIES LTD.

E-MOX 250 mg/5 ml E.I.P.I.CO. MED S.R.L.

JULPHAMOX 250 mg/5 ml GULF PHARMACEUTICAL

INDUSTRIES S.R.L.

OSPAMOX 250 mg/5 ml 250 mg/5 ml SANDOZ GMBH

J01CA04 AMOXICILLINUM PULB. SUSP. 250 mg/5 ml

MOXILEN FORTE 250 mg/5 ml MEDOCHEMIE LTD.

J01CA04 AMOXICILLINUM CAPS. 500 mg

AMOXICILINA ANTIBIOTICE 500 mg ANTIBIOTICE SA

500 mg

AMOXICILINA ARENA 500 mg 500 mg ARENA GROUP SA

AMOXICILINA FORTE 500 mg 500 mg OZONE LABORATORIES LTD.

AMOXICILINA SANDOZ 500 mg 500 mg SANDOZ SRL

CAPSULE

E-MOX 500 mg E.I.P.I.CO. MED S.R.L.

EPHAMOX 500 mg EUROPHARM SA

MOXILEN 500 mg MEDOCHEMIE LTD.

J01CA04 AMOXICILLINUM COMPR. FILM. 500 mg

OSPAMOX 500 mg 500 mg SANDOZ GMBH

J01CA04 AMOXICILLINUM COMPR. PT. DISPERSIE 1000 mg

ORALĂ

DUOMOX 1000 mg 1000 mg ASTELLAS PHARMA EUROPE BV

J01CA04 AMOXICILLINUM COMPR. PT. DISPERSIE 250 mg

ORALĂ

DUOMOX 250 mg 250 mg ASTELLAS PHARMA EUROPE BV

J01CA04 AMOXICILLINUM COMPR. PT. DISPERSIE 500 mg

ORALĂ

DUOMOX 500 mg 500 mg ASTELLAS PHARMA EUROPE BV

J01CA04 AMOXICILLINUM COMPR. PT. DISPERSIE 750 mg

ORALĂ

DUOMOX 750 mg 750 mg ASTELLAS PHARMA EUROPE BV

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| **81** |**J01CE02**| **PHENOXYMETHYLPENICILLINUM** | |

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CONCENTRAŢIE FIRMA

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J01CE02 PHENOXY- COMPR. 1000000 ui

METHYLPENICILLINUM

PENICILINA V 1 000 000 U.I. 1000000 ui EUROPHARM SA

J01CE02 PHENOXY- COMPR. FILM. 1000000 ui

METHYLPENICILLINUM

OSPEN(R) 1000 1000000 ui SANDOZ GMBH

J01CE02 PHENOXY- COMPR. FILM. 1500000 ui

METHYLPENICILLINUM

OSPEN(R) 1500 1500000 ui SANDOZ GMBH

J01CE02 PHENOXY- SIROP 400000 ui/5 ml

METHYLPENICILLINUM

OSPEN 400 400000 ui/5 ml SANDOZ GMBH

J01CE02 PHENOXY- COMPR. FILM. 500000 ui

METHYLPENICILLINUM

OSPEN(R) 500 500000 ui SANDOZ GMBH

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| **82** |**J01CE08**| **BENZATHINI BENZYLPENICILLINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01CE08 BENZATHINI PULB. PT. SUSP. INJ. 1200000 ui

BENZYLPENICILLINUM

MOLDAMIN(R) 1200000 ui ANTIBIOTICE SA

J01CE08 BENZATHINI PULB. PT. SUSP. INJ. 600000 ui

BENZYLPENICILLINUM

MOLDAMIN(R) 600000 ui ANTIBIOTICE SA

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| **83** |**J01CF04**| **OXACILLINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01CF04 OXACILLINUM CAPS. 250 mg

OXACILINA 250 mg FARMACOM SA

OXACILINA 250 mg 250 mg ANTIBIOTICE SA

OXACILINA ARENA 250 mg 250 mg ARENA GROUP SA

OXACILINA FARMEX 250 mg 250 mg FARMEX COMPANY SRL

OXACILINA SANDOZ 250 mg 250 mg SANDOZ SRL

J01CF04 OXACILLINUM CAPS. 500 mg

OXACILINA 500 mg 500 mg ANTIBIOTICE SA

OXACILINA ARENA 500 mg 500 mg ARENA GROUP SA

OXACILINA FORTE 500 mg 500 mg OZONE LABORATORIES LTD.

OXACILINA SANDOZ 500 mg 500 mg SANDOZ SRL

OXALIN 500 mg 500 mg EUROPHARM SA

J01CF04 OXACILLINUM PULB. PT. SOL. INJ./ 1 g

PERF. I.M./I.V.

OXACILINA ANTIBIOTICE 1 g 1 g ANTIBIOTICE SA

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| **84** |**J01CR02**| **AMOXICILLINUM + ACIDUM CLAVULANICUM** | |

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Prescriere limitată: **Tratamentul de scurtă durată a infecţiilor bacteriene**

**atunci când este suspectată rezistenţa la amoxicilină.**

**Infecţii la care este dovedită rezistenţa la**

**amoxicilină.**

A fost raportată hepatotoxicitate la acest medicament.

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01CR02 AMOXICILLINUM + COMPR. FILM. 1000 mg

ACIDUM CLAVULANICUM

AMOKSIKLAV 2 x 1000 mg 1000 mg LEK PHARMACEUTICALS D.D.

MEDOCLAV 1000 mg 1000 mg MEDOCHEMIE LTD.

J01CR02 AMOXICILLINUM + COMPR. FILM. ELIB. 1062.5 mg

ACIDUM CLAVULANICUM PREL.

AUGMENTIN(TM) SR 1062.5 mg BEECHAM GROUP PLC

J01CR02 AMOXICILLINUM + PULB. PT. SUSP. ORALĂ 125 mg + 31.25/5 m

ACIDUM CLAVULANICUM

MEDOCLAV 156,25 mg/5 ml 125 mg + 31.25/5 ml MEDOCHEMIE LTD.

J01CR02 AMOXICILLINUM + PULB. PT. SUSP. ORALĂ 156.25 mg/5 ml

ACIDUM CLAVULANICUM

AMOKSIKLAV 156,25 mg/5 ml 156.25 mg/5 ml LEK PHARMACEUTICALS D.D.

BIOCLAVID 156.25 mg/5 ml 156.25 mg/5 ml SANDOZ GMBH

J01CR02 AMOXICILLINUM + COMPR. DISP. 250/62,5 mg

ACIDUM CLAVULANICUM

FORCID SOLUTAB 250/62,5 250/62,5 mg ASTELLAS PHARMA EUROPE BV

J01CR02 AMOXICILLINUM + COMPR. FILM. 250 mg + 125 mg

ACIDUM CLAVULANICUM

MEDOCLAV 375 mg 250 mg + 125 mg MEDOCHEMIE LTD.

J01CR02 AMOXICILLINUM + PULB. PT. SUSP. ORALĂ 250 mg +

ACIDUM CLAVULANICUM 62.5 mg/5 ml

MEDOCLAV FORTE 312,5 mg/5 ml 250 mg + 62.5 mg/5 ml MEDOCHEMIE LTD.

J01CR02 AMOXICILLINUM + PULB. PT. SUSP. ORALĂ 312.5 mg/5 ml

ACIDUM CLAVULANICUM

BIOCLAVID 312.5 mg/5 ml 312.5 mg/5 ml SANDOZ GMBH

J01CR02 AMOXICILLINUM + PULB. PT. SUSP. ORALĂ 312.5 mg/5 ml

ACIDUM CLAVULANICUM

AMOKSIKLAV 312.5 mg/5 ml 312.5 mg/5 ml LEK PHARMACEUTICALS D.D.

ENHANCIN 312,5 mg/5 ml 312.5 mg/5 ml RANBAXY UK LIMITED

J01CR02 AMOXICILLINUM + PULB. PT. SUSP. ORALĂ 400 mg + 57 mg/5 m

ACIDUM CLAVULANICUM

AUGMENTIN BIS 400 mg + 57 mg/5 ml SMITHKLINE BEECHAM PLC

J01CR02 AMOXICILLINUM + COMPR. DISP. 500/125 mg

ACIDUM CLAVULANICUM

FORCID SOLUTAB 500/125 500/125 mg ASTELLAS PHARMA EUROPE BV

J01CR02 AMOXICILLINUM + COMPR. FILM. 500 mg + 125 mg

ACIDUM CLAVULANICUM

AUGMENTIN 625 mg 500 mg + 125 mg BEECHAM GROUP PLC

MEDOCLAV 625 mg 500 mg + 125 mg MEDOCHEMIE LTD.

J01CR02 AMOXICILLINUM + COMPR. FILM. 625 mg

ACIDUM CLAVULANICUM

AMOKSIKLAV 2 x 625 mg 625 mg LEK PHARMACEUTICALS D.D.

BIOCLAVID 625 mg 625 mg SANDOZ GMBH

J01CR02 AMOXICILLINUM + PULB. PT. SUSP. ORALĂ 642.90 mg/5 ml

ACIDUM CLAVULANICUM

AUGMENTIN(R) ES 642.90 mg/5 ml SMITHKLINE BEECHAM PLC

J01CR02 AMOXICILLINUM + COMPR. DISP. 875 mg + 125 mg

ACIDUM CLAVULANICUM

FORCID SOLUTAB 875/125 875 mg + 125 mg ASTELLAS PHARMA EUROPE BV

J01CR02 AMOXICILLINUM + COMPR. FILM. 875 mg + 125 mg

ACIDUM CLAVULANICUM

AUGMENTIN 1 g 875 mg + 125 mg BEECHAM GROUP PLC

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| **85** |**J01DB01**| **CEFALEXINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01DB01 CEFALEXINUM COMPR. FILM. 1000 mg

OSPEXIN 1000 mg 1000 mg SANDOZ GMBH

J01DB01 CEFALEXINUM GRAN. PT. SUSP. ORALĂ 125 mg/5 ml

CEFALEXIN SANDOZ 125 mg/5 ml 125 mg/5 ml SANDOZ SRL

GRANULE PENTRU SUSPENSIE

ORALĂ

KEFLEX(R) 125 mg/5 ml 125 mg/5 ml ACTAVIS GROUP HF

OSPEXIN(R) 125 mg/5 ml 125 mg/5 ml SANDOZ GMBH

J01DB01 CEFALEXINUM PULB. PT. SUSP. ORALĂ 125 mg/5 ml

CEFALEXIN 125 mg/5 ml 125 mg/5 ml OZONE LABORATORIES LTD.

J01DB01 CEFALEXINUM CAPS. 250 mg

CEFALEXIN 250 mg 250 mg OZONE LABORATORIES LTD.

CEFALEXIN SANDOZ 250 mg 250 mg SANDOZ SRL

CAPSULE

CEFALEXINA 250 mg 250 mg ANTIBIOTICE SA

CEFALEXINA ARENA 250 mg 250 mg ARENA GROUP SA

CEFALEXINA MEDICO UNO 250 mg 250 mg MEDICO UNO PHARMACEUTICAL

S.R.L.

OSPEXIN(R) 250 mg 250 mg SANDOZ GMBH

SPORIDEX 250 mg 250 mg TERAPIA SA

J01DB01 CEFALEXINUM GRAN. PT. SUSP. ORALĂ 250 mg/5 ml

CEFALEXIN SANDOZ 250 mg/5 ml 250 mg/5 ml SANDOZ SRL

GRANULE PENTRU SUSPENSIE

ORALĂ

KEFLEX(R) 250 mg/5 ml 250 mg/5 ml ACTAVIS GROUP HF

OSPEXIN(R) 250 mg/5 ml 250 mg/5 ml SANDOZ GMBH

J01DB01 CEFALEXINUM PULB. PT. SUSP. ORALĂ 250 mg/5 ml

CEFALEXIN 250 mg/5 ml 250 mg/5 ml OZONE LABORATORIES LTD.

J01DB01 CEFALEXINUM CAPS. 500 mg

CEFALEXIN 500 mg 500 mg OZONE LABORATORIES LTD.

CEFALEXINA 500 mg 500 mg ANTIBIOTICE SA

CEFALEXINA ARENA 500 mg 500 mg ARENA GROUP SA

SPORIDEX 500 mg 500 mg TERAPIA S.A.

J01DB01 CEFALEXINUM COMPR. FILM. 500 mg

CEFALEXIN SANDOZ 500 mg 500 mg SANDOZ SRL

COMPRIMATE FILMATE

OSPEXIN 500 mg 500 mg SANDOZ GMBH

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| **86** |**J01DB05**| **CEFADROXILUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01DB05 CEFADROXILUM COMPR. FILM. 1000 mg

CEXYL 1000 mg 1000 mg SANDOZ S.R.L.

J01DB05 CEFADROXILUM GRAN. PT. SUSP. ORALĂ 125 mg/5 ml

CEXYL 125 mg/5 ml 125 mg/5 ml SANDOZ S.R.L.

J01DB05 CEFADROXILUM CAPS. 250 mg

CEXYL 250 mg 250 mg SANDOZ S.R.L.

J01DB05 CEFADROXILUM GRAN. SUSP. ORALĂ 250 mg/5 ml

CEXYL 250 mg/5 ml 250 mg/5 ml SANDOZ S.R.L.

J01DB05 CEFADROXILUM CAPS. 500 mg

CEFADROXIL 500 mg OZONE LABORATORIES LTD.

CEFADROXIL TERAPIA 500 mg TERAPIA S.A.

CEFORAN(R) 500 mg 500 mg ANTIBIOTICE SA

CEXYL 500 mg 500 mg SANDOZ S.R.L.

J01DB05 CEFADROXILUM GRAN. SUSP. ORALĂ 500 mg/5 ml

CEXYL 500 mg/5 ml 500 mg/5 ml SANDOZ S.R.L.

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| **87** |**J01DC02**| **CEFUROXIMUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01DC02 CEFUROXIMUM COMPR. ACOPERITE 125 mg

AXYCEF(R) 125 125 mg SANDOZ SRL

J01DC02 CEFUROXIMUM COMPR. FILM. 125 mg

ZINNAT(R) 125 mg 125 mg GLAXO WELLCOME UK LTD.

J01DC02 CEFUROXIMUM GRAN. PT. SUSP. ORALĂ 125 mg/5 ml

CEROXIM 125 mg/5 ml 125 mg/5 ml RANBAXY UK LIMITED

ZINNAT 125 mg/5 ml GLAXO WELLCOME UK LTD.

J01DC02 CEFUROXIMUM PULB. PT. SUSP. ORALĂ 125 mg/5 ml

AXYCEF(R) 125 mg/5 ml 125 mg/5 ml SANDOZ SRL

J01DC02 CEFUROXIMUM COMPR. 250 mg

CEROXIM 250 mg 250 mg RANBAXY U.K. LIMITED

J01DC02 CEFUROXIMUM COMPR. ACOPERITE 250 mg

AXYCEF(R) 250 250 mg SANDOZ SRL

J01DC02 CEFUROXIMUM COMPR. FILM. 250 mg

ZINNAT(R) 250 mg 250 mg GLAXO WELLCOME UK LTD.

J01DC02 CEFUROXIMUM GRAN. PT. SUSP. ORALĂ 250 mg/5 ml

CEROXIM 250 mg/5 ml 250 mg/5 ml RANBAXY UK LIMITED

J01DC02 CEFUROXIMUM COMPR. 500 mg

CEROXIM 500 mg 500 mg RANBAXY U.K. LIMITED

J01DC02 CEFUROXIMUM COMPR. ACOPERITE 500 mg

AXYCEF(R) 500 500 mg SANDOZ SRL

J01DC02 CEFUROXIMUM COMPR. FILM. 500 mg

ZINNAT(R) 500 mg 500 mg GLAXO WELLCOME UK LTD.

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| **88** |**J01DC04**| **CEFACLORUM** | |

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Reacţii asemănătoare bolii serului au fost raportate la utilizarea acestui medicament, în special de către copii.

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01DC04 CEFACLORUM GRAN. PT. SUSP. ORALĂ 125 mg/5 ml

CECLODYNE 125 mg/5 ml 125 mg/5 ml SANDOZ SRL

CECLOR(R) 125 mg/5 ml 125 mg/5 ml ACTAVIS GROUP HF

CEFACLOR 125 mg/5 ml 125 mg/5 ml OZONE LABORATORIES LTD.

VERCEF 125 mg/5 ml 125 mg/5 ml TERAPIA S.A.

J01DC04 CEFACLORUM PULB. PT. SUSP. ORALĂ 125 mg/5 ml

CEFAKLOR 125 mg/5 ml 125 mg/5 ml HEMOFARM S.R.L.

CLORACEF(R) 125 125 mg/5 ml DAR AL DAWA PHARMA S.R.L

J01DC04 CEFACLORUM CAPS. 250 mg

CECLODYNE 250 mg 250 mg SANDOZ SRL

CEFACLOR 250 mg 250 mg OZONE LABORATORIES LTD.

CLORACEF(R) 250 250 mg DAR AL DAWA PHARMA S.R.L.

MEDOCLOR 250 250 mg MEDOCHEMIE LTD.

J01DC04 CEFACLORUM GRAN. PT. SUSP. ORALĂ 250 mg/5 ml

CECLODYNE 250 mg/5 ml 250 mg/5 ml SANDOZ SRL

CECLOR(R) 250 mg/5 ml 250 mg/5 ml ACTAVIS GROUP HF

CEFACLOR 250 mg/5 ml 250 mg/5 ml OZONE LABORATORIES LTD.

J01DC04 CEFACLORUM PULB. PT. SUSP. ORALĂ 250 mg/5 ml

CEC HEXAL FORTE 250 mg/5 ml 250 mg/5 ml HEXAL AG

CEFAKLOR 250 mg/5 ml 250 mg/5 ml HEMOFARM S.R.L.

CLORACEF(R) 250 250 mg/5 ml DAR AL DAWA PHARMA S.R.L.

J01DC04 CEFACLORUM COMPR. ELIB. PREL. 375 mg

CECLOR(R) MR 375 mg ACTAVIS GROUP HF

CECLOZONE MR 375 mg 375 mg OZONE LABORATORIES LTD.

J01DC04 CEFACLORUM COMPR. FILM. ELIB. 375 mg

MODIF.

CECLODYNE(R) MR 375 mg 375 mg SANDOZ SRL

J01DC04 CEFACLORUM CAPS. 500 mg

CECLODYNE FORTE 500 mg 500 mg SANDOZ SRL

CEFACLOR 500 mg 500 mg OZONE LABORATORIES LTD.

CLORACEF(R) FORTE 500 500 mg DAR AL DAWA PHARMA S.R.L.

MEDOCLOR 500 500 mg MEDOCHEMIE LTD.

J01DC04 CEFACLORUM COMPR. ELIB. PREL. 500 mg

CECLOR(R) MR 500 mg ACTAVIS GROUP HF

J01DC04 CEFACLORUM COMPR. FILM. ELIB. 500 mg

MODIF.

CECLODYNE(R) MR 500 mg 500 mg SANDOZ SRL

J01DC04 CEFACLORUM COMPR. ELIB. PREL. 750 mg

CECLOR(R) MR 750 mg ACTAVIS GROUP HF

CECLOZONE MR 750 mg 750 mg OZONE LABORATORIES LTD.

J01DC04 CEFACLORUM COMPR. FILM. ELIB. 750 mg

MODIF.

CECLODYNE(R) MR 750 mg 750 mg SANDOZ SRL

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| **89** |**J01DD08**| **CEFIXIMUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01DD08 CEFIXIMUM GRAN. PT. SUSP. ORALĂ 100 mg/5 ml

SUPRAX 100 mg/5 ml GEDEON RICHTER LTD.

J01DD08 CEFIXIMUM CAPS. 200 mg

EFICEF(R) 200 mg 200 mg ANTIBIOTICE SA

J01DD08 CEFIXIMUM COMPR. FILM. 200 mg

SUPRAX 200 mg GEDEON RICHTER LTD.

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| **90** |**J01EE01**| **SULFAMETHOXAZOLUM + TRIMETHOPRIMUM** | |

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Există un risc crescut de reacţie adversă severă la administrarea acestui medicament la persoane în vârstă.

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01EE01 SULFAMETHOXAZOLUM + SUSP. ORALĂ 200 mg/40 mg/5 ml

TRIMETHOPRIMUM

EPITRIM 200 mg/40 mg/5 ml E.I.P.I.CO. MED S.R.L.

J01EE01 SULFAMETHOXAZOLUM + SIROP 25 mg/5 mg/ml

TRIMETHOPRIMUM

SUMETROLIM 25 mg/5 mg/ml EGIS PHARMACEUTICALS

P.L.C.

J01EE01 SULFAMETHOXAZOLUM + COMPR. 400 mg/80 mg

TRIMETHOPRIMUM

BISEPTRIM 400 mg/80 mg EUROPHARM SA

CO-TRIM ELL 400 mg/80 mg ARENA GROUP S.A.

SUMETROLIM 400 mg/80 mg EGIS PHARMACEUTICALS

P.L.C.

TAGREMIN 400 mg/80 mg ZENTIVA S.A.

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| **91** |**J01FA01**| **ERYTHROMYCINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01FA01 ERYTHROMYCINUM COMPR. 200 mg

ERITROMAGIS 200 mg 200 mg ARENA GROUP SA

ERITROMICINA 200 mg 200 mg ANTIBIOTICE SA

ERITROMICINA EUROPHARM 200 mg 200 mg EUROPHARM SA

ERITROMICINA SANDOZ 200 mg 200 mg SANDOZ S.R.L.

COMPRIMATE

J01FA01 ERYTHROMYCINUM PULB. PT. SUSP. ORALĂ 200 mg/5 ml

ERITRO 200 200 mg/5 ml LEK PHARMATECH SRL

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| **92** |**J01FA09**| **CLARITHROMYCINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01FA09 CLARITHROMYCINUM GRAN. PT. SUSP. ORALĂ 125 mg/5 ml

FROMILID(R) 125 mg/5 ml 125 mg/5 ml KRKA D.D.

KLABAX 125 mg/5 ml 125 mg/5 ml TERAPIA S.A.

KLACID(R) 125 mg/5 ml ABBOTT SPA

LEKOKLAR 125 mg/5 ml 125 mg/5 ml SANDOZ S.R.L.

J01FA09 CLARITHROMYCINUM COMPR. FILM. 250 mg

CLAR 250 250 mg MEDICAROM GROUP S.R.L.

CLARITROMICINA 250 mg 250 mg OZONE LABORATORIES LTD.

FROMILID 250 250 mg KRKA D.D. NOVO MESTO

KLABAX 250 mg 250 mg TERAPIA S.A.

KLACID(R) 250 mg ABBOTT SPA

KLERIMED(R) 250 250 mg MEDOCHEMIE LTD.

LEKOKLAR(R) 250 mg 250 mg LEK PHARMACEUTICALS D.D.

J01FA09 CLARITHROMYCINUM GRAN. PT. SUSP. ORALĂ 250 mg/5 ml

KLABAX 250 mg/5 ml 250 mg/5 ml TERAPIA S.A.

LEKOKLAR 250 mg/5 ml 250 mg/5 ml SANDOZ SRL

J01FA09 CLARITHROMYCINUM COMPR. FILM. 500 mg

CLAR 500 500 mg MEDICAROM GROUP S.R.L.

CLARITROMICINA 500 mg 500 mg OZONE LABORATORIES LTD.

FROMILID 500 500 mg KRKA D.D. NOVO MESTO

KLABAX 500 mg 500 mg TERAPIA S.A.

KLERIMED(R) 500 500 mg MEDOCHEMIE LTD.

LEKOKLAR(R) 500 mg 500 mg LEK PHARMACEUTICALS D.D.

J01FA09 CLARITHROMYCINUM COMPR. FILM. ELIB. 500 mg

MODIF.

KLABAX MR 500 mg 500 mg TERAPIA S.A.

LEKOKLAR XL 500 mg 500 mg LEK PHARMACEUTICALS D.D.

J01FA09 CLARITHROMYCINUM COMPR. FILM. ELIB. 500 mg

PREL.

FROMILID(R) UNO 500 mg KRKA D.D.

KLACID SR 500 mg ABBOTT LABORATORIES LTD.

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| **93** |**J01MA01**| **OFLOXACINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01MA01 OFLOXACINUM COMPR. FILM. 200 mg

OFLOXACIN 200 mg 200 mg ANTIBIOTICE SA

OFLOXIN 200 200 mg ZENTIVA AS

ZANOCIN 200 mg RANBAXY UK LIMITED

J01MA01 OFLOXACINUM COMPR. FILM. ELIB. 400 mg

PREL.

ZANOCIN(R) OD 400 400 mg RANBAXY U.K. LIMITED

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| **94** |**J01MA02**| **CIPROFLOXACINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01MA02 CIPROFLOXACINUM CAPS. 250 mg

EUCIPRIN 250 mg EUROPHARM SA

J01MA02 CIPROFLOXACINUM COMPR. FILM. 250 mg

CIFRAN 250 mg RANBAXY UK LIMITED

CIPHIN 250 250 mg ZENTIVA A.S.

CIPRINOL 250 mg 250 mg KRKA D.D. NOVO MESTO

CIPROCIN 250 mg 250 mg E.I.P.I.CO. MED S.R.L.

CIPROFLOXACINA ALKALOID 250 mg ALKALOID D.O.O.

250 mg

CIPROLEN(R) 250 mg 250 mg AC HELCOR SRL

CIPROLET 250 mg 250 mg DR. REDDY'S LABORATORIES

CIPROZONE 250 mg 250 mg OZONE LABORATORIES LTD.

CUMINOL 250 mg 250 mg GEDEON RICHTER ROMÂNIA

J01MA02 CIPROFLOXACINUM COMPR. FILM. 500 mg

CIFRAN 500 mg RANBAXY UK LIMITED

CIPHIN 500 500 mg ZENTIVA A.S.

CIPRINOL 500 mg 500 mg KRKA D.D. NOVO MESTO

CIPRO QUIN(R) 500 mg ANTIBIOTICE SA

CIPROBAY(R) 500 500 mg BAYER HEALTHCARE AG

CIPROCIN 500 mg 500 mg E.I.P.I.CO MED S.R.L.

CIPRODAR 500 mg DAR AL DAWA PHARMA S.R.L.

CIPROFLOXACINA ALKALOID 500 mg ALKALOID D.O.O.

500 mg

CIPROLEN(R) 500 mg 500 mg AC HELCOR SRL

CIPROLET 500 mg 500 mg DR. REDDY'S LABORATORIES

CIPROZONE FORTE 500 mg 500 mg OZONE LABORATORIES LTD.

CUMINOL 500 mg 500 mg GEDEON RICHTER ROMÂNIA

SIFLOKS(R) 500 mg ECZACIBASI ILAC SANAYI VE

TICARET AS

J01MA02 CIPROFLOXACINUM COMPR. FILM. 750 mg

CIPRINOL 750 mg 750 mg KRKA D.D. NOVO MESTO

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| **95** |**J01MA03**| **PEFLOXACINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01MA03 PEFLOXACINUM COMPR. FILM. 400 mg

PEFLOXACIN LAROPHARM 400 mg LAROPHARM S.R.L.

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| **96** |**J01MA06**| **NORFLOXACINUM** | |

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Prescriere limitată: **Enterocolită bacteriană.**

**Infecţii de tract urinar.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01MA06 NORFLOXACINUM COMPR. FILM. 400 mg

EPINOR 400 mg E.I.P.I.CO. MED S.R.L.

H-NORFLOXACIN 400 mg 400 mg AC HELCOR SRL

NOLICIN 400 mg 400 mg KRKA D.D. NOVO MESTO

NORFLOX - 400 400 mg LEK PHARMATECH SRL

NORFLOXACIN 400 mg 400 mg OZONE LABORATORIES LTD.

NORFLOXACIN OZONE 400 mg 400 mg OZONE LABORATORIES LTD.

NORFLOXACINA LPH 400 mg 400 mg LABORMED PHARMA SA

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| **97** |**J01MB02**| **ACIDUM NALIDIXICUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01MB02 ACIDUM NALIDIXICUM CAPS. 500 mg

NALIXID 500 mg 500 mg ZENTIVA SA

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| **98** |**J01XD01**| **METRONIDAZOLUM** | |

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Prescriere limitată: **Tratamentul infecţiilor cu anaerobi.**

**Tratamentul infecţiilor cu protozoare sensibile la**

**metronidazol.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01XD01 METRONIDAZOLUM COMPR. 250 mg

METRONIDAZOL 250 mg (J01XD01) 250 mg ARENA GROUP SA

J01XD01 METRONIDAZOLUM COMPR. FILM. 250 mg

FLAGYL 250 mg LABORATOIRE AVENTIS

J01XD01 METRONIDAZOLUM SUSP. ORALĂ 4%

FLAGYL 4% (J01XD01) 4% LABORATOIRE AVENTIS

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| **99** |**J01XD02**| **TINIDAZOLUM** | |

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Prescriere limitată: **Tratamentul infecţiilor cu anaerobi.**

**Tratamentul infecţiilor cu protozoare sensibile la**

**tinidazol.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01XD02 TINIDAZOLUM COMPR. FILM. 500 mg

FASIGYN (J01XD02) 500 mg PFIZER EUROPE MA EEIG

TINIZOL(R) 500 mg (J01XD02) 500 mg ZENTIVA S.A.

TIPROGYN 500 500 mg AC HELCOR SRL

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| **100** |**J02AB02**| **KETOCONAZOLUM** | |

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Prescriere limitată: **Candidoză genitală simptomatică recurentă după**

**tratamentul local a cel puţin două episoade.**

**Tratamentul candidozelor muco-cutanate cronice şi**

**candidozelor orofaringiene care nu pot fi tratate cu**

**antifungice locale, la pacienţii care prezintă**

**rezistenţă sau intoleranţă la fluconazol şi**

**intraconazol.**

**Micoze sistemice la care alte forme de terapie**

**antifungică nu au avut efect.**

A fost raportată hepatotoxicitate la ketoconazol.

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J02AB02 KETOCONAZOLUM COMPR. 200 mg

KEFUNGIN 200 mg ANTIBIOTICE SA

KETOCONAZOL 200 mg 200 mg MAGISTRA C & C

KETOSTIN 200 mg 200 mg AC HELCOR SRL

NIZORAL 200 mg JANSSEN PHARMACEUTICA NV

NIZORAL 200 mg 200 mg TERAPIA SA

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| **101** |**J02AC01**| **FLUCONAZOLUM** | |

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Prescriere limitată: **Candidoze genitale.**

**Candidoze ale mucoaselor orofaringiene, esofagiene,**

**bronhopulmonare non-invazive.**

**Infecţii cu candida ale pielii.**

**Candidoze sistemice.**

**Profilaxia candidozelor la pacienţii cu risc aflaţi în**

**tratament cu antibiotic.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J02AC01 FLUCONAZOLUM CAPS. 100 mg

DIFLAZON 100 mg 100 mg KRKA D.D.

FLUCONAZOLE TEVA 100 mg 100 mg TEVA PHARMACEUTICALS SRL

FLUCORIC 100 mg 100 mg TERAPIA S.A.

FLUCOVIM 100 100 mg VIM SPECTRUM SRL

FUNGOLON 100 mg 100 mg BALKANPHARMA RAZGRAD AD

J02AC01 FLUCONAZOLUM CAPS. 150 mg

DIFLAZON 150 mg 150 mg KRKA D.D.

DIFLUCAN 150 mg 150 mg PFIZER EUROPE MA EEIG

FLUCONAZOL 150 mg 150 mg OZONE LABORATORIES LTD.

FLUCONAZOL MEDICO UNO 150 mg 150 mg MEDICO UNO PHARMACEUTICAL

SRL

FLUCONAZOL MEDOCHEMIE 150 mg 150 mg MEDOCHEMIE ROMANIA SRL

FLUCONAZOL SANDOZ(R) 150 150 mg SANDOZ SRL

FLUCONAZOL TERAPIA 150 mg 150 mg TERAPIA SA

FLUCONAZOLE TEVA 150 mg 150 mg TEVA PHARMACEUTICALS SRL

FLUCORIC 150 mg 150 mg TERAPIA S.A.

FLUCOVIM 150 150 mg VIM SPECTRUM SRL

MYCOMAX 150 150 mg ZENTIVA AS

MYCOSYSTA(R) 150 mg 150 mg GEDEON RICHTER PLC.

J02AC01 FLUCONAZOLUM CAPS. 200 mg

DIFLAZON 200 mg 200 mg KRKA D.D.

FLUCONAZOLE TEVA 200 mg 200 mg TEVA PHARMACEUTICALS SRL

J02AC01 FLUCONAZOLUM CAPS. 50 mg

DIFLAZON 50 mg 50 mg KRKA D.D.

DIFLUCAN 50 mg 50 mg PFIZER EUROPE MA EEIG

FLUCONAZOL 50 mg 50 mg SLAVIA PHARM SRL

FLUCONAZOL MEDOCHEMIE 50 mg 50 mg MEDOCHEMIE ROMANIA SRL

FLUCONAZOL SANDOZ(R) 50 50 mg SANDOZ SRL

FLUCONAZOL TERAPIA 50 mg 50 mg TERAPIA S.A.

FLUCONAZOLE TEVA 50 mg 50 mg TEVA PHARMACEUTICALS SRL

FLUCORIC 50 mg 50 mg TERAPIA S.A.

FLUCOVIM 50 50 mg VIM SPECTRUM SRL

FUNGOLON 50 mg 50 mg BALKANPHARMA RAZGRAD AD

J02AC01 FLUCONAZOLUM PULB. PT. SUSP. ORALĂ 50 mg/5 ml

DIFLUCAN(R) 50 mg/5 ml 50 mg/5 ml PFIZER EUROPE MA EEIG

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| **102** |**J05AB01**| **ACICLOVIRUM** | |

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Prescriere limitată: **Herpes genital.**

**Tratamentul episodic sau supresiv al herpesului genital**

**recurent.**

**Herpes cutanat iniţial moderat/sever.**

**Tratamentul episodic sau supresiv al herpesului cutanat**

**recurent (forme moderate/severe).**

**Herpes zoster.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J05AB01 ACICLOVIRUM CAPS. 200 mg

ACICLOVIR 200 mg 200 mg SLAVIA PHARM SRL

EUVIROX 200 mg 200 mg EUROPHARM SA

J05AB01 ACICLOVIRUM COMPR. 200 mg

ACICLOVIR 200 mg 200 mg TERAPIA SA

CLOVIRAL 200 mg 200 mg ANTIBIOTICE SA

ZOVIRAX 200 mg GLAXO WELLCOME FOUNDATION

LTD.

J05AB01 ACICLOVIRUM COMPR. DISP. 200 mg

ACICLOVIR 200 mg 200 mg OZONE LABORATORIES LTD.

LOVIR 200 mg 200 mg RANBAXY UK LIMITED

J05AB01 ACICLOVIRUM PULB. PT. SOL. INJ./ 250 mg

PERF.

VIROLEX 250 mg KRKA D.D. NOVO MESTO

J05AB01 ACICLOVIRUM CAPS. 400 mg

ACICLOVIR 400 mg 400 mg ARENA GROUP S.A.

J05AB01 ACICLOVIRUM COMPR. 400 mg

ACICLOVIR 400 mg 400 mg EGIS PHARMACEUTICALS

P.L.C.

J05AB01 ACICLOVIRUM COMPR. FILM. 400 mg

ACIKLOVIR 400 mg A & G MED TRADING S.R.L.

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| **103** |**L02BG01**| **AMINOGLUTETHIMIDUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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L02BG01 AMINOGLUTETHIMIDUM COMPR. 250 mg

ROGLUTEN(R) 250 mg 250 mg ACTAVIS S.R.L.

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| **104** |**M01AB01**| **INDOMETACINUM** | |

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A se administra cu precauţie la pacienţii cu istoric de factori de risc sau afecţiuni gastrointestinale.

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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M01AB01 INDOMETACINUM SUPOZ. 50 mg

INDOMETACIN 50 mg 50 mg MAGISTRA C & C

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| **105** |**M01AB05**| **DICLOFENACUM** | |

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A se administra cu precauţie la pacienţii cu istoric de factori de risc sau afecţiuni gastrointestinale.

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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M01AB05 DICLOFENACUM COMPR. FILM. ELIB. 100 mg

PREL.

DICLOTARD(R) 100 mg 100 mg TERAPIA SA

REFEN(R) RETARD 100 mg HEMOFARM S.R.L.

VOLTAREN(R) RETARD 100 mg NOVARTIS PHARMA GMBH

M01AB05 DICLOFENACUM SUPOZ. 100 mg

CLAFEN 100 mg 100 mg ANTIBIOTICE SA

DICLOFENAC 100 mg 100 mg SINTOFARM SA

DICLOFENAC SODIC 100 mg 100 mg MAGISTRA C & C

DICLOGESIC 100 SUPOZITOARE 100 mg DAR AL DAWA PHARMA SRL

EPIFENAC 100 mg E.I.P.I.CO. MED S.R.L.

VOLTAREN(R) 100 mg NOVARTIS PHARMA GMBH

M01AB05 DICLOFENACUM SUPOZ. 120 mg

TRATUL 120 120 mg GEROT PHARMAZEUTIKA GMBH

M01AB05 DICLOFENACUM CAPS. ELIB. PREL. 150 mg

DICLOREUM 150 mg 150 mg ALFA WASSERMANN SPA

M01AB05 DICLOFENACUM COMPR. FILM. GASTROREZ. 25 mg

RHEUMAVEK 25 mg FARAN LABORATORIES S.A.

VOLTAREN(R) 25 25 mg NOVARTIS PHARMA GMBH

M01AB05 DICLOFENACUM COMPR. GASTROREZ. 25 mg

EPIFENAC 25 mg E.I.P.I.CO. MED S.R.L.

M01AB05 DICLOFENACUM DRAJ. GASTROREZ. 25 mg

DICLOFENAC 25 mg 25 mg ARENA GROUP SA

M01AB05 DICLOFENACUM SOL. INJ. 25 mg/ml

RHEUMAVEK 25 mg/ml FARAN LABORATORIES S.A.

VOLTAREN(R) 25 mg/ml NOVARTIS PHARMA GMBH

M01AB05 DICLOFENACUM SOL. INJ. 30 mg/ml

TRATUL(R) 30 mg/ml GEROT PHARMAZEUTIKA GMBH

M01AB05 DICLOFENACUM CAPS. GASTROREZ. 50 mg

TRATUL 50 50 mg GEROT PHARMAZEUTIKA GMBH

M01AB05 DICLOFENACUM COMPR. FILM. GASTROREZ. 50 mg

CLAFEN 50 mg 50 mg ANTIBIOTICE SA

DICLOFENAC 50 mg 50 mg AC HELCOR PHARMA SRL

VOLTAREN(R) 50 50 mg NOVARTIS PHARMA GMBH

M01AB05 DICLOFENACUM DRAJ. 50 mg

VOLTAREN RAPID(R) 50 mg NOVARTIS PHARMA GMBH

M01AB05 DICLOFENACUM DRAJ. GASTROREZ. 50 mg

DICLOFENAC 50 mg 50 mg ARENA GROUP SA

M01AB05 DICLOFENACUM SUPOZ. 50 mg

VOLTAREN(R) 50 mg NOVARTIS PHARMA GMBH

M01AB05 DICLOFENACUM SUPOZ. 60 mg

TRATUL 60 60 mg GEROT PHARMAZEUTIKA GMBH

M01AB05 DICLOFENACUM COMPR. ELIB. MODIF. 75 mg

DICLAC(R) 75 ID 75 mg HEXAL AG

M01AB05 DICLOFENACUM SOL. INJ. 75 mg

DICLAC 75 mg HEXAL AG

VURDON 75 mg HELP S.A. PHARMACEUTICALS

M01AB05 DICLOFENACUM SOL. INJ. 75 mg/3 ml

ALMIRAL 75 mg/3 ml MEDOCHEMIE LTD.

DICLOFENAC 75 mg 75 mg/3 ml TERAPIA SA

DICLOFENAC AL I.M. 75 mg/3 ml ALIUD PHARMA GMBH & CO.KG

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| **106** |**M01AB15**| **KETOROLACUM TROMETHAMIN** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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M01AB15 KETOROLACUM COMPR. FILM. 10 mg

TROMETHAMIN

KETANOV 10 mg 10 mg TERAPIA S.A.

KETOROL 10 mg DR. REDDY'S LABORATORIES

M01AB15 KETOROLACUM SOL. INJ. 30 mg/ml

TROMETHAMIN

KETANOV 30 mg/ml TERAPIA S.A.

KETOROL 30 mg/ml DR. REDDY'S LABORATORIES

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| **107** |**M01AB16**| **ACECLOFENACUM** | |

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Prescriere limitată: **Tratamentul simptomatic al puseelor de poliartrită reumatoidă, osteoartrită, spondilită anchilozantă, artroză sau afecţiunilor musculo-scheletale acute.**

A se administra cu precauţie la pacienţii cu istoric de factori de risc sau afecţiuni gastrointestinale.

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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M01AB16 ACECLOFENACUM COMPR. FILM. 100 mg

AFLAMIL 100 mg GEDEON RICHTER PLC.

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| 108 |M01AC02| TENOXICAMUM | |

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A se administra cu precauţie la pacienţii cu istoric de factori de risc sau afecţiuni gastrointestinale.

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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M01AC02 TENOXICAMUM CAPS. 20 mg

TENOXICAM LPH 20 mg 20 mg LABORMED PHARMA SA

M01AC02 TENOXICAMUM COMPR. 20 mg

TENOXICAM 20 mg 20 mg ARENA GROUP SA

M01AC02 TENOXICAMUM COMPR. FILM. 20 mg

NEO-ENDUSIX(R) 20 mg ANFARM HELLAS S.A.

PHARMACEUTICALS

TILCOTIL 20 mg ROCHE ROMANIA S.R.L.

M01AC02 TENOXICAMUM LIOF. + SOLV. PT. SOL. 20 mg

INJ.

NEO-ENDUSIX(R) 20 mg ANFARM HELLAS S.A.

PHARMACEUTICALS

M01AC02 TENOXICAMUM LIOF. ŞI SOLV. PT. SOL. 20 mg

INJ.

TILCOTIL 20 mg ROCHE ROMANIA S.R.L.

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| **109** |**M01AC06**| **MELOXICAMUM** | |

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A se administra cu precauţie la pacienţii cu istoric de factori de risc sau afecţiuni gastrointestinale.

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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M01AC06 MELOXICAMUM COMPR. 15 mg

CELOMIX 15 mg ACTAVIS GROUP HF.

MELARTRIN 15 mg 15 mg TERAPIA SA

MELOX 15 mg 15 mg MEDOCHEMIE LTD

MELOXICAM 15 mg 15 mg VIM SPECTRUM SRL

MELOXICAM LPH 15 mg 15 mg LABORMED PHARMA SA

MELOXICAM MCC 15 mg 15 mg MAGISTRA C & C SRL

MELOXICAM SANDOZ 15 mg 15 mg HEXAL AG

MOVALIS(R) 15 mg 15 mg BOEHRINGER INGELHEIM INT.

GMBH

RECOXA 15 15 mg ZENTIVA AS

M01AC06 MELOXICAMUM SUPOZ. 15 mg

MELOXICAM 15 mg 15 mg MAGISTRA C & C

MOVALIS(R) 15 mg 15 mg BOEHRINGER INGELHEIM INT.

GMBH

M01AC06 MELOXICAMUM SOL. INJ. 15 mg/1.5 ml

MOVALIS(R) 15 mg/1.5 ml BOEHRINGER INGELHEIM INT.

GMBH

M01AC06 MELOXICAMUM COMPR. 7.5 mg

MELOX 7.5 mg 7.5 mg MEDOCHEMIE LTD

M01AC06 MELOXICAMUM COMPR. 7.5 mg

MELOXICAM 7,5 mg 7.5 mg VIM SPECTRUM SRL

MELOXICAM LPH 7,5 mg 7.5 mg LABORMED PHARMA SA

MELOXICAM MCC 7,5 mg 7.5 mg MAGISTRA C & C SRL

MELOXICAM SANDOZ 7,5 mg 7.5 mg HEXAL AG

MOVALIS(R) 7,5 mg 7.5 mg BOEHRINGER INGELHEIM INT.

GMBH

M01AC06 MELOXICAMUM SUPOZ. 7.5 mg

MELOXICAM 7,5 mg 7.5 mg MAGISTRA C & C

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| **110** |**M01AE03**| **KETOPROFENUM** | |

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A se administra cu precauţie la pacienţii cu istoric de factori de risc sau afecţiuni gastrointestinale.

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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M01AE03 KETOPROFENUM COMPR. FILM. 100 mg

RUBIFEN 100 mg 100 mg ANTIBIOTICE SA

M01AE03 KETOPROFENUM CAPS. ELIB. PREL. 100 mg

KETOPROFEN SR 100 mg 100 mg TERAPIA SA

M01AE03 KETOPROFENUM COMPR. FILM. 100 mg

KETONAL FORTE 100 mg 100 mg LEK PHARMACEUTICALS D.D.

KETOPROXIN 100 mg 100 mg AC HELCOR PHARMA SRL

PROFENID(R) 100 mg 100 mg LAB. AVENTIS

M01AE03 KETOPROFENUM LIOF. + SOLV. PT. SOL. 100 mg

INJ.

PROFENID(R) 100 mg 100 mg LAB. AVENTIS

M01AE03 KETOPROFENUM SUPOZ. 100 mg

KETOMAG 100 mg MAGISTRA C & C

KETONAL 100 mg 100 mg LEK PHARMACEUTICALS D.D.

RUBIFEN(R) 100 mg 100 mg ANTIBIOTICE SA

M01AE03 KETOPROFENUM SOL. INJ. 100 mg/2 ml

KETONAL 100 mg/2 ml 100 mg/2 ml LEK PHARMACEUTICALS D.D.

M01AE03 KETOPROFENUM SOL. INJ./CONC. SOL. 100 mg/2 ml

PERF.

KETOPROFEN 100 mg/2 ml 100 mg/2 ml TERAPIA SA

M01AE03 KETOPROFENUM CAPS. ELIB. PREL. 150 mg

KETONAL(R) DUO 150 mg 150 mg SANDOZ S.R.L.

M01AE03 KETOPROFENUM COMPR. ELIB. PREL. 150 mg

KETONAL RETARD 150 mg LEK PHARMACEUTICALS D.D.

M01AE03 KETOPROFENUM CAPS. ELIB. PREL. 200 mg

KETALGON 200 mg 200 mg NOVIA FARM SOLUTIONS SRL

KETONAL UNO 200 mg SANDOZ S.R.L.

KETOPROFEN SR 200 mg 200 mg TERAPIA SA

M01AE03 KETOPROFENUM COMPR. FILM. ELIB. 200 mg

PREL.

PROFENID(R) LP 200 mg 200 mg LAB. AVENTIS

M01AE03 KETOPROFENUM COMPR. FILM. 50 mg

KETOPROXIN 50 mg 50 mg AC HELCOR PHARMA SRL

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| **111** |**M03BX07**| **TETRAZEPAMUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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M03BX07 TETRAZEPAMUM COMPR. FILM. 50 mg

MYOLASTAN(R) 50 mg 50 mg SANOFI-SYNTHELABO FRANCE

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| **112** |**M04AA01**| **ALLOPURINOLUM\*** | |

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NOTĂ:

**Doza trebuie ajustată în concordanţă cu funcţia renală.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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M04AA01 ALLOPURINOLUM COMPR. 100 mg

MILURIT 100 mg 100 mg EGIS PHARMACEUTICALS LTD.

M04AA01 ALLOPURINOLUM COMPR. 300 mg

MILURIT 300 mg 300 mg EGIS PHARMACEUTICALS LTD.

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| **113** |**M04AC01**| **COLCHICINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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M04AC01 COLCHICINUM COMPR. 1 mg

COLCHICINA 1 mg BIOFARM SA

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| **114** |**N02AD01**| **PENTAZOCINUM** | |

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Prescriere limitată: **Durere severă, care nu răspunde la analgezice non-opioide.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N02AD01 PENTAZOCINUM SOL. INJ. 30 mg/ml

FORTRAL 30 mg/ml KRKA D.D. NOVO MESTO

FORTWIN(R) 30 mg/ml TERAPIA S.A.

N02AD01 PENTAZOCINUM COMPR. 50 mg

FORTRAL 50 mg 50 mg KRKA D.D. NOVO MESTO

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| **115** |**N02AX02**| **TRAMADOLUM** | |

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Prescriere limitată: **Durere severă, care nu răspunde la analgezice**

**non-opioide.**

**Pentru durere acută la care tratamentul cu aspirină**

**şi/sau paracetamol este contraindicat sau nu a dat**

**rezultate.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice (mai puţin formele injectabile) şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N02AX02 TRAMADOLUM COMPR. ELIB. MODIF. 100 mg

TRAMADOLOR(R) 100 ID 100 mg HEXAL AG

N02AX02 TRAMADOLUM COMPR. ELIB. PREL. 100 mg

TRALGIT SR 100 100 mg ZENTIVA AS

TRAMADOL(R) RETARD 100 mg KRKA D.D.

N02AX02 TRAMADOLUM COMPR. FILM. ELIB. 100 mg

PREL.

TRAMAL RETARD 100 mg 100 mg GRUNENTHAL GMBH

N02AX02 TRAMADOLUM SOL. INJ. 100 mg

MABRON 100 mg MEDOCHEMIE LTD.

TRADOLAN 100 mg LANNACHER HEILMITTEL GMBH

Prescriere limitată: **Tratamentul de scurtă durată al durerii acute.**

N02AX02 TRAMADOLUM SUPOZ. 100 mg

TRADOLAN 100 mg LANNACHER HEILMITTEL GMBH

TRAMADOL 100 mg KRKA D.D.

TRAMAG 100 100 mg MAGISTRA C & C

TRAMAL(R) 100 mg GRUNENTHAL GMBH

N02AX02 TRAMADOLUM SOL. INJ. 100 mg/2 ml

TRALGIT 100 100 mg/2 ml ZENTIVA A.S.

Prescriere limitată: **Tratamentul de scurtă durată al durerii acute.**

N02AX02 TRAMADOLUM PIC. ORALE, SOL. 100 mg/ml

TRALGIT 100 mg/ml ZENTIVA A.S.

N02AX02 TRAMADOLUM SOL. ORALA 100 mg/ml

TRADOLAN 100 mg/ml LANNACHER HEILMITTEL GMBH

N02AX02 TRAMADOLUM COMPR. ELIB. PREL. 150 mg

TRALGIT SR 150 150 mg ZENTIVA AS

N02AX02 TRAMADOLUM COMPR. FILM. ELIB. 150 mg

PREL.

TRAMADOL RETARD 150 mg 150 mg KRKA D.D. NOVO MESTO

TRAMAL RETARD 150 mg 150 mg GRUNENTHAL GMBH

N02AX02 TRAMADOLUM COMPR. ELIB. PREL. 200 mg

TRALGIT SR 200 200 mg ZENTIVA AS

N02AX02 TRAMADOLUM COMPR. FILM. ELIB. 200 mg

PREL.

TRAMADOL RETARD 200 mg 200 mg KRKA D.D. NOVO MESTO

TRAMAL RETARD 200 mg 200 mg GRUNENTHAL GMBH

N02AX02 TRAMADOLUM CAPS. 50 mg

K-ALMA(R) 50 mg ANTIBIOTICE SA

MABRON 50 mg 50 mg MEDOCHEMIE LTD.

TRALGIT 50 50 mg ZENTIVA A.S.

TRAMACALM 50 mg AC HELCOR SRL

TRAMADOL 50 mg KRKA D.D.

TRAMADOL LPH 50 mg 50 mg LABORMED PHARMA SA

TRAMADOL AL 50 50 mg ALIUD(R) PHARMA GMBH &

CO.KG

TRAMADOL ARENA 50 mg ARENA GROUP S.A.

TRAMAL(R) 50 mg GRUNENTHAL GMBH

URGENDOL 50 mg MEDICAROM GROUP SRL

N02AX02 TRAMADOLUM COMPR. 50 mg

TRAMADOL 50 mg 50 mg OZONE LABORATORIES LTD.

TRAMADOL EEL 50 mg BIO EEL SRL

TRAMAG 50 50 mg MAGISTRA C & C

N02AX02 TRAMADOLUM COMPR. FILM. 50 mg

TRADOLAN 50 mg 50 mg LANNACHER HEILMITTEL GMBH

N02AX02 TRAMADOLUM SOL. INJ. 50 mg

TRADOLAN 50 mg 50 mg LANNACHER HEILMITTEL GMBH

Prescriere limitată: **Tratamentul de scurtă durată al durerii acute.**

N02AX02 TRAMADOLUM SOL. INJ. 50 mg/ml

TRALGIT 50 50 mg/ml ZENTIVA A.S.

TRAMADOL 50 mg/ml KRKA D.D.

TRAMADOL(R) AL 100 Fiole 50 mg/ml ALIUD(R) PHARMA GMBH &

CO.KG

TRAMAL(R) 100 50 mg/ml GRUNENTHAL GMBH

TRAMAL(R) 50 50 mg/ml GRUNENTHAL GMBH

URGENDOL 50 mg/ml MEDICAROM GROUP SRL

Prescriere limitată: **Tratamentul de scurtă durată al durerii acute.**

N02AX02 TRAMADOLUM PIC. ORALE, SOL.

TRAMADOL AL PICATURI ALIUD PHARMA GMBH & CO.KG

N02AX02 TRAMADOLUM PICATURI ORALE - SOL. 100 mg/ml

TRAMAL(R) 100 mg/ml GRUNENTHAL GMBH

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| **116** |**N02CC01**| **SUMATRIPTANUM\*** | |

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Prescriere limitată: **Atacurile de migrenă la pacienţii care primesc sau au primit medicaţie profilactică şi la care crizele migrenoase nu au răspuns la tratamentul oral cu ergotamină sau alte medicamente antimigrenoase, sau la care aceste medicamente sunt contraindicate.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N02CC01 SUMATRIPTANUM COMPR. 100 mg

SUMIGRA 100 mg 100 mg SANDOZ S.R.L.

N02CC01 SUMATRIPTANUM COMPR. FILM. 100 mg

IMIGRAN(R) 100 100 mg GLAXO WELLCOME UK LTD.

SUMACTA 100 mg 100 mg ACTAVIS GROUP PTC EHF.

SUMATRIPTAN 100 mg DR. REDDY'S LABORATORIES

N02CC01 SUMATRIPTANUM COMPR. 50 mg

SUMIGRA 50 mg 50 mg SANDOZ S.R.L.

N02CC01 SUMATRIPTANUM COMPR. FILM. 50 mg

IMIGRAN(R) 50 50 mg GLAXO WELLCOME UK LTD.

SUMACTA 50 mg 50 mg ACTAVIS GROUP PTC EHF.

SUMATRIPTAN 50 mg DR. REDDY'S LABORATORIES

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| **117** |**N03AF01**| **CARBAMAZEPINUM** | **Protocol: N025G** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N03AF01 CARBAMAZEPINUM SUSP. ORALA 100 mg/5 ml

TIMONIL SIROP 100 mg/5 ml DESITIN ARZNEIMITTEL GMBH

N03AF01 CARBAMAZEPINUM COMPR. RET. 150 mg

TIMONIL 150 RETARD 150 mg DESITIN

N03AF01 CARBAMAZEPINUM COMPR. 200 mg

CARBAMAZEPIN 200 mg SLAVIA PHARM SRL

CARBAMAZEPIN EEL 200 mg BIO EEL SRL

CARBAMAZEPINA 200 mg OZONE LABORATORIES LTD.

CARBAMAZEPINA ARENA 200 mg 200 mg ARENA GROUP SA

CARBAMAZEPINA LPH 200 mg 200 mg LABORMED PHARMA SA

CARBAVIM 200 mg VIM SPECTRUM SRL

CARBEPSIL 200 200 mg AC HELCOR SRL

FINLEPSIN 200 mg AWD PHARMA GMBH & CO.KG

NEUROTOP 200 mg GEROT PHARMAZEUTIKA GMBH

TAVER 200 mg MEDOCHEMIE LTD.

TEGRETOL(R) 200 200 mg NOVARTIS PHARMA GMBH

N03AF01 CARBAMAZEPINUM COMPR. FILM. ELIB. 200 mg

PREL.

TEGRETOL CR 200 200 mg NOVARTIS PHARMA GMBH

N03AF01 CARBAMAZEPINUM COMPR. ELIB. PREL. 300 mg

NEUROTOP(R) RETARD 300 mg 300 mg GEROT PHARMAZEUTIKA GMBH

N03AF01 CARBAMAZEPINUM COMPR. RET. 300 mg

TIMONIL 300 RETARD 300 mg DESITIN

N03AF01 CARBAMAZEPINUM COMPR. 400 mg

CARBEPSIL 400 400 mg AC HELCOR SRL

TEGRETOL(R) 400 400 mg NOVARTIS PHARMA GMBH

N03AF01 CARBAMAZEPINUM COMPR. FILM. ELIB. 400 mg

PREL.

TEGRETOL CR 400 400 mg NOVARTIS PHARMA GMBH

N03AF01 CARBAMAZEPINUM COMPR. RET. 400 mg

FINLEPSIN 400 RETARD 400 mg AWD PHARMA GMBH & CO.KG

N03AF01 CARBAMAZEPINUM COMPR. ELIB. PREL. 600 mg

NEUROTOP(R) RETARD 600 mg 600 mg GEROT PHARMAZEUTIKA GMBH

N03AF01 CARBAMAZEPINUM COMPR. RET. 600 mg

TIMONIL 600 RETARD 600 mg DESITIN

N03AF01 CARBAMAZEPINUM COMPR. FILM. ELIB. 200 mg

PREL.

FINLEPSIN 200 RETARD 200 mg AWD PHARMA GMBH & CO.KG

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| **118** |**N03AX12**| **GABAPENTINUM** | **Protocol: N025G** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N03AX12 GABAPENTINUM CAPS. 100 mg

GABAGAMMA 100 mg 100 mg WORWAG PHARMA GMBH & CO.KG

GABALEPT 100 mg 100 mg PLIVA LJUBLJANA D.O.O.

N03AX12 GABAPENTINUM CAPS. 300 mg

GABAGAMMA 300 mg 300 mg WORWAG PHARMA GMBH & CO.KG

GABALEPT 300 mg 300 mg PLIVA LJUBLJANA D.O.O.

GABARAN 300 mg 300 mg RANBAXY UK LTD.

N03AX12 GABAPENTINUM CAPS. 400 mg

GABAGAMMA 400 mg 400 mg WORWAG PHARMA GMBH & CO.KG

GABALEPT 400 mg 400 mg PLIVA LJUBLJANA D.O.O.

GABARAN 400 mg 400 mg RANBAXY UK LTD.

N03AX12 GABAPENTINUM COMPR. FILM. 600 mg

GABARAN 600 mg 600 mg RANBAXY UK LTD.

N03AX12 GABAPENTINUM COMPR. FILM. 800 mg

GABARAN 800 mg 800 mg RANBAXY UK LTD.

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| **119** |**N05AD01**| **HALOPERIDOLUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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N05AD01 HALOPERIDOLUM SOL. INJ. 50 mg/ml

HALOPERIDOL DECANOAT 50 mg/ml GEDEON RICHTER LTD.

N05AD01 HALOPERIDOLUM COMPR. 5 mg

HALDOL 5 mg JANSSEN PHARMACEUTICA NV

N05AD01 HALOPERIDOLUM SOL. INJ. 5 mg/ml

HALOPERIDOL 5 mg/ml 5 mg/ml GEDEON RICHTER LTD.

N05AD01 HALOPERIDOLUM PIC. ORALE - SOL. 2 mg/ml

HALOPERIDOL 2 mg/ml 2 mg/ml GEDEON RICHTER ROMANIA SA

N05AD01 HALOPERIDOLUM PICATURI ORALE - SOL. 2 mg/ml

HALOPERIDOL 2 mg/ml TERAPIA SA

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| **120** |**N05BA01**| **DIAZEPAMUM** | |

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NOTĂ:

**Diazepamum este utilizat ca agent anxiolitic, anticonvulsivant şi relaxant muscular de tip central. În tratamentul anxietăţii se utilizează ca sedativ în anxietatea acută de tip sever cât şi în tratamentul agitaţiei asociată cu delirium tremens.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N05BA01 DIAZEPAMUM COMPR. 10 mg

DIAZEPAM 10 mg TERAPIA SA

DIAZEPAM 10 mg 10 mg GEDEON RICHTER ROMANIA SA

N05BA01 DIAZEPAMUM SOL. RECTALA 10 mg/2.5 ml

DIAZEPAM DESITIN(R) SOLUŢIE 10 mg/2.5 ml DESITIN

RECTALA 10 mg

N05BA01 DIAZEPAMUM SOL. INJ. 10 mg/2 ml

DIAZEPAM 10 mg 10 mg/2 ml TERAPIA SA

N05BA01 DIAZEPAMUM SOL. RECTALA 5 mg/2.5 ml

DIAZEPAM DESITIN(R) SOLUŢIE 5 mg/2.5 ml DESITIN

RECTALĂ 5 mg

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| **121** |**N05BA03**| **MEDAZEPAMUM\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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N05BA03 MEDAZEPAMUM COMPR. 10 mg

MEDAZEPAM 10 mg ARENA GROUP SA

N05BA03 MEDAZEPAMUM CAPS. 10 mg

ANSILAN 10 mg 10 mg LEK PHARMACEUTICALS D.D.

N05BA03 MEDAZEPAMUM COMPR. 10 mg

MEDAZEPAM 10 mg 10 mg LABORMED PHARMA SA

RUDOTEL 10 mg AWD PHARMA GMBH & CO.KG

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| **122** |**N05BA06**| **LORAZEPAMUM\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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N05BA06 LORAZEPAMUM COMPR. 1 mg

ANXIAR(R) 1 mg 1 mg GEDEON RICHTER ROMANIA SA

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| **123** |**N05BA08**| **BROMAZEPAMUM\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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N05BA08 BROMAZEPAMUM COMPR. 1.5 mg

BROMAZEPAM LPH 1.5 mg 1.5 mg LABORMED PHARMA SA

CALMEPAM(R) 1.5 mg GLAXOSMITHKLINE (GSK) SRL

N05BA08 BROMAZEPAMUM COMPR. 3 mg

BROMAZEPAM LPH 3 mg 3 mg LABORMED PHARMA SA

CALMEPAM(R) 3 mg GLAXOSMITHKLINE (GSK) SRL

LEXOTAN 3 mg ROCHE ROMANIA S.R.L.

LEXOTANIL 3 mg TERAPIA S.A.

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| **124** |**N05BA12**| **ALPRAZOLAMUM\*** | |

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Prescriere limitată: **Tulburări de panică, în cazul eşecului la tratamente similare.**

**Pentru tratamentul de scurtă durată al anxietăţii moderate sau severe şi al anxietăţii asociate cu depresia.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N05BA12 ALPRAZOLAMUM COMPR. 0,25 mg

XANAX 0,25 mg 0,25 mg PFIZER EUROPE MA EEIG

N05BA12 ALPRAZOLAMUM COMPR. 0,5 mg

XANAX 0,5 mg 0,5 mg PFIZER EUROPE MA EEIG

N05BA12 ALPRAZOLAMUM COMPR. 0.25 mg

ALPRAZOLAMLPH(R) 0,25 mg 0.25 mg LABORMED PHARMA SA

FRONTIN 0,25 mg 0.25 mg EGIS PHARMACEUTICALS PLC

PRAZOLEX(R) 0,25 mg 0.25 mg GEDEON RICHTER ROMANIA SA

N05BA12 ALPRAZOLAMUM COMPR. 0.5 mg

ALPRAZOLAM LPH(R) 0,5 mg 0.5 mg LABORMED PHARMA SA

FRONTIN 0,5 mg 0.5 mg EGIS PHARMACEUTICALS PLC

PRAZOLEX(R) 0,5 mg 0.5 mg GEDEON RICHTER ROMANIA SA

N05BA12 ALPRAZOLAMUM COMPR. ELIB. PREL. 0.5 mg

NEUROL(R) SR 0.5 0.5 mg ZENTIVA AS

N05BA12 ALPRAZOLAMUM COMPR. 1 mg

ALPRAZOLAM LPH(R) 1 mg 1 mg LABORMED PHARMA SA

FRONTIN 1 mg EGIS PHARMACEUTICALS PLC

PRAZOLEX(R) 1 mg 1 mg GEDEON RICHTER ROMANIA SA

XANAX 1 mg 1 mg PFIZER EUROPE MA EEIG

N05BA12 ALPRAZOLAMUM COMPR. ELIB. PREL. 1 mg

NEUROL(R) SR 1 1 mg ZENTIVA AS

N05BA12 ALPRAZOLAMUM COMPR. 2 mg

XANAX 2 mg 2 mg PFIZER EUROPE MA EEIG

N05BA12 ALPRAZOLAMUM COMPR. ELIB. PREL. 2 mg

NEUROL(R) SR 2 2 mg ZENTIVA AS

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| **125** |**N05CD02**| **NITRAZEPAMUM** | |

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Cod restricţie 3007: **Tratamentul de scurtă durată al insomniei.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N05CD02 NITRAZEPAMUM COMPR. 2.5 mg

NITRAZEPAM LPH(R) 2,5 mg 2.5 mg LABORMED PHARMA SA

N05CD02 NITRAZEPAMUM COMPR. 5 mg

NITRAZEPAM 5 mg 5 mg GEDEON RICHTER ROMANIA SA

NITRAZEPAM LPH(R) 5 mg 5 mg LABORMED PHARMA SA

N05CD02 NITRAZEPAMUM COMPR. 5 mg

NITRAZEPAM 5 mg 5 mg GEDEON RICHTER ROMANIA SA

NITRAZEPAM LPH(R) 5 mg 5 mg LABORMED PHARMA SA

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| **126** |**N05CF01**| **ZOPICLONUM\*** | |

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Cod restricţie 3007: **Pentru tratamentul de scurtă durată al insomniei.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N05CF01 ZOPICLONUM COMPR. FILM. 7.5 mg

ALS-ZOPICLON 7.5 mg 7.5 mg ALSIFCOM INTERMED SRL

IMOVANE 7.5 mg 7.5 mg SANOFI AVENTIS

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| **127** |**N05CF02**| **ZOLPIDEMUM\*** | |

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Cod restricţie 3007: **Pentru tratamentul de scurtă durată al insomniei.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N05CF02 ZOLPIDEMUM COMPR. FILM. 10 mg

HYPNOGEN 10 mg 10 mg ZENTIVA AS

LADINOX 10 mg GEDEON RICHTER ROMANIA

S.A.

SANVAL(R) 10 mg 10 mg LEK PHARMACEUTICALS D.D.

ZOLPIDEM 10 mg 10 mg LABORMED PHARMA SA

ZOLPIDEM ANTIBIOTICE 10 mg 10 mg ANTIBIOTICE S.A.

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| **128** |**N06AA04**| **CLOMIPRAMINUM\*** | |

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Prescriere limitată: **Tratamentul simptomatic al depresiei în special atunci**

**când este necesară sedarea.**

**Tratamentul stărilor fobice şi obsesiv-compulsive.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N06AA04 CLOMIPRAMINUM DRAJ. 10 mg

ANAFRANIL(R) 10 mg 10 mg NOVARTIS PHARMA GMBH

N06AA04 CLOMIPRAMINUM DRAJ. 25 mg

ANAFRANIL(R) 25 mg 25 mg NOVARTIS PHARMA GMBH

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| **129** |**N06AA09**| **AMITRIPTYLINUM\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N06AA09 AMITRIPTYLINUM CAPS. RET. 25 mg

AMITRIPTILIN 25 R. DESITIN 25 mg DESITIN

N06AA09 AMITRIPTYLINUM COMPR. FILM. 25 mg

AMITRIPTILINA ARENA 25 mg 25 mg ARENA GROUP S.A.

N06AA09 AMITRIPTYLINUM CAPS. RET. 50 mg

AMITRIPTILIN 50 R. DESITIN 50 mg DESITIN

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| **130** |**N06AA12**| **DOXEPINUM\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N06AA12 DOXEPINUM DRAJ. 25 mg

DOXEPIN 25 mg 25 mg TERAPIA SA

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| **131** |**N06AB03**| **FLUOXETINUM\*** | |

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Prescriere limitată: **Tratamentul depresiilor cu sau fără anxietate în**

**special când componenta de sedare nu este necesară.**

**Tratamentul bulimiei nervoase.**

**Tratamentul tulburărilor obsesiv-compulsive.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N06AB03 FLUOXETINUM CAPS. 20 mg

FLUOXETINE 20 mg 20 mg DR. REDDY'S LABORATORIES

FLUOXIN 20 mg VIM SPECTRUM SRL

FLURAN 20 mg RANBAXY U.K. LIMITED

MAGRILAN 20 mg 20 mg MEDOCHEMIE LTD.

N06AB03 FLUOXETINUM COMPR. DISP. 20 mg

PROZAC 20 mg 20 mg ELI LILLY SA

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| **132** |**N06AB04**| **CITALOPRAMUM\*\*** | Protocol: N008F |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N06AB04 CITALOPRAMUM COMPR. FILM. 10 mg

CITALORAN 10 mg 10 mg RANBAXY UK LIMITED

LINISAN 10 mg 10 mg GEDEON RICHTER ROMANIA

S.A.

N06AB04 CITALOPRAMUM COMPR. FILM. 20 mg

CITALORAN 20 mg 20 mg RANBAXY UK LIMITED

LINISAN 20 mg 20 mg GEDEON RICHTER ROMANIA

S.A.

N06AB04 CITALOPRAMUM COMPR. FILM. 40 mg

CITALORAN 40 mg 40 mg RANBAXY UK LIMITED

LINISAN 40 mg 40 mg GEDEON RICHTER ROMANIA

S.A.

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| **133** |**N06AB05**| **PAROXETINUM\*** | |

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Prescriere limitată: **Tratamentul tulburărilor depresive majore.**

**Tratamentul tulburărilor obsesiv-compulsive.**

**Tratamentul atacurilor de panică.**

**Tratamentul anxietăţii.**

**Tratamentul fobiei sociale.**

**Tratamentul bolii de stres posttraumatic.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N06AB05 PAROXETINUM COMPR. 20 mg

ARKETIS 20 mg MEDOCHEMIE LTD.

N06AB05 PAROXETINUM COMPR. FILM. 20 mg

ALS-PAROXETIN 20 mg 20 mg ALSIFCOM INTERMED SRL

PALUXETIL 20 mg 20 mg HEXAL AG

PAXETEN 20 mg 20 mg ACTAVIS GROUP HF.

REXETIN 20 mg GEDEON RICHTER PLC.

SEROXAT 20 mg 20 mg SMITHKLINE BEECHAM PLC

N06AB05 PAROXETINUM COMPR. FILM. 40 mg

PALUXETIL 40 mg 40 mg HEXAL AG

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| **134** |**N06AB06**| **SERTRALINUM\*** | |

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Prescriere limitată: **Tratamentul tulburărilor depresive inclusiv cu**

**componenta anxioasă.**

**Tratamentul tulburări obsesiv-compulsive.**

**Tratamentul atacurilor de panică.**

**Tratamentul fobiei sociale.**

**Tratamentul bolii de stres posttraumatic.**

Eficienţa tratamentului în boala de stres posttraumatic a fost demonstrată doar pentru sexul feminin.

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N06AB06 SERTRALINUM COMPR. FILM. 100 mg

ALS-SERTRALINA 100 mg 100 mg ALSIFCOM INTERMED SRL

ASENTRA(R) 100 mg KRKA D.D.

SERLIFT 100 mg 100 mg TERAPIA S.A.

SERTRALIN SANDOZ 100 mg 100 mg HEXAL AG

SERTRALINA 100 mg 100 mg ARENA GROUP S.A.

SERTRALINA DR. REDDY'S 100 mg 100 mg DR. REDDY'S LABORATORIES

STIMULOTON(R) 100 mg 100 mg EGIS PHARMACEUTICALS LTD.

N06AB06 SERTRALINUM SOL. ORALA 20 mg/ml

ZOLOFT(R) 20 mg/ml PFIZER EUROPE MA EEIG

N06AB06 SERTRALINUM COMPR. FILM. 50 mg

ALS-SERTRALINA 50 mg 50 mg ALSIFCOM INTERMED SRL

ASENTRA(R) 50 mg KRKA D.D.

SERLIFT 50 mg 50 mg TERAPIA S.A.

SERTRALIN 50 mg 50 mg OZONE LABORATORIES LTD.

SERTRALIN SANDOZ 50 mg 50 mg HEXAL AG

SERTRALINA 50 mg 50 mg ARENA GROUP SA

SERTRALINA DR. REDDY'S 50 mg 50 mg DR. REDDY'S LABORATORIES

STIMULOTON(R) 50 mg 50 mg EGIS PHARMACEUTICALS LTD.

ZOLOFT 50 mg 50 mg PFIZER EUROPE MA EEIG

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| **135** |**N06AB08**| **FLUVOXAMINUM\*** | |

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Prescriere limitată: **Tratamentul tulburărilor depresive majore.**

**Tratamentul tulburărilor obsesiv-compulsive.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N06AB08 FLUVOXAMINUM COMPR. FILM. 100 mg

FEVARIN(R) 100 100 mg SOLVAY PHARMACEUTICALS BV

FLUVOXAMINE TEVA 100 mg 100 mg TEVA PHARMACEUTICALS SRL

N06AB08 FLUVOXAMINUM COMPR. FILM. 50 mg

FEVARIN(R) 50 50 mg SOLVAY PHARMACEUTICALS BV

FLUVOXAMINE TEVA 50 mg 50 mg TEVA PHARMACEUTICALS SRL

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| **136** |**N06AX03**| **MIANSERINUM\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N06AX03 MIANSERINUM COMPR. FILM. 10 mg

MIANSERIN 10 10 mg REMEDICA LTD.

N06AX03 MIANSERINUM DRAJ. 10 mg

MIANSERIN 10 mg 10 mg TERAPIA SA

N06AX03 MIANSERINUM COMPR. FILM. 30 mg

MIANSERIN 30 30 mg REMEDICA LTD.

N06AX03 MIANSERINUM DRAJ. 30 mg

MIANSERIN 30 mg 30 mg TERAPIA SA

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| **137** |**N06AX11**| **MIRTAZAPINUM\*** | |

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Prescriere limitată: **Tratamentul episoadelor depresive majore.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N06AX11 MIRTAZAPINUM COMPR. DISP. 15 mg

REMERON(R) SOLTAB 15 mg 15 mg ORGANON NV

N06AX11 MIRTAZAPINUM COMPR. FILM. 15 mg

ESPRITAL(R) 15 15 mg ZENTIVA AS

MIRZATEN(R) 15 mg 15 mg KRKA D.D.

N06AX11 MIRTAZAPINUM COMPR. DISP. 30 mg

REMERON(R) SOLTAB 30 mg 30 mg ORGANON NV

N06AX11 MIRTAZAPINUM COMPR. FILM. 30 mg

ESPRITAL(R) 30 30 mg ZENTIVA AS

MIRTAZAPINE-TEVA 30 mg 30 mg TEVA PHARMACEUTICALS SRL

MIRZATEN(R) 30 mg 30 mg KRKA D.D.

PHARMATAZ 30 mg 30 mg ACTAVIS GROUP HF.

N06AX11 MIRTAZAPINUM COMPR. DISP. 45 mg

REMERON(R) SOLTAB 45 mg 45 mg ORGANON NV

N06AX11 MIRTAZAPINUM COMPR. FILM. 45 mg

ESPRITAL(R) 45 45 mg ZENTIVA AS

MIRZATEN(R) 45 mg 45 mg KRKA D.D.

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| **138** |**N06AX16**| **VENLAFAXINUM\*\*** | **Protocol: N013F** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N06AX16 VENLAFAXINUM CAPS. ELIB. PREL. 150 mg

EFECTIN ER 150 mg 150 mg WYETH LEDERLE PHARMA GMBH

VELAXIN 150 mg 150 mg EGIS PHARMACEUTICALS

P.L.C.

N06AX16 VENLAFAXINUM COMPR. 37.5 mg

VELAXIN 37,5 mg 37.5 mg EGIS PHARMACEUTICALS PLC

VENLAFAXINA LPH 37,5 mg 37.5 mg LABORMED PHARMA SA

N06AX16 VENLAFAXINUM CAPS. ELIB. PREL. 75 mg

EFECTIN ER 75 mg 75 mg WYETH LEDERLE PHARMA GMBH

VELAXIN 75 mg 75 mg EGIS PHARMACEUTICALS

P.L.C.

N06AX16 VENLAFAXINUM COMPR. 75 mg

VELAXIN 75 mg 75 mg EGIS PHARMACEUTICALS PLC

VENLAFAXINA LPH 75 mg 75 mg LABORMED PHARMA SA

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| **139** |**N07AA01**| **NEOSTIGMINI BROMIDUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N07AA01 NEOSTIGMINI BROMIDUM SOL. INJ. 0.5 mg/ml

MIOSTIN 0,5 mg/ml 0.5 mg/ml ZENTIVA S.A.

N07AA01 NEOSTIGMINI BROMIDUM COMPR. 15 mg

NEOSTIGMINA LPH 15 mg 15 mg LABORMED PHARMA SA

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| **140** |**P01AB01**| **METRONIDAZOLUM** | |

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Prescriere limitată: **Tratamentul infecţiilor cu anaerobi.**

**Tratamentul infecţiilor cu protozoare sensibile la**

**metronidazol.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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P01AB01 METRONIDAZOLUM COMPR. 250 mg

METRONIDAZOL 250 mg (P01AB01) 250 mg ZENTIVA SA

METRONIDAZOL 250 mg (P01AB1) 250 mg ARENA GROUP SA

P01AB01 METRONIDAZOLUM COMPR. FILM. 250 mg

FLAGYL 250 mg LABORATOIRE AVENTIS

P01AB01 METRONIDAZOLUM SUSP. ORALA 4%

FLAGYL 4% (P01AB01) 4% LABORATOIRE AVENTIS

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| **141** |**P01AB02**| **TINIDAZOLUM** | |

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Prescriere limitată: **Tratamentul infecţiilor cu anaerobi.**

**Tratamentul infecţiilor cu protozoare sensibile la**

**metronidazol.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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P01AB02 TINIDAZOLUM COMPR. FILM. 500 mg

FASIGYN (P01AB02) 500 mg PFIZER EUROPE MA EEIG

TINIZOL(R) 500 mg (P01AB02) 500 mg ZENTIVA S.A.

TIPROGYN 500 500 mg AC HELCOR SRL

P01AB02 TINIDAZOLUM COMPR. FILM. 500 mg

FASIGYN (P01AB02) 500 mg PFIZER EUROPE MA EEIG

TINIZOL(R) 500 mg (J01XD02) 500 mg ZENTIVA S.A.

TIPROGYN 500 500 mg AC HELCOR SRL

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| **142** |**P02CA03**| **ALBENDAZOLUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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P02CA03 ALBENDAZOLUM SUSP. ORALA 0.4 g/10 ml

ZENTEL 0,4 g/10 ml 0.4 g/10 ml GLAXOSMITHKLINE EXPORT

LTD.

P02CA03 ALBENDAZOLUM COMPR. FILM. 200 mg

DUADOR 200 mg 200 mg GEDEON RICHTER ROMANIA SA

ZENTEL 200 mg 200 mg GLAXOSMITHKLINE EXPORT

LTD.

P02CA03 ALBENDAZOLUM COMPR. 400 mg

ESKAZOLE 400 mg GLAXO SMITHKLINE EXPORT

LTD.

P02CA03 ALBENDAZOLUM SUSP. ORALA 400 mg

ALBENDAZOL BIOFARM 400 mg 400 mg BIOFARM S.A.

P02CA03 ALBENDAZOLUM COMPR. FILM 200 mg

ALBENDAZOL 200 mg OZONE LABORATORIES LTD.

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| **143** |**P02CE01**| **LEVAMISOLUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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P02CE01 LEVAMISOLUM COMPR. 150 mg

DECARIS 150 mg 150 mg GEDEON RICHTER ROMANIA SA

P02CE01 LEVAMISOLUM COMPR. 50 mg

DECARIS 50 mg 50 mg GEDEON RICHTER ROMANIA SA

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| **144** |**R03AC02**| **SALBUTAMOLUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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R03AC02 SALBUTAMOLUM SUSP. INHAL PRESURIZATĂ 100 µg/doză

ASTHALIN INHALER 100 µg/doză CIPLA (UK) LIMITED

ECOSAL Easi-Breath 100 µg/doză IVAX-PHARMACEUTICALS

S.R.O.

VENTOLIN 100 INHALER CFC-FREE 100 µg/doză GLAXOWELLCOME UK LTD.

R03AC02 SALBUTAMOLUM SOL. INHAL. 5 mg/ml

VENTOLIN(R) 5 mg/ml GLAXOWELLCOME UK LTD.

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| **145** |**R03BA01**| **BECLOMETASONUM\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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R03BA01 BECLOMETASONUM AEROSOL SOL. INHAL. 100 µg/doză

ECOBEC 100 µg 100 µg/doză IVAX-PHARMACEUTICALS

CFC FREE S.R.O.

ECOBEC EASI-BREATHE 100 µg/doză IVAX-PHARMACEUTICALS

100 µg CFC FREE S.R.O.

R03BA01 BECLOMETASONUM SPRAY NAZ., SUSP. 100 µg/doză

RINOCLENIL 100 100 µg/doză CHIESI FARMACEUTICI S.P.A.

R03BA01 BECLOMETASONUM AEROSOL SOL. INHAL. 250 µg/doză

ECOBEC 250 µg/doză 250 µg/doză IVAX-PHARMACEUTICALS

CFC FREE S.R.O.

ECOBEC EASI-BREATHE 250 µg/doză IVAX-PHARMACEUTICALS

250 µg/doză CFC FREE S.R.O.

R03BA01 BECLOMETASONUM SOL. DE INHALAT 250 µg/doză

PRESURIZATĂ

BECLOFORTER(R) CFC-Free 250 µg/doză GLAXO WELLCOME UK LTD.

R03BA01 BECLOMETASONUM SOL. INHALAT 250 µg/doză

PRESURIZATĂ

CLENIL(R) JET 250 µg/doză CHIESI FARMACEUTICI SPA

250 µg/doză

R03BA01 BECLOMETASONUM SOL. DE INHALAT 50 µg/doză

PRESURIZATĂ

BECOTIDER(R) CFC-Free 50 µg/doză GLAXO WELLCOME UK LTD.

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| **146** |**R03BA02**| **BUDESONIDUM\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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R03BA02 BUDESONIDUM PULB. INHAL. 200 µg/doză

FRENOLYN 200 200 µg/doză MEDOCHEMIE ROMÂNIA SRL

R03BA02 BUDESONIDUM PULB. INHAL. 200 µg/doză

PULMICORT TURBUHALER 200 µg/doză ASTRAZENECA AB

200 µg/doză

R03BA02 BUDESONIDUM PULB. INHAL. 400 µg/doză

FRENOLYN 400 400 µg/doză MEDOCHEMIE ROMÂNIA SRL

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| **147** |**R03BB01**| **IPRATROPII BROMIDUM\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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R03BB01 IPRATROPII BROMIDUM AEROSOL 20 µg/doză

IPRAVENT 20 - INHALER 20 µg/doză CIPLA (UK) LIMITED

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| **148** |**R03CC02**| **SALBUTAMOLUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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R03CC02 SALBUTAMOLUM SOL. ORALA 0.04%

SALBUTAMOL T 0.04% TIS FARMACEUTIC SA

R03CC02 SALBUTAMOLUM SOL. INJ. 0.5 mg/ml

VENTOLIN(R) 0.5 mg/ml GLAXO WELLCOME UK LTD.

R03CC02 SALBUTAMOLUM SIROP 2 mg/5 ml

SALBUTAMOL EIPICO 2 mg/5 ml 2 mg/5 ml E.I.P.I.CO. MED S.R.L.

VENTOLIN(R) 2 mg/5 ml GLAXOWELLCOME UK LTD.

R03CC02 SALBUTAMOLUM SOL. ORALA 2 mg/5 ml

SALBUTAMOL 2 mg/5 ml TERAPIA S.A.

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| **149** |**R03DA04**| **THEOPHYLLINUM** | |

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Datorită efectelor variabile ale alimentelor asupra absorbţiei teofilinei, pacienţii care folosesc un anumit preparat nu trebuie să îi schimbe cu un altul fără o monitorizare adecvată.

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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R03DA04 THEOPHYLLINUM CAPS. ELIB. PREL. 100 mg

TEOFIUNA SR 100 mg 100 mg TERAPIA SA

THEO SR 100 100 mg GLAXOSMITHKLINE (GSK) SRL

R03DA04 THEOPHYLLINUM CAPS. ELIB. PREL. 200 mg

TEOFIUNA SR 200 mg 200 mg TERAPIA SA

TEOTARD(R) 200 200 mg KRKA D.D.

THEO SR 200 200 mg GLAXOSMITHKLINE (GSK) SRL

R03DA04 THEOPHYLLINUM CAPS. ELIB. PREL. 300 mg

TEOFILINA SR 300 mg 300 mg TERAPIA SA

THEO SR 300 300 mg GLAXOSMITHKLINE (GSK) SRL

R03DA04 THEOPHYLLINUM CAPS. ELIB. PREL. 350 mg

TEOTARD(R) 350 350 mg KRKA D.D.

R03DA04 THEOPHYLLINUM CAPS. ELIB. PREL. 50 mg

TEOFILINA SR 50 mg 50 mg TERAPIA SA

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| **150** |**R05DA04**| **CODEINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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R05DA04 CODEINUM COMPR. 15 mg

CODEINA FOSFAT 15 mg SLAVIA PHARM SRL

CODEINA FOSFAT 15 mg 15 mg OZONE LABORATORIES LTD.

CODEINA FOSFAT LPH 15 mg 15 mg LABORMED PHARMA SA

CODEINA FOSFORICĂ 15 mg BIO EEL SRL

CODEINA FOSFORICĂ 15 mg 15 mg MAGISTRA C & C

FARMACOD 15 mg FARMACOM SA

FOSFAT DE CODEINĂ 15 mg 15 mg SINTOFARM SA

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| **151** |**R06AB04**| **CHLORPHENAMINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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R06AB04 CHLORPHENAMINUM COMPR. 4 mg

CLORFENIRAMIN 4 mg LABORMED PHARMA SA

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| **152** |**R06AE07**| **CETIRIZINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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R06AE07 CETIRIZINUM COMPR. FILM. 10 mg

CELERG 10 mg AC HELCOR PHARMA SRL

R06AE07 CETIRIZINUM COMPR. FILM. 10 mg

LETIZEN(R) 10 mg 10 mg KRKA D.D.

R06AE07 CETIRIZINUM SOL. ORALA 1 mg/ml

LETIZEN 1 mg/ml KRKA D.D.

R06AE07 CETIRIZINUM PICĂTURI ORALE - SOL. 10 mg/ml

ZYRTEC(R) 10 mg/ml U.C.B. GMBH

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| **153** |**R06AX17**| **KETOTIFENUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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R06AX17 KETOTIFENUM CAPS. 1 mg

KETOF 1 mg 1 mg HEXAL AG

R06AX17 KETOTIFENUM COMPR. 1 mg

H-KETOTIFEN 1 mg AC HELCOR SRL

KETOTIFEN 1 mg MAGISTRA C & C

KETOTIFEN LPH(R) 1 mg 1 mg LABORMED PHARMA SA

R06AX17 KETOTIFENUM SIROP 1 mg/5 ml

FRENASMA 1 mg/5 ml FARAN LABORATORIES S.A.

KETOF 1 mg/5 ml 1 mg/5 ml HEXAL AG

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| **154** |**S01AX13**| **CIPROFLOXACINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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S01AX13 CIPROFLOXACINUM UNG. OFT. 0.3%

CIPLOX 0.3% CIPLA (UK) LIMITED

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| **155** |**S01BC03**| **DICLOFENACUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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S01BC03 DICLOFENACUM PICĂTURI OFT. - SOL. 0.1%

DICLOGESIC 0,1% PICĂTURI 0.1% DAR AL DAWA PHARMA S.R.L.

OFTALMICE, SOLUŢIE

UNICLOPHEN(R) 0,1% 0.1% UNIMED PHARMA LTD.

VOLTAREN OPHTHA CD 0.1% NOVARTIS PHARMA GMBH

S01BC03 DICLOFENACUM PIC. OFT. - SOL. 1 mg/ml

DICLOFENAC RPH 1 mg/ml ROMPHARM COMPANY SRL

S01BC03 DICLOFENACUM PIC. OFT. - SOL. 1 mg/ml

VURDON 1 mg/ml HELP S.A. PHARMACEUTICALS

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| **156** |**S01CA05**| **COMBINAŢII (BETHAMETASONUM +** | |

| | | **ANTIINFECŢIOASE)** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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S01CA05 COMBINAŢII UNG. OFT. 0,2 g + 0,5 g

(BETHAMETASONUM +

ANTIINFECŢIOASE)

BETABIOPTAL 0,2 g + 0,5 g FARMILA FARMACEUTICI

S01CA05 COMBINAŢII PICĂTURI OFT. SUSP. 0,2 g + 0,5 g

(BETHAMETASONUM +

ANTIINFECŢIOASE)

BETABIOPTAL 0,2 g + 0,5 g FARMILA FARMACEUTICI

MILANO SPA

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**SUBLISTA B - MEDICAMENTE CU NIVEL DE COMPENSARE 50% DIN PREŢUL DE REFERINŢĂ**

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| **157** |**A02BC02**| **PANTOPRAZOLUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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A02BC02 PANTOPRAZOLUM COMPR. FILM. GASTROREZ. 20 mg

CONTROLOC 20 mg 20 mg ALTANA PHARMA AG

Prescriere limitată: **Menţinerea rezultatelor terapiei refluxului gastro-esofagian**

Prescriere limitată: **Boala de reflux gastro-esofagian**

Prescriere limitată: **Profilaxia ulcerului gastro-duodenal asociat tratamentului cu antiinflamatoare nesteroidiene pe termen lung la pacienţii cu factori de risc gastrointestinal.**

**Se aplică pentru toate denumirile comerciale şi formele farmaceutice corespunzătoare concentraţiei de 20 mg.**

A02BC02 PANTOPRAZOLUM COMPR. FILM. GASTROREZ. 40 mg

CONTROLOC 40 mg 40 mg ALTANA PHARMA AG

Prescriere limitată: **Boala de reflux gastro-esofagian.**

Prescriere limitată: **Sindromul Zollinger-Ellison**

Prescriere limitată: **Tratamentul ulcerului gastric şi duodenal.**

**Se aplică pentru toate denumirile comerciale şi formele farmaceutice corespunzătoare concentraţiei de 40 mg.**

A02BC02 PANTOPRAZOLUM LIOF. PT. SOL. INJ. 40 mg

CONTROLOC 40 mg LIOFILIZAT 40 mg ALTANA PHARMA AG

PENTRU SOLUŢIE INJECTABILĂ

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| **158** |**A02BC05**| **ESOMEPRAZOLUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A02BC05 ESOMEPRAZOLUM COMPR. FILM. GASTROREZ. 40 mg

NEXIUM 40 mg 40 mg ASTRAZENECA AB

Prescriere limitată: **Terapia refluxului gastro-esofagian.**

Prescriere limitată: **Sindromul Zollinger-Ellison.**

**Se aplică pentru toate denumirile comerciale şi formele farmaceutice corespunzătoare concentraţiei de 40 mg.**

A02BC05 ESOMEPRAZOLUM LIOF. PT. SOL. INJ./ 40 mg

PERF.

NEXIUM(R) 40 mg ASTRAZENECA AB

A02BC05 ESOMEPRAZOLUM COMPR. FILM. GASTROREZ. 20 mg

NEXIUM 20 mg 20 mg ASTRAZENECA AB

Prescriere limitată: **Tratamentul ulcerului gastric şi duodenal.**

Prescriere limitată: **Menţinerea rezultatelor terapiei refluxului gastro-esofagian.**

Prescriere limitată: **Profilaxia ulcerului gastro-duodenal asociat tratamentului cu antiinflamatoare nesteroidiene pe termen lung la pacienţii cu factori de risc gastrointestinali.**

**Se aplică pentru toate denumirile comerciale şi formele farmaceutice corespunzătoare concentraţiei de 20 mg.**

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| **159** |**A02BX02**| **SUCRALFATUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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A02BX02 SUCRALFATUM COMPR. 1 g

GASTROFAIT 1 g E.I.P.I.CO. MED S.R.L.

SUCRALAN(R) 1 g LANNACHER HEILMITTEL GMBH

VENTER 1 g KRKA D.D.

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| **160** |**A02BX05**| **BISMUTHI SUBCITRAS** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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A02BX05 BISMUTHI SUBCITRAS COMPR. FILM. 120 mg

DE-NOL 120 mg ASTELLAS PHARMA EUROPE

B.V.

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| **161** |**A03AB06**| **OTILONIUM BROMIDUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A03AB06 OTILONIUM BROMIDUM COMPR. FILM. 40 mg

SPASMOMEN(R) 40 mg A. MENARINI IND. FARM.

RIUNITE SRL

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| **162** |**A06AD15**| **MACROGOLUM\* (2)** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A06AD15 MACROGOLUM PULB. PT. SOL. ORALĂ

FORTRANS(R) BEAUFOUR IPSEN INT.

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| **163** |**A07AA11**| **RIFAXIMINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A07AA11 RIFAXIMINUM COMPR. FILM. 200 mg

NORMIX 200 mg 200 mg ALFA WASSERMANN SPA

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| **164** |**A07EA06**| **BUDESONIDUM\*\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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Prescriere limitată: **Inducerea remisiunii formelor uşoare/moderate de boala Crohn cu afectare ileală sau/şi de colon ascendent.**

A07EA06 BUDESONIDUM CAPS. GASTROREZ. 3 mg

BUDENOFALK 3 mg DR. FALK PHARMA GMBH

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| **165** |**A07XA04**| **RACECADOTRILUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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A07XA04 RACECADOTRILUM CAPS. 100 mg

HIDRASEC 100 mg 100 mg LAB. FOURNIER SA

A07XA04 RACECADOTRILUM PULB. PT. SOL. ORALĂ 10 mg

HIDRASEC 10 mg 10 mg LAB. FOURNIER SA

A07XA04 RACECADOTRILUM PULB. PT. SOL. ORALĂ 30 mg

HIDRASEC 30 mg 30 mg LAB. FOURNIER SA

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| **166** |**A08AA10**| **SIBUTRAMINUM\*\*\*\*** | **Protocol: A003E** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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A08AA10 SIBUTRAMINUM CAPS. 10 mg

LINDAXA 10 10 mg ZENTIVA A.S.

REDUCTIL 10 mg 10 mg ABBOTT GMBH & CO.KG

A08AA10 SIBUTRAMINUM CAPS. 15 mg

LINDAXA 15 15 mg ZENTIVA A.S.

REDUCTIL 15 mg 15 mg ABBOTT GMBH & CO.KG

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| **167** |**A08AB01**| **ORLISTATUM\*\*\*\*** | **Protocol: A001E** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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A08AB01 ORLISTATUM CAPS. 120 mg

XENICAL 120 mg 120 mg ROCHE REGISTRATION LTD.

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| **168** |**A08AX01**| **RIMONABANTUM\*\*\*\*** | **Protocol: A031E** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A08AX01 RIMONABANTUM COMPR. FILM. 20 mg

ACOMPLIA 20 mg 20 mg SANOFI AVENTIS

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| **169** |**A11CC03**| **ALFACALCIDOLUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A11CC03 ALFACALCIDOLUM CAPS. MOI 0.25 µg

ALPHA D3 0,25 µg 0.25 µg TEVA PHARMACEUTICALS SRL

A11CC03 ALFACALCIDOLUM CAPS. MOI 0.50 µg

ALPHA D3 0.50 µg 0.50 µg TEVA PHARMACEUTICALS

S.R.L.

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| **170** |**A16AX01**| **ACIDUM TIOCTICUM (ALFA-LIPOICUM)\*\*#** | **Protocol: A021E** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A16AX01 ACIDUM TIOCTICUM SOL. PERF. 12 mg/ml

(ALFA-LIPOICUM)

THIOGAMMA(R) TURBO-SE 12 mg/ml WORWAG PHARMA GMBH & CO.KG

THIOGAMMA(R) TURBO-SET 12 mg/ml WORWAG PHARMA GMBH & CO.KG

A16AX01 ACIDUM TIOCTICUM CONC. PT. SOL. PERF. 30 mg/ml

(ALFA-LIPOICUM)

THIOGAMMA(R) 600 INJEKT 30 mg/ml WORWAG PHARMA GMBH & CO.KG

A16AX01 ACIDUM TIOCTICUM COMPR. FILM. 600 mg

(ALFA-LIPOICUM)

THIOGAMMA(R) 600 oral 600 mg WORWAG PHARMA GMBH & CO.KG

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| **171** |**B01AB04**| **DALTEPARINUM\*\*#** | **Protocol: B008D** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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B01AB04 DALTEPARINUM SOL. INJ. 10000 ui/ml

FRAGMIN 10000 UI/ml 10000 ui/ml PFIZER EUROPE MA EEIG

B01AB04 DALTEPARINUM SOL. INJ. 15000 ui/0.6 ml

FRAGMIN 15000 UI/0,6 ml 15000 ui/0.6 ml PFIZER EUROPE MA EEIG

B01AB04 DALTEPARINUM SOL. INJ. 2500 ui/0.2 ml

FRAGMIN 2500 UI/0,2 ml 2500 ui/0.2 ml PFIZER EUROPE MA EEIG

B01AB04 DALTEPARINUM SOL. INJ. 5000 ui/0.2 ml

FRAGMIN 5000 UI/0,2 ml 5000 ui/0.2 ml PFIZER EUROPE MA EEIG

B01AB04 DALTEPARINUM SOL. INJ. 7500 ui/0.3 ml

FRAGMIN 7500 UI/0,3 ml 7500 ui/0.3 ml PFIZER EUROPE MA EEIG

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| **172** |**B01AB05**| **ENOXAPARINUM\*\*#** | **Protocol: B008D** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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B01AB05 ENOXAPARINUM SOL. INJ. 2000 ui

anti-Xa/0.2 ml

CLEXANE 2000 ui 2000 ui anti-Xa/0.2 ml LAB. AVENTIS

anti-Xa/0.2 ml

B01AB05 ENOXAPARINUM SOL. INJ. 4000 ui

anti-Xa/0,4 ml

CLEXANE 4000 ui 4000 ui anti-Xa/0,4 ml LAB. AVENTIS

anti-Xa/0.4 ml

B01AB05 ENOXAPARINUM SOL. INJ. 6000 ui

anti-Xa/0.6 ml

CLEXANE 6000 ui 6000 ui anti-Xa/0.6 ml LAB. AVENTIS

anti-Xa/0.6 ml

B01AB05 ENOXAPARINUM SOL. INJ. 8000 ui

anti-Xa/0.8 ml

CLEXANE 8000 ui 8000 ui anti-Xa/0.8 ml LAB. AVENTIS

anti-Xa/0.8 ml

B01AB05 ENOXAPARINUM SOL. INJ. 2000 ui

anti-Xa/0.2 ml

CLEXANE 2000 ui 2000 ui anti-Xa/0.2 ml LAB. AVENTIS

anti-Xa/0.2 ml

B01AB05 ENOXAPARINUM SOL. INJ. 4000 ui

anti-Xa/0,4 ml

CLEXANE 4000 ui 4000 ui LAB. AVENTIS

anti-Xa/0.4 ml anti-Xa/0,4 ml

B01AB05 ENOXAPARINUM SOL. INJ. 6000 ui

anti-Xa/0.6 ml

CLEXANE 6000 ui 6000 ui anti-Xa/0.6 ml LAB. AVENTIS

anti-Xa/0.6 ml

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| **173** |**B01AB06**| **NADROPARINUM\*\*#** | Protocol: B008D |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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B01AB06 NADROPARINUM SOL. INJ. 11400 ui

AXa/0.6 ml

FRAXODI 11400 UI 11400 ui AXa/0.6 ml GLAXO GROUP LTD.

anti-factor Xa/0,6 ml

B01AB06 NADROPARINUM SOL. INJ. 15200 ui

AXa/0.8 ml

FRAXODI 15200 UI 15200 ui AXa/0.8 ml GLAXO GROUP LTD.

anti-factor Xa/0.8 ml

B01AB06 NADROPARINUM SOL. INJ. 2850 ui

AFXa/0.3 ml

FRAXIPARINE(R) 2850 UI 2850 ui AFXa/0.3 ml GLAXO GROUP LTD.

anti-factor Xa/0,3 ml

B01AB06 NADROPARINUM SOL. INJ. 3800 ui

AFXa/0.4 ml

FRAXIPARINE(R) 3800 UI 3800 ui AFXa/0.4 ml GLAXO GROUP LTD.

anti-factor Xa/0,4 ml

B01AB06 NADROPARINUM SOL. INJ. 5700 ui

AFXa/0.6 ml

FRAXIPARINE(R) 5700 UI 5700 ui AFXa/0.6 ml GLAXO GROUP LTD.

anti-factor Xa/0.6 ml

B01AB06 NADROPARINUM SOL. INJ. 7600 ui

AXa/0.8 ml

FRAXIPARINE(R) 7600 UI 7600 ui AXa/0.8 ml GLAXO GROUP LTD.

anti-factor Xa/0,8 ml

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| **174** |**B01AB08**| **REVIPARINUM\*\*#** | **Protocol: B008D** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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B01AB08 REVIPARINUM SOL. INJ. 1432 ui/0.25 ml

CLIVARIN(R) 1432 UI/0.25 ml 1432 ui/0.25 ml ABBOTT GMBH & CO.KG

B01AB08 REVIPARINUM SOL. INJ. 3436 ui/0.6 ml

CLIVARIN(R) 3436 UI/0,6 ml 3436 ui/0.6 ml ABBOTT GMBH & CO.KG

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| **175** |**B01AB10**| **TINZAPARINUM\*\*#** | Protocol: B008D |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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B01AB10 TINZAPARINUM SOL. INJ. 10000 u ANTIF. Xa/ml

INNOHEP 10000 U ANTIF. Xa/ml LEO PHARMACEUTICAL

PRODUCTS

B01AB10 TINZAPARINUM SOL. INJ. 20000 u ANTIF. Xa/ml

INNOHEP 20000 U ANTIF. Xa/ml LEO PHARMACEUTICAL

PRODUCTS

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| **176** |**B01AB11**| **SULODEXIDUM\*\*** | **Protocol: B014I** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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B01AB11 SULODEXIDUM CAPS. MOI 250 ULS

VESSEL DUE F 250 ULS ALFA WASSERMANN SPA

B01AB11 SULODEXIDUM SOL. INJ. 600 ULS/2 ml

VESSEL DUE F 600 ULS/2 ml ALFA WASSERMANN SPA

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| **177** |**B01AC04**| **CLOPIDOGRELUM\*\*** | **Protocol: B009I;**|

| | | | **B010I** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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B01AC04 CLOPIDOGRELUM COMPR. FILM. 75 mg

PLAVIX 75 mg 75 mg SANOFI PHARMA - BRISTOL

MYERS SQUIBB

Cod restricţie 1719: **Prevenţia recurenţei accidentului vascular ischemic sau a accidentului ischemic tranzitor la pacienţii cu istoric de episoade ischemice cerebrovasculare conform protocolului de prescriere.**

Cod restricţie 1722: **Prevenţia recurenţei infarctului de miocard sau a anginei instabile la pacienţii cu istoric de evenimente ischemice cardiace simptomatice conform protocolului de prescriere.**

Cod restricţie 3008: **Tratamentul antiagregant al ateromatozei extensive (carotidiene, coronariene şi periferice).**

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| **178** |**B01AC30**| **COMBINATII (DIPYRIDAMOLUM + ACIDUM** | **Protocol: B010I** |

| | | **ACETYLSALICYLICUM)\*\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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B01AC30 COMBINATII CAPS. ELIB. MODIF.

(DIPYRIDAMOLUM +

ACIDUM

ACETYLSALICYLICUM)

AGGRENOX BOEHRINGER INGELHEIM

INTERNATIONAL GMBH

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| **179** |**B01AX05**| **FONDAPARINUX SODIUM\*\*#** | **Protocol: B008D** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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B01AX05 FONDAPARINUX SODIUM SOL. INJ. ÎN SERINGĂ 10 mg/0.8 ml

PREUMPLUTĂ

ARIXTRA 10 mg/0.8 ml 10 mg/0.8 ml GLAXO GROUP LTD.

B01AX05 FONDAPARINUX SODIUM SOL. INJ. ÎN SERINGĂ 2.5 mg/0.5 ml

PREUMPLUTĂ

ARIXTRA 2.5 mg/0.5 ml 2.5 mg/0.5 ml GLAXO GROUP LTD.

B01AX05 FONDAPARINUX SODIUM SOL. INJ. ÎN SERINGĂ 5 mg/0.4 ml

PREUMPLUTĂ

ARIXTRA 5 mg/0.4 ml 5 mg/0.4 ml GLAXO GROUP LTD.

B01AX05 FONDAPARINUX SODIUM SOL. INJ. ÎN SERINGĂ 7.5 mg/0.6 ml

PREUMPLUTĂ

ARIXTRA 7.5 mg/0.6 ml 7.5 mg/0.6 ml GLAXO GROUP LTD.

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| **180** |**B03AC02**| **COMPLEX DE HIDROXID DE FER (III) SUCROZA** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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B03AC02 COMPLEX DE HIDROXID SOL. INJ./PERF. 20 mg/ml

DE FER (III) SUCROZA

VENOFER(R) 20 mg/ml VIFOR FRANCE S.A.

Cod restricţie 2070: **Anemie feriprivă, la pacienţii care au prezentat o reacţie de hipersensibilitate documentată la fier polimaltozat şi la care este indicată administrarea continuă intravenoasă.**

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| **181** |**B01AC18**| **TRIFLUSALUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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B01AC18 TRIFLUSALUM CAPS. 300 mg

AFLEN(R) 300 mg ZENTIVA S.A.

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| **182** |**C01BB02**| **MEXILETINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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C01BB02 MEXILETINUM CAPS. 200 mg

MEXITIL(R) 200 mg 200 mg BOEHRINGER INGELHEIM INT.

GMBH

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| **183** |**C01EB17**| **IVABRADINUM\*\*** | **Protocol: C003I** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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C01EB17 IVABRADINUM COMPR. FILM. 5 mg

CORLENTOR 5 mg 5 mg LES LAB. SERVIER

C01EB17 IVABRADINUM COMPR. FILM. 7.5 mg

CORLENTOR 7,5 mg 7.5 mg LES LAB. SERVIER

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| **184** |**C02AC05**| **MOXONIDINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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Prescriere limitată: **Hipertensiune arterială esenţială la pacienţii care primesc tratament antihipertensiv concomitent.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

C02AC05 MOXONIDINUM COMPR. FILM. 0.2 mg

MOXOGAMMA 0,2 mg 0.2 mg WORWAG PHARMA GMBH

PHYSIOTENS 0,2 0.2 mg SOLVAY PHARMACEUTICALS

GMBH

C02AC05 MOXONIDINUM COMPR. FILM. 0.3 mg

MOXOGAMMA 0,3 mg 0.3 mg WORWAG PHARMA GMBH

C02AC05 MOXONIDINUM COMPR. FILM. 0.4 mg

MOXOGAMMA 0,4 mg 0.4 mg WORWAG PHARMA GMBH

PHYSIOTENS 0.4 0.4 mg SOLVAY PHARMACEUTICALS

GMBH

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| **185** |**C02AC06**| **RILMENIDINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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C02AC06 RILMENIDINUM COMPR. 1 mg

TENAXUM 1 mg LES LABORATOIRES SERVIER

INDUSTRIE

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| **186** |**C02CA01**| **PRAZOSINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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C02CA01 PRAZOSINUM COMPR. 1 mg

MINIPRESS(R) 1 mg 1 mg PFIZER EUROPE MA EEIG

C02CA01 PRAZOSINUM COMPR. 2 mg

MINIPRESS(R) 2 mg 2 mg PFIZER EUROPE MA EEIG

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| **187** |**C03DA04**| **EPLERENONUM\*#** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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Prescriere limitată: **Insuficienţă cardiacă cu o fracţie de ejecţie a ventriculului stâng de 40% sau mai puţin, apărută la 3 - 14 zile de la un infarct miocardic acut. Tratamentul cu eplerenone trebuie început la maximum 14 zile de la data apariţiei infarctului miocardic acut. Data infarctului miocardic acut şi data iniţierii tratamentului cu eplerenone trebuie documentate în fişa pacientului.**

Electroliţii serici trebuie să fie verificaţi periodic.

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

C03DA04 EPLERENONUM COMPR. FILM. 25 mg

INSPRA 25 mg 25 mg PFIZER EUROPE MA EEIG

C03DA04 EPLERENONUM COMPR. FILM. 50 mg

INSPRA 50 mg 50 mg PFIZER EUROPE MA EEIG

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| **188** |**C04AE02**| **NICERGOLINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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C04AE02 NICERGOLINUM COMPR. FILM. 10 mg

NICERGOLINA LPH 10 mg 10 mg LABORMED PHARMA SA

C04AE02 NICERGOLINUM DRAJ. 10 mg

NICERIUM(R) 10 10 mg HEXAL AG

SINERGOLIN 10 10 mg SINTOFARM SA

C04AE02 NICERGOLINUM CAPS. ELIB. MODIF. 15 mg

NICERIUM(R) 15 15 mg HEXAL AG

C04AE02 NICERGOLINUM CAPS. ELIB. MODIF. 30 mg

NICERIUM(R) 30 UNO 30 mg HEXAL AG

C04AE02 NICERGOLINUM COMPR. FILM. 30 mg

NICERGOLINA LPH 30 mg 30 mg LABORMED PHARMA SA

SERMION 30 mg PFIZER EUROPE MA EEIG

C04AE02 NICERGOLINUM DRAJ. 30 mg

SINERGOLIN 30 30 mg SINTOFARM SA

C04AE02 NICERGOLINUM COMPR. FILM. 5 mg

NICERGOLINA LPH 5 mg 5 mg LABORMED PHARMA SA

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| **189** |**C04AX07**| **VINCAMINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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C04AX07 VINCAMINUM DRAJ. 10 mg

VINCAMINA 10 mg BIOFARM SA

C04AX07 VINCAMINUM COMPR. 20 mg

VINCAMIL 20 mg FARMACEUTICI ECOBI S.A.S.

C04AX07 VINCAMINUM CAPS. ELIB. PREL. 30 mg

OXYBRAL SR 30 mg 30 mg GLAXO SMITHKLINE (GSK) SRL

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| **190** |**C04AXN1**| **GINKGO BILOBA\*\*** | **Protocol: C001I** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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C04AXN1 GINKGO BILOBA COMPR. FILM. 120 mg

GINGIUM 120 m 120 mg HEXAL AG

C04AXN1 GINKGO BILOBA COMPR. FILM. 40 mg

GINGIUM 40 mg 40 mg HEXAL AG

TEBOKAN 40 mg DR. WILLMAR SCHWABE GMBH &

CO KG

C04AXN1 GINKGO BILOBA CAPS. 80 mg

BILOBIL FORTE 80 mg KRKA D.D. NOVO MESTO

C04AXN1 GINKGO BILOBA COMPR. FILM. 80 mg

GINGIUM 80 mg 80 mg HEXAL AG

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| **191** |**C05CA53**| **DIOSMINUM (COMBINATII)\*\*** | **Protocol: B016I** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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C05CA53 DIOSMINUM COMPR. FILM. 500 mg

(COMBINATII)

DETRALEX(R) 500 mg LES LAB. SERVIER IND.

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| **192** |**C07AB12**| **NEBIVOLOLUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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C07AB12 NEBIVOLOLUM COMPR. 5 mg

NEBILET(R) 5 mg BERLIN CHEMIE AG MENARINI

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| **193** |**C07BB07**| **COMBINATII (BISOPROLOLUM +** | |

| | | **HYDROCHLOROTHIAZIDUM)** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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C07BB07 COMBINATII COMPR. FILM.

(BISOPROLOLUM +

HYDROCHLOROTHIAZIDUM)

LODOZ 10 mg MERCK KGAA

LODOZ 2,5 mg MERCK KGAA

LODOZ 5 mg MERCK KGAA

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| **194** |**C07EBN1**| **COMBINATII (METOPROLOLUM + FELODIPINUM)** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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C07EBN1 COMBINATII COMPR. ELIB. PREL. 50 mg + 5 mg

(METOPROLOLUM +

FELODIPINUM)

LOGIMAX(R) 50 mg + 5 mg ASTRAZENECA AB

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| **195** |**C08CA09**| **LACIDIPINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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C08CA09 LACIDIPINUM COMPR. FILM. 4 mg

LACIPIL 4 mg 4 mg GLAXO OPERATIONS UK LTD.

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| **196** |**C08CA13**| **LERCANIDIPINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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C08CA13 LERCANIDIPINUM COMPR. FILM. 10 mg

LERIDIP 10 mg BERLIN CHEMIE AG MENARINI

GROUP

C08CA13 LERCANIDIPINUM COMPR. FILM. 20 mg

LERIDIP 20 20 mg BERLIN CHEMIE AG MENARINI

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| **197** |**C09AA04**| **PERINDOPRILUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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Utilizarea inhibitorilor enzimelor de conversie a angiotensinei în timpul sarcinii este contraindicată deoarece medicamentele din această categorie au fost asociate cu moartea fătului in utero.

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

C09AA04 PERINDOPRILUM COMPR. FILM. 10 mg

PRESTARIUM 10 mg 10 mg LES LAB. SERVIER IND.

C09AA04 PERINDOPRILUM COMPR. 4 mg

PRESTARIUM(R) 4 mg 4 mg LES LAB. SERVIER IND.

C09AA04 PERINDOPRILUM COMPR. FILM. 5 mg

PRESTARIUM 5 mg 5 mg LES LAB. SERVIER IND.

C09AA04 PERINDOPRILUM COMPR. 8 mg

PRESTARIUM(R) 8 mg 8 mg LES LAB. SERVIER IND.

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| **198** |**C09AA07**| **BENAZEPRILUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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Utilizarea inhibitorilor enzimelor de conversie a angiotensinei în timpul sarcinii este contraindicată deoarece medicamentele din această categorie au fost asociate cu moartea fătului in utero.

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

C09AA07 BENAZEPRILUM COMPR. FILM. 10 mg

BENAZEPRIL STADA 10 mg 10 mg STADA ARZNEIMITTEL AG

CIBACEN(R) 10 mg 10 mg NOVARTIS PHARMA GMBH

C09AA07 BENAZEPRILUM COMPR. FILM. 20 mg

BENAZEPRIL STADA 20 mg 20 mg STADA ARZNEIMITTEL AG

CIBACEN(R) 20 mg 20 mg NOVARTIS PHARMA GMBH

C09AA07 BENAZEPRILUM COMPR. FILM. 5 mg

BENAZEPRIL STADA 5 mg 5 mg STADA ARZNEIMITTEL AG

CIBACEN(R) 5 mg 5 mg NOVARTIS PHARMA GMBH

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| **199** |**C09AA10**| **TRANDOLAPRILUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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Utilizarea inhibitorilor enzimelor de conversie a angiotensinei în timpul sarcinii este contraindicată deoarece medicamentele din această categorie au fost asociate cu moartea fătului in utero.

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

C09AA10 TRANDOLAPRILUM CAPS. 0.5 mg

GOPTEN(R) 0,5 mg 0.5 mg ABBOTT GMBH & CO.KG

C09AA10 TRANDOLAPRILUM CAPS. 2 mg

GOPTEN(R) 2 mg 2 mg ABBOTT GMBH & CO.KG

C09AA10 TRANDOLAPRILUM CAPS. 4 mg

GOPTEN(R) 4 mg 4 mg ABBOTT GMBH & CO.KG

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| **200** |**C09AA15**| **ZOFENOPRILUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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Utilizarea inhibitorilor enzimelor de conversie a angiotensinei în timpul sarcinii este contraindicată deoarece medicamentele din această categorie au fost asociate cu moartea fătului in utero.

C09AA15 ZOFENOPRILUM COMPR. FILM. 30 mg

ZOMEN(R) 30 mg 30 mg BERLIN CHEMIE AG

C09AA15 ZOFENOPRILUM COMPR. FILM. 7.5 mg

ZOMEN(R) 7,5 mg 7.5 mg BERLIN CHEMIE AG

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| **201** |**C09BA04**| **COMBINATII (PERINDOPRILUM + INDAPAMIDUM)** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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Utilizarea inhibitorilor enzimelor de conversie a angiotensinei în timpul sarcinii este contraindicată deoarece medicamentele din această categorie au fost asociate cu moartea fătului in utero.

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

C09BA04 COMBINATII COMPR. 2 mg + 0.625 mg

(PERINDOPRILUM +

INDAPAMIDUM)

NOLIPREL(R) 2 mg + 0.625 mg LES LAB. SERVIER IND.

C09BA04 COMBINATII COMPR. 4 mg + 1.25 mg

(PERINDOPRILUM +

INDAPAMIDUM)

NOLIPREL FORTE(R) 4 mg + 1.25 mg LES LAB. SERVIER IND.

PRESTARIUM PLUS 4 mg + 1.25 mg LES LAB. SERVIER IND.

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| **202** |**C09BA06**| **COMBINATII (QUINAPRILUM +** | |

| | | **HYDROCHLOROTHIAZIDUM)** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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Utilizarea inhibitorilor enzimelor de conversie a angiotensinei în timpul sarcinii este contraindicată deoarece medicamentele din această categorie au fost asociate cu moartea fătului in utero.

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

C09BA06 COMBINATII COMPR. FILM. 10 mg/12.5 mg

(QUINAPRILUM +

HYDROCHLOROTHIAZIDUM)

ACCUZIDE 10 mg/12.5 mg PFIZER EUROPE MA EEIG

C09BA06 COMBINATII COMPR. FILM. 20 mg/12.5 mg

(QUINAPRILUM +

HYDROCHLOROTHIAZIDUM)

ACUZIDE FORTE 20 mg/12.5 mg PFIZER EUROPE MA EEIG

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| **203** |**C09BA09**| **COMBINATII (FOSINOPRILUM +** | |

| | | **HYDROCHLOROTHIAZIDUM)** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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Utilizarea inhibitorilor enzimelor de conversie a angiotensinei în timpul sarcinii este contraindicată deoarece medicamentele din această categorie au fost asociate cu moartea fătului in utero.

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

C09BA09 COMBINATII COMPR. 20 mg/12.5 mg

(FOSINOPRILUM +

HYDROCHLOROTHIAZIDUM)

FOSINOZIDE 20 mg/12,5 mg 20 mg/12.5 mg BRISTOL MYERS SQUIBB KFT

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| **204** |**C09BB02**| **COMBINATII (NITRENDIPINUM + ENALAPRILUM)** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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Utilizarea inhibitorilor enzimelor de conversie a angiotensinei în timpul sarcinii este contraindicată deoarece medicamentele din această categorie au fost asociate cu moartea fătului in utero.

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

C09BB02 COMBINATII COMPR. 10 mg + 20 mg

(NITRENDIPINUM +

ENALAPRILUM)

ENEAS 10 mg + 20 mg VITA CIENTIFICA SL

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| **205** |**C09BB10**| **COMBINATII (VERAPAMILUM + TRANDOLAPRILUM)** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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Utilizarea inhibitorilor enzimelor de conversie a angiotensinei în timpul sarcinii este contraindicată deoarece medicamentele din această categorie au fost asociate cu moartea fătului in utero.

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

C09BB10 COMBINATII COMPR. FILM. ELIB. 180 mg/2 mg

(VERAPAMILUM + MODIF.

TRANDOLAPRILUM)

TARKA 180 mg/2 mg ABBOTT GMBH & CO.KG

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| **206** |**C09CA03**| **VALSARTANUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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Prescriere limitată: **Tratamentul hipertensiunii arteriale la pacienţii cu**

**intoleranţă la inhibitorii enzimei de conversie ai**

**angiotensinei.**

**Tratamentul hipertensiunii arteriale la pacienţii ale**

**căror valori tensionale nu pot fi controlate adecvat cu**

**celelalte clase de medicamente antihipertensive.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

C09CA03 VALSARTANUM COMPR. FILM. 160 mg

DIOVAN 160 mg 160 mg NOVARTIS PHARMA GMBH

C09CA03 VALSARTANUM COMPR. FILM. 80 mg

DIOVAN 80 mg 80 mg NOVARTIS PHARMA GMBH

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| **207** |**C09CA04**| **IRBESARTANUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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Prescriere limitată: **Tratamentul hipertensiunii arteriale la pacienţii cu**

**intoleranţă la inhibitorii enzimei de conversie ai**

**angiotensinei.**

**Tratamentul hipertensiunii arteriale la pacienţii ale**

**căror valori tensionale nu pot fi controlate adecvat cu**

**celelalte clase de medicamente antihipertensive.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

C09CA04 IRBESARTANUM COMPR. FILM. 150 mg

APROVEL 150 mg 150 mg SANOFI PHARMA-BRISTOL

MYERS SQUIBB

C09CA04 IRBESARTANUM COMPR. FILM. 300 mg

APROVEL 300 mg 300 mg SANOFI PHARMA-BRISTOL

MYERS SQUIBB

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| **208** |**C09CA06**| **CANDESARTANUM CILEXETIL** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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Prescriere limitată: **Tratamentul hipertensiunii arteriale la pacienţii cu**

**intoleranţă la inhibitorii enzimei de conversie ai**

**angiotensinei.**

**Tratamentul hipertensiunii arteriale la pacienţii ale**

**căror valori tensionale nu pot fi controlate adecvat cu**

**celelalte clase de medicamente antihipertensive.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

C09CA06 CANDESARTANUM COMPR. 16 mg

CILEXETIL

ATACAND 16 mg ASTRAZENECA AB

C09CA06 CANDESARTANUM COMPR. 8 mg

CILEXETIL

ATACAND 8 mg ASTRAZENECA AB

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| **209** |**C09CA07**| **TELMISARTANUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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Prescriere limitată: **Tratamentul hipertensiunii arteriale la pacienţii cu**

**intoleranţă la inhibitorii enzimei de conversie ai**

**angiotensinei.**

**Tratamentul hipertensiunii arteriale la pacienţii ale**

**căror valori tensionale nu pot fi controlate adecvat cu**

**celelalte clase de medicamente antihipertensive.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

C09CA07 TELMISARTANUM COMPR. 40 mg

MICARDIS 40 mg 40 mg BOEHRINGER INGELHEIM INT.

GMBH

PRITOR 40 mg 40 mg BAYER HEALTHCARE AG

C09CA07 TELMISARTANUM COMPR. 80 mg

MICARDIS 80 mg 80 mg BOEHRINGER INGELHEIM INT.

GMBH

PRITOR 80 mg 80 mg BAYER HEALTHCARE AG

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| **210** |**C09DA01**| **COMBINATII (LOSARTANUM +** | |

| | | **HYDROCHLOROTHIAZIDUM)** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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Prescriere limitată: **Tratamentul hipertensiunii arteriale la pacienţii cu**

**intoleranţă la inhibitorii enzimei de conversie ai**

**angiotensinei.**

**Tratamentul hipertensiunii arteriale la pacienţii ale**

**căror valori tensionale nu pot fi controlate adecvat cu**

**celelalte clase de medicamente antihipertensive.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

C09DA01 COMBINATII COMPR. FILM. 50 mg + 12.5 mg

(LOSARTANUM +

HYDROCHLOROTHIAZIDUM)

HYZAAR(R) 50 mg/12,5 mg 50 mg + 12.5 mg MERCK SHARP & DOHME

ROMANIA S.R.L

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| **211** |**C09DA03**| **COMBINATII (VALSARTANUM +** | |

| | | **HYDROCHLOROTHIAZIDUM)** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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Prescriere limitată: **Tratamentul hipertensiunii arteriale la pacienţii cu**

**intoleranţă la inhibitorii enzimei de conversie ai**

**angiotensinei.**

**Tratamentul hipertensiunii arteriale la pacienţii ale**

**căror valori tensionale nu pot fi controlate adecvat cu**

**celelalte clase de medicamente antihipertensive.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

C09DA03 COMBINATII COMPR. FILM. 80 mg/12.5 mg

(VALSARTANUM +

HYDROCHLOROTHIAZIDUM)

CO-DIOVAN 80 mg/12,5 mg 80 mg/12.5 mg NOVARTIS PHARMA GMBH

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| **212** |**C09DA04**| **COMBINATII (IRBERSARTANUM +** | |

| | | **HYDROCHLOROTHIAZIDUM)** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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Prescriere limitată: **Tratamentul hipertensiunii arteriale la pacienţii cu**

**intoleranţă la inhibitorii enzimei de conversie ai**

**angiotensinei.**

**Tratamentul hipertensiunii arteriale la pacienţii ale**

**căror valori tensionale nu pot fi controlate adecvat cu**

**celelalte clase de medicamente antihipertensive.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

C09DA04 COMBINATII COMPR. 15 u mg/12.5 mg

(IRBERSARTANUM +

HYDROCHLOROTHIAZIDUM)

COAPROVEL 150 mg/12.5 mg 150 mg/12.5 mg SANOFI PHARMA-BRISTOL

MYERS SQUIBB SNC

C09DA04 COMBINATII COMPR. 300 mg/12.5 mg

(IRBERSARTANUM +

HYDROCHLOROTHIAZIDUM)

COAPROVEL 300 mg/12.5 mg 300 mg/12.5 mg SANOFI PHARMA-BRISTOL

MYERS SQUIBB SNC

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| **213** |**C09DA07**| **COMBINATII (TELMISARTANUM +** | |

| | | **HYDROCHLOROTHIAZIDUM)** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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Prescriere limitată: **Tratamentul hipertensiunii arteriale la pacienţii cu**

**intoleranţă la inhibitorii enzimei de conversie ai**

**angiotensinei.**

**Tratamentul hipertensiunii arteriale la pacienţii ale**

**căror valori tensionale nu pot fi controlate adecvat cu**

**celelalte clase de medicamente antihipertensive.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

C09DA07 COMBINATII COMPR. 80/12.5 mg

(TELMISARTANUM +

HYDROCHLOROTHIAZIDUM)

MICARDISPLUS 80/12.5 mg 80/12.5 mg BOEHRINGER INGELHEIM INT.

GMBH

C09DA07 COMBINATII COMPR. 80 mg/12.5 mg

(TELMISARTANUM +

HYDROCHLOROTHIAZIDUM)

PRITOR PLUS 80 mg/12,5 mg 80 mg/12.5 mg BAYER HEALTHCARE AG

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| **214** |**C09DB01**| **COMBINATII (VALSARTANUM + AMLODIPINUM)** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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Prescriere limitată: **Tratamentul hipertensiunii arteriale la pacienţii cu**

**intoleranţă la inhibitorii enzimei de conversie ai**

**angiotensinei.**

**Tratamentul hipertensiunii arteriale la pacienţii ale**

**căror valori tensionale nu pot fi controlate adecvat cu**

**celelalte clase de medicamente antihipertensive.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

C09DB01 COMBINATII COMPR. FILM. 10 mg/160 mg

(VALSARTANUM +

AMLODIPINUM)

EXFORGE 10 mg/160 mg 10 mg/160 mg NOVARTIS EUROPHARM LTD.

C09DB01 COMBINATII COMPR. FILM. 5 mg/160 mg

(VALSARTANUM +

AMLODIPINUM)

EXFORGE 5 mg/160 mg 5 mg/160 mg NOVARTIS EUROPHARM LTD.

C09DB01 COMBINATII COMPR. FILM. 5 mg/80 mg

(VALSARTANUM +

AMLODIPINUM)

EXFORGE 5 mg/80 mg 5 mg/80 mg NOVARTIS EUROPHARM LTD.

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| **215** |**C10AA04**| **FLUVASTATINUM** | **Protocol: CE01E** |

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Prescriere limitată: **Se utilizează pentru pacienţii care îndeplinesc criteriile de eligibilitate stabilite prin Protocolul de prescriere a medicamentelor hipolipemiante.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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C10AA04 FLUVASTATINUM CAPS. 20 mg

LESCOL(R) 20 20 mg NOVARTIS PHARMA GMBH

C10AA04 FLUVASTATINUM CAPS. 40 mg

LESCOL(R) 40 40 mg NOVARTIS PHARMA GMBH

C10AA04 FLUVASTATINUM COMPR. ELIB. PREL. 80 mg

LESCOL(R) XL 80 mg NOVARTIS PHARMA GMBH

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| **216** |**C10AA05**| **ATORVASTATINUM** | **Protocol: CE01E** |

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Prescriere limitată: **Se utilizează pentru pacienţii care îndeplinesc criteriile de eligibilitate stabilite prin Protocolul de prescriere a medicamentelor hipolipemiante.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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C10AA05 ATORVASTATINUM COMPR. FILM. 10 mg

SORTIS 10 mg 10 mg PFIZER EUROPE MA EEIG

C10AA05 ATORVASTATINUM COMPR. FILM. 20 mg

SORTIS 20 mg 20 mg PFIZER EUROPE MA EEIG

C10AA05 ATORVASTATINUM COMPR. FILM. 40 mg

SORTIS 40 mg 40 mg PFIZER EUROPE MA EEIG

C10AA05 ATORVASTATINUM COMPR. FILM. 80 mg

SORTIS 80 mg 80 mg PFIZER EUROPE MA EEIG

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| **217** |**C10AA07**| **ROSUVASTATINUM** | **Protocol: CE01E** |

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Prescriere limitată: **Se utilizează pentru pacienţii care îndeplinesc criteriile de eligibilitate stabilite prin Protocolul de prescriere a medicamentelor hipolipemiante.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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C10AA07 ROSUVASTATINUM COMPR. FILM. 10 mg

CRESTOR 10 mg 10 mg ASTRAZENECA UK LTD.

C10AA07 ROSUVASTATINUM COMPR. FILM. 20 mg

CRESTOR 20 mg 20 mg ASTRAZENECA UK LTD.

C10AA07 ROSUVASTATINUM COMPR. FILM. 40 mg

CRESTOR 40 mg 40 mg ASTRAZENECA UK LTD.

C10AA07 ROSUVASTATINUM COMPR. FILM. 5 mg

CRESTOR 5 mg 5 mg ASTRAZENECA UK LTD.

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| **218** |**C10AB02**| **BEZAFIBRATUM** | **Protocol: CE01E** |

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Prescriere limitată: **Se utilizează pentru pacienţii care îndeplinesc criteriile de eligibilitate stabilite prin Protocolul de prescriere a medicamentelor hipolipemiante.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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C10AB02 BEZAFIBRATUM DRAJ. 200 mg

REGADRIN(R) B 200 mg BERLIN CHEMIE AG MENARINI

GROUP

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| **219** |**C10AB08**| **CIPROFIBRATUM** | **Protocol: CE01E** |

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Prescriere limitată: **Se utilizează pentru pacienţii care îndeplinesc criteriile de eligibilitate stabilite prin Protocolul de prescriere a medicamentelor hipolipemiante.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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C10AB08 CIPROFIBRATUM CAPS. 100 mg

LIPANOR(R) 100 mg 100 mg SANOFI-AVENTIS FRANCE

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| **220** |**C10AX06**| **ACID OMEGA-3-ESTERI ETILICI 90\*\*** | **Protocol: C004I** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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C10AX06 ACID OMEGA-3-ESTERI CAPS. MOI 1000 mg

ETILICI 90

OMACOR(R) 1000 mg PRONOVA BIOCARE AS

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| **221** |**C10AX09**| **EZETIMIBUM** | |

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Prescriere limitată: **Se utilizează pentru pacienţii care îndeplinesc criteriile de eligibilitate stabilite prin Protocolul de prescriere a medicamentelor hipolipemiante.**

**Cod restricţie 2649: Tratamentul, în combinaţie cu dietă şi exerciţiu fizic, ce presupune asocierea cu un inhibitor de HMG CoA reductaza (statină) la pacienţii al căror nivel de colesterol nu este controlat adecvat cu o statină şi care au: (a) boală coronariană. Controlul inadecvat sub tratament cu o statină este definit astfel: (1) nivel al colesterolului peste pragul iniţial după cel puţin 3 luni de tratament cu o statină în doza zilnică optimă de statine concomitent cu dietă şi exerciţii fizice. Doza, durata tratamentului cu statine şi nivelul colesterolului controlat inadecvat trebuie să fie înregistrate în dosarul medical al pacientului la momentul iniţierii tratamentului cu ezetinimb. Valoarea colesterolului controlat inadecvat trebuie să fie mai recent de două luni la momentul iniţierii tratamentului cu ezetinib; SAU (2) Controlul inadecvat al colesterolului cu nivele ale acestuia mai mari decât 155 mg/dl după cel puţin 3 luni de tratament cu o doză zilnică optimă de statine concomitent cu dietă şi exerciţii fizice. Doza, durata tratamentului cu statine şi nivelul colesterolului controlat inadecvat trebuie să fie înregistrate în dosarul medical al pacientului la momentul iniţierii tratamentului cu ezetinib. Valoarea colesterolului controlat inadecvat trebuie să fie mai recentă de două luni la momentul iniţierii tratamentului cu ezetinib.**

**Cod restricţie 2650: Tratamentul, în combinaţie cu dietă şi exerciţiu fizic, ce presupune asocierea cu un inhibitor de HMG CoA reductaza (statină) la pacienţii al căror nivel de colesterol nu este controlat adecvat cu o statină şi care au: (b) diabet zaharat. Controlul inadecvat sub tratament cu o statină este definit astfel: (1) nivel al colesterolului peste pragul iniţial după cel puţin 3 luni de tratament cu o statină în doza zilnică optimă de statine, concomitent cu dietă şi exerciţii fizice. Doza, durata tratamentului cu statine şi nivelul colesterolului controlat inadecvat trebuie să fie înregistrate în dosarul medical al pacientului la momentul iniţierii tratamentului cu ezetinimb. Valoarea colesterolului controlat inadecvat trebuie să fie mai recent de două luni la momentul iniţierii tratamentului cu ezetinib; SAU (2) Controlul inadecvat al colesterolului cu nivele ale acestuia mai mari decât 155 mg/dl după cel puţin 3 luni de tratament cu o doză zilnică optimă de statine concomitent cu dietă şi exerciţii fizice. Doza, durata tratamentului cu statine şi nivelul colesterolului controlat inadecvat trebuie să fie înregistrate în dosarul medical al pacientului la momentul iniţierii tratamentului cu ezetimib. Valoarea colesterolului controlat inadecvat trebuie să fie mai recentă de două luni la momentul iniţierii tratamentului cu ezetimib.**

**Cod restricţie 2651: Tratamentul, în combinaţie cu dietă şi exerciţiu fizic, ce presupune asocierea cu un inhibitor de HMG CoA reductaza (statină) la pacienţii al căror nivel de colesterol nu este controlat adecvat cu o statină şi care au: (c) boala vasculară periferică. Controlul inadecvat sub tratament cu o statină este definit astfel: (1) nivel al colesterolului peste pragul iniţial după cel puţin 3 luni de tratament cu o statină în doza zilnică optimă de statine, concomitent cu dietă şi exerciţii fizice. Doza, durata tratamentului cu statine şi nivelul colesterolului controlat inadecvat trebuie să fie înregistrate în dosarul medical al pacientului la momentul iniţierii tratamentului cu ezetinimb. Valoarea colesterolului controlat inadecvat trebuie să fie mai recent de două luni la momentul iniţierii tratamentului cu ezetinib; SAU (2) Controlul inadecvat al colesterolului cu nivele ale acestuia mai mari decât 155 mg/dl după cel puţin 3 luni de tratament cu o doza zilnică optimă de statine concomitent cu dietă şi exerciţii fizice. Doza, durata tratamentului cu statine şi nivelul colesterolului controlat inadecvat trebuie să fie înregistrate în dosarul medical al pacientului la momentul iniţierii tratamentului cu ezetinib. Valoarea colesterolului controlat inadecvat trebuie să fie mai recentă de două luni la momentul iniţierii tratamentului cu ezetimib.**

**Cod restricţie 2652: Tratamentul, în combinaţie cu dietă şi exerciţiu fizic, ce presupune asocierea cu un inhibitor de HMG CoA reductaza (statină) la pacienţii al căror nivel de colesterol nu este controlat adecvat cu o statină şi care au: (d) hipercolesterolemie familială heterozigotă. Controlul inadecvat sub tratament cu o statină este definit astfel: (1) nivel al colesterolului peste pragul iniţial după cel puţin 3 luni de tratament cu o statină în doza zilnică optimă de statine, concomitent cu dietă şi exerciţii fizice. Doza, durata tratamentului cu statine şi nivelul colesterolului controlat inadecvat trebuie să fie înregistrate în dosarul medical al pacientului la momentul iniţierii tratamentului cu ezetinimb. Valoarea colesterolului controlat inadecvat trebuie să fie mai recent de două luni la momentul iniţierii tratamentului cu ezetinib; SAU (2) Controlul inadecvat al colesterolului cu nivele ale acestuia mai mari decât 155 mg/dl după cel puţin 3 luni de tratament cu o doza zilnică optimă de statine concomitent cu dietă şi exerciţii fizice. Doza, durata tratamentului cu statine şi nivelul colesterolului controlat inadecvat trebuie să fie înregistrate în dosarul medical al pacientului la momentul iniţierii tratamentului cu ezetimib. Valoarea colesterolului controlat inadecvat trebuie să fie mai recentă de două luni la momentul iniţierii tratamentului cu ezetimib.**

**Cod restricţie 2653: Tratamentul, în combinaţie cu dietă şi exerciţiu fizic, ce presupune asocierea cu un inhibitor de HMG CoA reductaza (statină) la pacienţii al căror nivel de colesterol nu este controlat adecvat cu o statină şi care au: (e) boala cerebrovasculară simptomatică. Controlul inadecvat sub tratament cu o statină este definit astfel: (1) nivel al colesterolului peste pragul iniţial după cel puţin 3 luni de tratament cu o statină în doza zilnică optimă de statine, concomitent cu dietă şi exerciţii fizice. Doza, durata tratamentului cu statine şi nivelul colesterolului controlat inadecvat trebuie să fie înregistrate în dosarul medical al pacientului la momentul iniţierii tratamentului cu ezetinimb. Valoarea colesterolului controlat inadecvat trebuie să fie mai recent de două luni la momentul iniţierii tratamentului cu ezetinib; SAU (2) Controlul inadecvat al colesterolului cu nivele ale acestuia mai mari decât 155 mg/dl după cel puţin 3 luni de tratament cu o doza zilnică optimă de statine concomitent cu dietă şi exerciţii fizice. Doza, durata tratamentului cu statine şi nivelul colesterolului controlat inadecvat trebuie să fie înregistrate în dosarul medical al pacientului la momentul iniţierii tratamentului cu ezetimib. Valoarea colesterolului controlat inadecvat trebuie să fie mai recentă de două luni la momentul iniţierii tratamentului cu ezetimib.**

**Cod restricţie 2667: Tratamentul, în combinaţie cu dietă şi exerciţiu fizic, ce presupune asocierea cu un inhibitor de HMG CoA reductaza (statină) la pacienţii al căror nivel de colesterol nu este controlat adecvat cu o statină şi care au: (f) istoric familial de boala coronariană. Controlul inadecvat sub tratament cu o statină este definit astfel: (1) nivel al colesterolului peste pragul iniţial după cel puţin 3 luni de tratament cu o statină în doza zilnică optimă de statine, concomitent cu dietă şi exerciţii fizice. Doza, durata tratamentului cu statine şi nivelul colesterolului controlat inadecvat trebuie să fie înregistrate în dosarul medical al pacientului la momentul iniţierii tratamentului cu ezetinimb. Valoarea colesterolului controlat inadecvat trebuie să fie mai recent de două luni la momentul iniţierii tratamentului cu ezetinib; SAU (2) Controlul inadecvat al colesterolului cu nivele ale acestuia mai mari decât 155 mg/dl după cel puţin 3 luni de tratament cu o doza zilnică optimă de statine concomitent cu dietă şi exerciţii fizice. Doza, durata tratamentului cu statine şi nivelul colesterolului controlat inadecvat trebuie să fie înregistrate în dosarul medical al pacientului la momentul iniţierii tratamentului cu ezetimib. Valoarea colesterolului controlat inadecvat trebuie să fie mai recentă de două luni la momentul iniţierii tratamentului cu ezetimib.**

**Cod restricţie 2668: Tratamentul, în combinaţie cu dietă şi exerciţiu fizic, ce presupune asocierea cu un inhibitor de HMG CoA reductaza (statină) la pacienţii al căror nivel de colesterol nu este controlat adecvat cu o statină şi care au: (g) HTA. Controlul inadecvat sub tratament cu o statină este definit astfel: (1) nivel al colesterolului peste pragul iniţial după cel puţin 3 luni de tratament cu o statină în doza zilnică optimă de statine, concomitent cu dietă şi exerciţii fizice. Doza, durata tratamentului cu statine şi nivelul colesterolului controlat inadecvat trebuie să fie înregistrate în dosarul medical al pacientului la momentul iniţierii tratamentului cu ezetinimb. Valoarea colesterolului controlat inadecvat trebuie să fie mai recent de două luni la momentul iniţierii tratamentului cu ezetinib; SAU (2) Controlul inadecvat al colesterolului cu nivele ale acestuia mai mari decât 155 mg/dl după cel puţin 3 luni de tratament cu o doză zilnică optimă de statine concomitent cu dietă şi exerciţii fizice. Doza, durata tratamentului cu statine şi nivelul colesterolului controlat inadecvat trebuie să fie înregistrate în dosarul medical al pacientului la momentul iniţierii tratamentului cu ezetimib. Valoarea colesterolului controlat inadecvat trebuie să fie mai recentă de două luni la momentul iniţierii tratamentului cu ezetimib.**

**Cod restricţie 1989: Pacienţi care îndeplinesc criteriile de eligibilitate pentru prescrierea de hipolipemiante (în concordanţă cu criteriile stabilite în Protocoalele de prescriere în vederea decontării) atunci când tratamentul cu un inhibitor de HMG CoA reductaza (statine) este contraindicat.**

**Cod restricţie 2669: Pacienţi care îndeplinesc criteriile de eligibilitate pentru prescrierea de hipolipemiante (în concordanţă cu criteriile stabilite în Protocoalele de prescriere în vederea decontării) atunci când tratamentul cu un inhibitor de HMG CoA reductaza (statin) trebuie întrerupt sau redus la mai puţin de 20 mg/zi datorită apariţiei efectelor secundare următoare: (i) Mialgie severă (simptome musculare fără creşterea CK) care survine pe perioada tratamentului cu statine; sau (ii) Miozita (creşterea importantă a CK, cu sau fără simptomatologie musculară) demonstrată prin valori de două ori mai mari decât limita superioară a normalului la o singură determinare sau o tendinţă de creştere la determinări consecutive, neexplicate de alte cauze; sau (iii) Persistenţa unor valori crescute ale transaminazelor, neexplicată de alte cauze (mai mult de trei ori decât valoarea limită maximă a normalului) în timpul tratamentului cu o statină.**

**Cod restricţie 1991: Homozygous sitosterolaemia;**

**Cod restricţie 2438: Pacienţi cu hipercolesterolemie familială (homozigotă) care sunt eligibili pentru tratamentul cu hipolipemiante (în concordanţă cu Protocolul de prescriere în vederea decontării), în combinaţie cu un inhibitor de HMG CoA reductase (statin).**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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C10AX09 EZETIMIBUM COMPR. 10 mg

EZETROL(R) 10 mg MERCK SHARP & DOHME

ROMANIA SRL

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| **222** |**C10BA02**| **COMBINATII (EZETIMIBUM + SIMVASTATINUM)** | |

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**Cod restricţie 2654: Tratamentul, în combinaţie cu dietă şi exerciţiu fizic, ce presupune asocierea cu un inhibitor de HMG CoA reductaza (statină) la pacienţii al căror nivel de colesterol nu este controlat adecvat cu o statină şi care au: (a) boală coronariană. Controlul inadecvat sub tratament cu o statină este definit astfel: (1) nivel al colesterolului peste pragul iniţial după cel puţin 3 luni de tratament cu o statină în doza zilnică optimă de statine, concomitent cu dietă şi exerciţii fizice. Doza, durata tratamentului cu statine şi nivelul colesterolului controlat inadecvat trebuie să fie înregistrate în dosarul medical al pacientului la momentul iniţierii tratamentului cu ezetinimb. Valoarea colesterolului controlat inadecvat trebuie să fie mai recent de două luni la momentul iniţierii tratamentului cu ezetinib; SAU (2) Controlul inadecvat al colesterolului cu nivele ale acestuia mai mari decât 155 mg/dl după cel puţin 3 luni de tratament cu o doză zilnică optimă de statine concomitent cu dietă şi exerciţii fizice. Doza, durata tratamentului cu statine şi nivelul colesterolului controlat inadecvat trebuie să fie înregistrate în dosarul medical al pacientului la momentul iniţierii tratamentului cu ezetimib. Valoarea colesterolului controlat inadecvat trebuie să fie mai recentă de două luni la momentul iniţierii tratamentului cu ezetimib.**

**Cod restricţie 2655: Tratamentul, în combinaţie cu dietă şi exerciţiu fizic, ce presupune asocierea cu un inhibitor de HMG CoA reductaza (statină) la pacienţii al căror nivel de colesterol nu este controlat adecvat cu o statină şi care au: (b) diabet zaharat. Controlul inadecvat sub tratament cu o statină este definit astfel: (1) nivel al colesterolului peste pragul iniţial după cel puţin 3 luni de tratament cu o statină în doza zilnică optimă de statine, concomitent cu dieta şi exerciţii fizice. Doza, durata tratamentului cu statine şi nivelul colesterolului controlat inadecvat trebuie să fie înregistrate în dosarul medical al pacientului la momentul iniţierii tratamentului cu ezetinimb. Valoarea colesterolului controlat inadecvat trebuie să fie mai recent de două luni la momentul iniţierii tratamentului cu ezetinib; SAU (2) Controlul inadecvat al colesterolului cu nivele ale acestuia mai mari decât 155 mg/dl după cel puţin 3 luni de tratament cu o doză zilnică optimă de statine concomitent cu dietă şi exerciţii fizice. Doza, durata tratamentului cu statine şi nivelul colesterolului controlat inadecvat trebuie să fie înregistrate în dosarul medical al pacientului la momentul iniţierii tratamentului cu ezetimib. Valoarea colesterolului controlat inadecvat trebuie să fie mai recentă de două luni la momentul iniţierii tratamentului cu ezetimib.**

**Cod restricţie 2656: Tratamentul, în combinaţie cu dietă şi exerciţiu fizic, ce presupune asocierea cu un inhibitor de HMG CoA reductaza (statină) la pacienţii al căror nivel de colesterol nu este controlat adecvat cu o statină şi care au: (c) boala vasculară periferică. Controlul inadecvat sub tratament cu o statină este definit astfel: (1) nivel al colesterolului peste pragul iniţial după cel puţin 3 luni de tratament cu o statină în doza zilnică optimă de statine, concomitent cu dietă şi exerciţii fizice.**

**Doza, durata tratamentului cu statine şi nivelul colesterolului controlat inadecvat trebuie să fie înregistrate în dosarul medical al pacientului la momentul iniţierii tratamentului cu ezetinimb. Valoarea colesterolului controlat inadecvat trebuie să fie mai recent de două luni la momentul iniţierii tratamentului cu ezetinib; SAU (2) Controlul inadecvat al colesterolului cu nivele ale acestuia mai mari decât 155 mg/dl după cel puţin 3 luni de tratament cu o doză zilnică optimă de statine concomitent cu dietă şi exerciţii fizice. Doza, durata tratamentului cu statine şi nivelul colesterolului controlat inadecvat trebuie să fie înregistrate în dosarul medical al pacientului la momentul iniţierii tratamentului cu ezetimib. Valoarea colesterolului controlat inadecvat trebuie să fie mai recentă de două luni la momentul iniţierii tratamentului cu ezetimib.**

**Cod restricţie 2657: Tratamentul, în combinaţie cu dietă şi exerciţiu fizic, ce presupune asocierea cu un inhibitor de HMG CoA reductaza (statină) la pacienţii al căror nivel de colesterol nu este controlat adecvat cu o statină şi care au: (d) hipercolesterolemie familială heterozigotă. Controlul inadecvat sub tratament cu o statină este definit astfel: (1) nivel al colesterolului peste pragul iniţial după cel puţin 3 luni de tratament cu o statină în doza zilnică optimă de statine, concomitent cu dietă şi exerciţii fizice. Doza, durata tratamentului cu statine şi nivelul colesterolului controlat inadecvat trebuie să fie înregistrate în dosarul medical al pacientului la momentul iniţierii tratamentului cu ezetinimb. Valoarea colesterolului controlat inadecvat trebuie să fie mai recent de două luni la momentul iniţierii tratamentului cu ezetinib; SAU (2) Controlul inadecvat al colesterolului cu nivele ale acestuia mai mari decât 155 mg/dl după cel puţin 3 luni de tratament cu o doză zilnică optimă de statine concomitent cu dietă şi exerciţii fizice. Doza, durata tratamentului cu statine şi nivelul colesterolului controlat inadecvat trebuie să fie înregistrate în dosarul medical al pacientului la momentul iniţierii tratamentului cu ezetimib. Valoarea colesterolului controlat inadecvat trebuie să fie mai recentă de două luni la momentul iniţierii tratamentului cu ezetimib.**

**Cod restricţie 2658: Tratamentul, în combinaţie cu dietă şi exerciţiu fizic, ce presupune asocierea cu un inhibitor de HMG CoA reductaza (statină) la pacienţii al căror nivel de colesterol nu este controlat adecvat cu o statină şi care au: (e) boală cerebrovasculară simptomatică. Controlul inadecvat sub tratament cu o statină este definit astfel: (1) nivel al colesterolului peste pragul iniţial după cel puţin 3 luni de tratament cu o statină în doza zilnică optimă de statine, concomitent cu dietă şi exerciţii fizice. Doza, durata tratamentului cu statine şi nivelul colesterolului controlat inadecvat trebuie să fie înregistrate în dosarul medical al pacientului la momentul iniţierii tratamentului cu ezetinimb. Valoarea colesterolului controlat inadecvat trebuie să fie mai recent de două luni la momentul iniţierii tratamentului cu ezetinib; SAU (2) Controlul inadecvat al colesterolului cu nivele ale acestuia mai mari decât 155 mg/dl după cel puţin 3 luni de tratament cu o doză zilnică optimă de statine concomitent cu dieta şi exerciţii fizice. Doza, durata tratamentului cu statine şi nivelul colesterolului controlat inadecvat trebuie să fie înregistrate în dosarul medical al pacientului la momentul iniţierii tratamentului cu ezetimib. Valoarea colesterolului controlat inadecvat trebuie să fie mai recentă de două luni la momentul iniţierii tratamentului cu ezetimib.**

**Cod restricţie 2678: Tratamentul, în combinaţie cu dietă şi exerciţiu fizic, ce presupune asocierea cu un inhibitor de HMG CoA reductaza (statină) la pacienţii al căror nivel de colesterol nu este controlat adecvat cu o statină şi care au: (f) istoric familial de boală coronariană. Controlul inadecvat sub tratament cu o statină este definit astfel: (1) nivel al colesterolului peste pragul iniţial după cel puţin 3 luni de tratament cu o statină în doza zilnică optimă de statine, concomitent cu dietă şi exerciţii fizice. Doza, durata tratamentului cu statine şi nivelul colesterolului controlat inadecvat trebuie să fie înregistrate în dosarul medical al pacientului la momentul iniţierii tratamentului cu ezetinimb. Valoarea colesterolului controlat inadecvat trebuie să fie mai recent de două luni la momentul iniţierii tratamentului cu ezetinib; SAU (2) Controlul inadecvat al colesterolului cu nivele ale acestuia mai mari decât 155 mg/dl după cel puţin 3 luni de tratament cu o doză zilnică optimă de statine concomitent cu dietă şi exerciţii fizice. Doza, durata tratamentului cu statine şi nivelul colesterolului controlat inadecvat trebuie să fie înregistrate în dosarul medical al pacientului la momentul iniţierii tratamentului cu ezetinimb. Valoarea colesterolului controlat inadecvat trebuie să fie mai recent de două luni la momentul iniţierii tratamentului cu ezetimib.**

**Cod restricţie 2679: Tratamentul, în combinaţie cu dietă şi exerciţiu fizic, ce presupune asocierea cu un inhibitor de HMG CoA reductaza (statină) la pacienţii al căror nivel de colesterol nu este controlat adecvat cu o statină şi care au: (g) HTA. Controlul inadecvat sub tratament cu o statină este definit astfel: (1) nivel al colesterolului peste pragul iniţial după cel puţin 3 luni de tratament cu o statină în doza zilnică optimă de statine, concomitent cu dietă şi exerciţii fizice. Doza, durata tratamentului cu statine şi nivelul colesterolului controlat inadecvat trebuie să fie înregistrate în dosarul medical al pacientului la momentul iniţierii tratamentului cu ezetinimb. Valoarea colesterolului controlat inadecvat trebuie să fie mai recent de două luni la momentul iniţierii tratamentului cu ezetinib; SA U (2) Controlul inadecvat al colesterolului cu nivele ale acestuia mai mari decât 155 mg/dl după cel puţin 3 luni de tratament cu o doză zilnică optimă de statine concomitent cu dietă şi exerciţii fizice. Doza, durata tratamentului cu statine şi nivelul colesterolului controlat inadecvat trebuie să fie înregistrate în dosarul medical al pacientului la momentul iniţierii tratamentului cu ezetinimb. Valoarea colesterolului controlat inadecvat trebuie să fie mai recent de două luni la momentul iniţierii tratamentului cu ezetimib.**

**Cod restricţie 2431: Pacienţii cu hipercolesterolemie familială (heterozigotă) care sunt eligibili pentru tratament cu hipo-lipemiante (în concordanţă cu criteriile stabilite prin Protocolul de prescriere în vederea decontării).**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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C10BA02 COMBINATII COMPR. 10 mg/10 mg

(EZETIMIBUM +

SIMVASTATINUM)

INEGY(R) 10 mg/10 mg 10 mg/10 mg MERCK SHARP & DOHME

ROMANIA S.R.L.

C10BA02 COMBINATII COMPR. 10 mg/20 mg

(EZETIMIBUM +

SIMVASTATINUM)

INEGY(R) 10 mg/20 mg 10 mg/20 mg MERCK SHARP & DOHME

ROMANIA S.R.L.

C10BA02 COMBINATII COMPR. 10 mg/40 mg

(EZETIMIBUM +

SIMVASTATINUM)

INEGY(R) 10 mg/40 mg 10 mg/40 mg MERCK SHARP & DOHME

ROMANIA S.R.L.

C10BA02 COMBINATII COMPR. 10 mg/80 mg

(EZETIMIBUM +

SIMVASTATINUM)

INEGY(R) 10 mg/80 mg 10 mg/80 mg MERCK SHARP & DOHME

ROMANIA S.R.L.

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| **223** |**C10BX03**| **COMBINATII (ATORVASTATINUM + AMLODIPINUM)** | **Protocol: CE01E** |

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Prescriere limitată: **Pentru utilizarea la pacienţii cu hipertensiune**

**arterială şi/sau angină pectorală care îndeplinesc**

**criteriile stabilite de Protocolul de prescriere a**

**medicamentelor hipolipemiante în vederea decontării,**

**şi: (a) care primesc în mod curent tratament cu un**

**blocant de canale de calciu.**

**Pentru utilizarea la pacienţii cu hipertensiune**

**arterială şi/sau angină pectorală care îndeplinesc**

**criteriile stabilite de Protocolul de prescriere a**

**medicamentelor hipolipemiante în vederea decontării,**

**şi: (b) al căror nivel al tensiunii arteriale şi/sau**

**angină pectorală sunt insuficient controlate cu alte**

**clase de antihipertensive şi/sau medicamente**

**anti-angină şi la care terapia adjuvantă cu blocanţi ai**

**canalelor de calciu ar fi adecvată;**

**Pentru utilizarea la pacienţii cu hipertensiune**

**arterială şi/sau angină pectorală care îndeplinesc**

**criteriile stabilite de Protocolul de prescriere a**

**medicamentelor hipolipemiante în vederea decontării, şi**

**(c) care nu tolerează efectele secundare ale altor**

**clase de antihipertensive şi/sau medicamente**

**anti-angină şi la care înlocuirea terapiei cu un**

**blocant de canale de calciu ar fi indicată.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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C10BX03 COMBINATII COMPR. FILM. 10 mg/10 mg

(ATORVASTATINUM +

AMLODIPINUM)

CADUET 10 mg/10 mg 10 mg/10 mg PFIZER EUROPE MA EEIG

C10BX03 COMBINATII COMPR. FILM. 5 mg/10 mg

(ATORVASTATINUM +

AMLODIPINUM)

CADUET 5 mg/10 mg 5 mg/10 mg PFIZER EUROPE MA EEIG

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| **224** |**D01AA02**| **NATAMYCINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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D01AA02 NATAMYCINUM CREMA 20 mg/g

PIMAFUCIN 20 mg/g ASTELLAS EUROPE B.V.

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| **226** |**D01BA02**| **TERBINAFINUM** | |

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Prescriere limitată: **Tratamentul de primă intenţie al onicomicozelor proximale sau extinse la care tratamentul topic a eşuat.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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D01BA02 TERBINAFINUM COMPR. 250 mg

LAMISIL(R) 250 mg NOVARTIS PHARMA GMBH

TERBINARAN 250 mg RANBAXY UK LIMITED

TERBISIL(R) 250 mg 250 mg GEDEON RICHTER LTD.

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| **227** |**D05AX02**| **CALCIPOTRIOLUM\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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D05AX02 CALCIPOTRIOLUM CREMA 50 µg/g

DAIVONEX 50 µg/g LEO PHARMACEUTICAL

PRODUCTS

D05AX02 CALCIPOTRIOLUM UNGUENT 50 µg/g

DAIVONEX UNGUENT 50 µg/g LEO PHARMACEUTICAL

PRODUCTS

D05AX02 CALCIPOTRIOLUM SOL. CUT. 50 µg/ml

DAIVONEX SOLUŢIE CUTANATĂ 50 µg/ml LEO PHARMACEUTICAL

PENTRU SCALP PRODUCTS

D05AX02 CALCIPOTRIOLUM UNGUENT 0.005%

SOREL(R) unguent 0,005% 0.005% LEK PHARMACEUTICALS D.D.

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| **228** |**D05AX52**| **COMBINATII (CALCIPOTRIOLUM +** | |

| | | **BETAMETHASONUM)\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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D05AX52 COMBINATII UNGUENT

(CALCIPOTRIOLUM +

BETAMETHASONUM)

DAIVOBET(R) UNGUENT LEO PHARMACEUTICAL

PRODUCTS

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| **230** |**D06AX01**| **ACIDUM FUSIDICUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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D06AX01 ACIDUM FUSIDICUM CREMA 2,00%

FUCIDIN(R) 2% LEO PHARMACEUTICAL

PRODUCTS

D06AX01 ACIDUM FUSIDICUM UNGUENT 2,00%

FUCIDIN(R) 2% LEO PHARMACEUTICAL

PRODUCTS

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| **231** |**D06AXN1**| **COMBINATII (NEOMYCINUM + BACITRACINUM)** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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D06AXN1 COMBINATII PULB. CUT.

(NEOMYCINUM +

BACITRACINUM)

BANEOCIN(R) SANDOZ GMBH

D06AXN1 COMBINATII UNGUENT

(NEOMYCINUM +

BACITRACINUM)

BANEOCIN(R) SANDOZ GMBH

NEOBACIN DAR AL DAWA PHARMA SRL

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| **232** |**D06BA01**| **SULFADIAZINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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D06BA01 SULFADIAZINUM CREMA 1,00%

DERMAZIN(R) 1% 1% LEK PHARMACEUTICALS D.D.

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| **233** |**D06BB04**| **PODOPHYLLOTOXINUM\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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D06BB04 PODOPHYLLOTOXINUM CREMA 1,5 mg/g

WARTEC 1,5 mg/g 1,5 mg/g STIEFEL LABORATORIES (UK)

LTD.

D06BB04 PODOPHYLLOTOXINUM SOL. CUT. 5 mg/ml

CONDYLINE 5 mg/ml ASTELLAS PHARMA EUROPE

B.V.

Prescriere limitată: **Pentru tratamentul verucilor.**

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| **235** |**D07AB02**| **HYDROCORTISONUM BUTYRATUM** | **Protocol: D001L** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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D07AB02 HYDROCORTISONUM CREMA 0.1%

BUTYRATUM

LOCOID(R) cremă 0,1% 0.1% ASTELLAS PHARMA EUROPE BV

LOCOID(R)LIPOCREAM 0,1% 0.1% ASTELLAS PHARMA EUROPE

B.V.

D07AB02 HYDROCORTISONUM EMULSIE CUT. 0.1%

BUTYRATUM

LOCOID CRELO(R) 0,1% 0.1% ASTELLAS PHARMA EUROPE BV

D07AB02 HYDROCORTISONUM SOL. CUT. 0.1%

BUTYRATUM

LOCOID(R) 0.1% ASTELLAS PHARMA EUROPE

B.V.

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| **236** |**D07AC13**| **MOMETASONUM** | **Protocol: D001L** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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D07AC13 MOMETASONUM CREMA 1 mg/g

ELOCOM 1 mg/g SCHERING PLOUGH EUROPE

D07AC13 MOMETASONUM SOL. CUT. 1 mg/g

ELOCOM 1 mg/g SCHERING PLOUGH EUROPE

D07AC13 MOMETASONUM UNGUENT 1 mg/g

ELOCOM 1 mg/g SCHERING PLOUGH EUROPE

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| **237** |**D07AC14**| **METHYLPREDNISOLONUM ACEPONAT** | **Protocol: D001L** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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D07AC14 METHYLPREDNISOLONUM EMULSIE CUT. 0.1%

ACEPONAT

ADVANTAN(R) MILK 0.1% INTENDIS GMBH

D07AC14 METHYLPREDNISOLONUM CREMA 1 mg/g

ACEPONAT

ADVANTAN 1 mg/g INTENDIS GmbH

D07AC14 METHYLPREDNISOLONUM UNGUENT 1 mg/g

ACEPONAT

ADVANTAN 1 mg/g INTENDIS GmbH

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| **238** |**D07AC17**| **FLUTICASONUM** | **Protocol: D001L** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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D07AC17 FLUTICASONUM CREMA 0.05%

CUTIVATE 0.05% GLAXO WELLCOME UK LIMITED

D07AC17 FLUTICASONUM UNGUENT 0.005%

CUTIVATE 0.005% GLAXO WELLCOME UK LIMITED

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| **239** |**D07AD01**| **CLOBETASOLUM\*** | **Protocol: D001L** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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D07AD01 CLOBETASOLUM CREMA 0.05%

DERMOVATE 0.05% GLAXOWELLCOME UK LTD.

D07AD01 CLOBETASOLUM SOL. CUT. 0.05%

DERMOVATE(R) 0.05% GLAXO WELLCOME UK LTD.

D07AD01 CLOBETASOLUM UNGUENT 0.05%

DERMIONE 0.05% OZONE LABORATORIES LTD.

DERMOVATE 0.05% GLAXOWELLCOME UK LTD.

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| **240** |**D07CA01**| **COMBINATII (HYDROCORTISONUM +** | **Protocol: D001L** |

| | | **ANTIINFECTIOASE)** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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D07CA01 COMBINATII CREMA

(HYDROCORTISONUM +

ANTIINFECTIOASE)

FUCIDIN(R) H LEO PHARMACEUTICAL

PRODUCTS

PIMAFUCORT ASTELLAS PHARMA EUROPE

B.V.

D07CA01 COMBINATII UNGUENT

(HYDROCORTISONUM +

ANTIINFECTIOASE)

PIMAFUCORT ASTELLAS PHARMA EUROPE

B.V.

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| **241** |**D07CC01**| **COMBINATII (BETAMETHASONUM +** | **Protocol: D001L** |

| | | **ANTIINFECTIOASE)** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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D07CC01 COMBINATII CREMA

(BETAMETHASONUM +

ANTIINFECTIOASE)

FUCICORT(R) LEO PHARMACEUTICAL

PRODUCTS

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| **242** |**D07XC03**| **COMBINATII (MOMETASONUM +** | **Protocol: D001L** |

| | | **AC. SALICILICUM)** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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D07XC03 COMBINATII UNGUENT

(MOMETASONUM + AC.

SALICILICUM)

ELOSALIC SCHERING PLOUGH EUROPE

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| **243** |**D10AD54**| **COMBINATII (MOMETASONUM + ERITROMICINUM)** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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D10AD54 COMBINATII GEL 0,05%/0,2%

(ISOTRETINOINUM +

ERITROMICINUM)

ISOTREXIN GEL 0,05%/0,2% STIEFEL LABORATORIES (UK)

LTD.

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| **244** |**D10AX03**| **ACIDUM AZELAICUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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D10AX03 ACIDUM AZELAICUM CREMA 200 mg/g

SKINOREN 200 mg/g INTENDIS GmbH

D10AX03 ACIDUM AZELAICUM GEL 15%

SKINOREN(R) 15% 15% INTENDIS GMBH

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| **245** |**D10BA01**| **ISOTRETINOINUM\*\*** | |

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**Cod restricţie 1354: Acnee chistică severă care nu răspunde la alte tipuri de tratamente.**

Acest medicament poate cauza defecte la naştere. Isotretinoin a fost incriminat pentru cauzarea frecventă a altor efecte toxice cu potenţial sever.

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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D10BA01 ISOTRETINOINUM CAPS. MOI 10 mg

ROACCUTANE 10 mg 10 mg ROCHE ROMANIA SRL

SOTRET 10 mg 10 mg RANBAXY U.K. LIMITED

D10BA01 ISOTRETINOINUM CAPS. MOI 20 mg

SOTRET 20 mg 20 mg RANBAXY U.K. LIMITED

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| **246** |**G01AA02**| **NATAMYCINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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G01AA02 NATAMYCINUM OVULE 100 mg

PIMAFUCIN(R) 100 mg ASTELLAS PHARMA EUROPE

B.V.

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| **247** |**G01AA51**| **COMBINATII** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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G01AA51 COMBINATII CREMA VAG. 10 g/400000 UI

MACMIROR COMPLEX 10 g/400000 UI POLICHEM SA

G01AA51 COMBINATII CAPS. MOI VAG. 500 mg/200000 UI

MACMIROR COMPLEX 500 mg/200000 UI POLICHEM SA

G01AA51 COMBINATII CAPS. MOI VAG.

POLYGYNAX LAB. INNOTECH INT.

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| **248** |**G01AF12**| **FENTICONAZOLUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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G01AF12 FENTICONAZOLUM CAPS. MOI VAG. 600 mg

LOMEXIN 600 mg 600 mg RECORDATI SPA

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| **249** |**G01AF15**| **BUTOCONAZOLUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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G01AF15 BUTOCONAZOLUM CREMA VAG.

GYNOFORT 2% GEDEON RICHTER LTD.

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| **251** |**G01AX05**| **NIFURATELUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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G01AX05 NIFURATELUM DRAJ. 200 mg

MACMIROR 200 mg POLICHEM SA

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| **252** |**G02CB03**| **CABERGOLINUM\*** | **Protocol: G001C** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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G02CB03 CABERGOLINUM COMPR. 0.5 mg

DOSTINEX 0.5 mg PFIZER EUROPE MA EEG

Prescriere limitată: **Prevenirea apariţiei lactaţiei în lăuzie.**

Cod restricţie 2659: **Hiperprolactinemia patologică pentru care nu este indicată intervenţia chirurgicală.**

Cod restricţie 2660: **Hiperprolactinemia patologică pentru care a fost utilizat tratament chirurgical dar cu rezultate incomplete.**

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| **253** |**G03AC02**| **LYNESTRENOLUM\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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G03AC02 LYNESTRENOLUM COMPR. 0.5 mg

EXLUTON(R) 0.5 mg ORGANON NV

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| **254** |**G03AC03**| **LEVONORGESTRELUM\*\*\*#** | **Protocol: G005N** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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G03AC03 LEVONORGESTRELUM DISPOZITIV INTRAUTERIN 52 mg

MIRENA 20 µg/24 h 52 mg SCHERING OY (SCHERING AG)

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| **255** |**G03CA04**| **ESTRIOLUM\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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G03CA04 ESTRIOLUM CREMA VAG. 0.1%

OVESTIN 0.1% ORGANON NV

G03CA04 ESTRIOLUM OVULE 0.5 mg

OVESTIN 0.5 mg ORGANON NV

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| **256** |**G03CA09**| **PROMESTRIENUM\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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G03CA09 PROMESTRIENUM CAPS. MOI VAG. 10 mg

COLPOTROPHINE(R) 10 mg LAB. THERAMEX

G03CA09 PROMESTRIENUM CREMA VAG. 1%

COLPOTROPHINE(R) 1% LAB. THERAMEX

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| **257** |**G03DA04**| **PROGESTERONUM\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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G03DA04 PROGESTERONUM CAPS. MOI 100 mg

UTROGESTAN(R) 100 mg 100 mg LAB. BESINS INTERNATIONAL

G03DA04 PROGESTERONUM GEL 1%

MASTOPROFEN 1% 1% ANTIBIOTICE SA

PROGESTOGEL 1% LAB. BESINS INTERNATIONAL

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| **258** |**G03DB01**| **DYDROGESTERONUM\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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G03DB01 DYDROGESTERONUM COMPR. FILM. 10 mg

DUPHASTON(R) 10 mg SOLVAY PHARMACEUTICALS BV

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| **259** |**G03DC03**| **LYNESTRENOLUM\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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G03DC03 LYNESTRENOLUM COMPR. 5 mg

ORGAMETRIL 5 mg ORGANON NV

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| **260** |**G03DC05**| **TIBOLONUM\*\*** | **Protocol: G007N** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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G03DC05 TIBOLONUM COMPR. 2,5 mg

LADYBON 2,5 mg ZENTIVA A.S.

G03DC05 TIBOLONUM COMPR. 2.5 mg

LIVIAL(R) 2,5 mg 2.5 mg ORGANON NV

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| **261** |**G03FA01**| **COMBINATII\*\*** | **Protocol: G002N** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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G03FA01 COMBINATII COMPR. FILM. 1 mg/0,5 mg

ACTIVELLE 1 mg/0,5 mg 1 mg/0,5 mg NOVO NORDISK A/S

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| **262** |**G03FA14**| **COMBINATII\*\*** | **Protocol: G002N** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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G03FA14 COMBINATII COMPR. FILM.

FEMOSTON(R) conti 1/5 SOLVAY PHARMACEUTICALS BV

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| **263** |**G03FA15**| **ESTRADIOLUMVALERAT + DIENOGEST\*\*** | **Protocol: G002N** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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G03FA15 ESTRADIOLUMVALERAT + DRAJ.

DIENOGEST

KLIMODIEN SCHERING AG

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| **264** |**G03FA17**| **COMBINATII\*\*** | **Protocol: G002N** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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G03FA17 COMBINATII COMPR. FILM.

ANGELIQ SCHERING AG

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| **265** |**G03FB01**| **COMBINATII\*\*** | **Protocol: G002N** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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G03FB01 COMBINATII DRAJ.

CYCLO PROGINOVA(R) SCHERING AG

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| **266** |**G03FB05**| **COMBINATII\*\*** | **Protocol: G002N** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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G03FB05 COMBINATII COMPR. FILM.

NOVOFEM NOVO NORDISK A/S

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| **267** |**G03FB08**| **COMBINATII\*\*** | **Protocol: G002N** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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G03FB08 COMBINATII COMPR. FILM.

FEMOSTON 2/10 SOLVAY PHARMACEUTICALS BV

G03FB08 COMBINATII COMPR. FILM.

FEMOSTON 2/10 SOLVAY PHARMACEUTICALS BV

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| **268** |**G03GA05**| **FOLITROPINUM ALFA\*\*\*\*#** | **Protocol: G003N** |

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Prescriere limitată: **Infertilitate anovulatorie.**

NOTĂ:

**Cu excepţia cazurilor de hipopituitarism sau amenoree primară, pacienta trebuie să fi fost tratată anterior cu citrat de clomifen şi/sau gonadorelin, iar tratamentul să fi rămas fără efect (sarcina nu a fost obţinută). Femeile care au urmat tratament pentru inducerea ovulaţiei cu alte clase de medicamente şi nu au obţinut o sarcină necesită evaluare laparoscopică pentru a exclude alte cauze care împiedică apariţia unei sarcini.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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G03GA05 FOLITROPINUM ALFA PULB. + SOLV. PT. SOL. 150 UI

INJ.

GONAL-f 150 UI 150 UI SERONO EUROPE LTD.

G03GA05 FOLITROPINUM ALFA PULB. + SOLV. PT. SOL. 75 UI

INJ.

GONAL-f 75 UI 75 UI SERONO EUROPE LTD.

Prescriere limitată: **Infertilitate anovulatorie**

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| **269** |**G03GA06**| **FOLLITROPINUM BETA\*\*\*\*#** | **Protocol: G008N** |

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Prescriere limitată: **Infertilitate anovulatorie.**

NOTĂ:

**Cu excepţia cazurilor de hipopituitarism sau amenoree primară, pacienta trebuie să fi fost tratată anterior cu citrat de clomifen şi/sau gonadorelin, iar tratamentul să fi rămas fără efect (sarcina nu a fost obţinută). Femeile care au urmat tratament pentru inducerea ovulaţiei cu alte clase de medicamente şi nu au obţinut o sarcină necesită evaluare laparoscopică pentru a exclude alte cauze care împiedică apariţia unei sarcini.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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G03GA06 FOLLITROPINUM BETA SOL. INJ. 100 UI/0.5 ml

PUREGON 100 UI/0,5 ml 100 UI/0.5 ml N.V. ORGANON

G03GA06 FOLLITROPINUM BETA SOL. INJ. 300 UI/0.36 ml

PUREGON 300 UI/0,36 ml 300 UI/0.36 ml N.V. ORGANON

G03GA06 FOLLITROPINUM BETA SOL. INJ. 50 UI/0.5 ml

PUREGON 50 UI/0,5 ml 50 UI/0.5 ml N.V. ORGANON

G03GA06 FOLLITROPINUM BETA SOL. INJ. 600 UI/0.72 ml

PUREGON 600 UI/0.72 ml 600 UI/0.72 ml N.V. ORGANON

G03GA06 FOLLITROPINUM BETA PULB + SOLV. PT. SOL. 100 UI/ml

INJ.

PUREGON 100 UI 100 UI/ml ORGANON NV

G03GA06 FOLLITROPINUM BETA PULB + SOLV. PT. SOL. 50 UI/ml

INJ

PUREGON 50 UI 50 UI/ml ORGANON NV

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| **271** |**G03GB02**| **CLOMIFENUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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G03GB02 CLOMIFENUM COMPR. 50 mg

CLOSTILBEGYT 50 mg EGIS PHARMACEUTICALS PLC

OVA-MIT 50 mg REMEDICA LTD.

Prescriere limitată: **Infertilitate anovulatorie**

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| **272** |**G03XC01**| **RALOXIFENUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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G03XC01 RALOXIFENUM COMPR. FILM. 60 mg

EVISTA 60 mg 60 mg ELI LILLY NEDERLAND BV

Cod restricţie 3006: **Monoterapie cu medicamente antiresorbtive pentru tratamentul şi profilaxia osteoporozei sexoidoprive la femei până la vârsta de 60 ani.**

NOTĂ:

**Agenţii antiresorbtivi utilizaţi în tratamentul osteoporozei instalate sunt: ALENDRONATE SODIUM, RISEDRONAT SODIUM, RALOXIFEN HYDROCHLORIDE, IBANDRONATE, ZOLENDRONATE ŞI STRONTIUM RANELATE (agent antiresorbtiv şi formator osos).**

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| **273** |**G04BD04**| **OXYBUTYNINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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G04BD04 OXYBUTYNINUM COMPR. 5 mg

DRIPTANE(R) 5 mg 5 mg LAB. FOURNIER SA

Prescriere limitată: **Hipereactivitate a detrusorului**

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| **274** |**G04BD07**| **TOLTERODINUM\*\*#** | **Protocol: G010N** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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G04BD07 TOLTERODINUM CAPS. ELIB. PREL. 4 mg

DETRUSITOL SR 4 mg 4 mg PFIZER EUROPE MA EEIG

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| **275** |**G04BD08**| **SOLIFENACINUM SUCCINATE\*\*#** | **Protocol: G009N** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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G04BD08 SOLIFENACINUM COMPR. FILM. 10 mg

SUCCINATE

VESICARE 10 mg 10 mg ASTELLAS PHARMA EUROPE

B.V.

G04BD08 SOLIFENACINUM COMPR. FILM. 5 mg

SUCCINATE

VESICARE 5 mg 5 mg ASTELLAS PHARMA EUROPE

B.V.

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| **276** |**G04BD09**| **TROSPIUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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G04BD09 TROSPIUM COMPR. FILM. 15 mg

INKONTAN 15 mg 15 mg PHARMAZEUTISCHE FABRIK

MONTAVIT GES. M.B.H.

G04BD09 TROSPIUM COMPR. FILM. 30 mg

INKONTAN 30 mg 30 mg PHARMAZEUTISCHE FABRIK

MONTAVIT GES. M.B.H.

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| **277** |**G04CA01**| **ALFUZOSINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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G04CA01 ALFUZOSINUM COMPR. ELIB. PREL. 10 mg

ALFURAN MR 10 mg 10 mg TERAPIA S.A.

XATRAL SR 10 mg 10 mg SANOFI-SYNTHELABO FRANCE

G04CA01 ALFUZOSINUM COMPR. FILM. ELIB. 5 mg

PREL.

XATRAL(R) LP 5 mg 5 mg SANOFI-SYNTHELABO FRANCE

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| **278** |**G04CA02**| **TAMSULOSINUM** | |

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Prescriere limitată: **Tratamentul hiperplaziei benigne de prostată.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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G04CA02 TAMSULOSINUM CAPS. ELIB. MODIF. 0,4 mg

TAMSOL 0,4 mg 0,4 mg GEDEON RICHTER ROMANIA

TAMSULOSIN ACTAVIS 0,4 mg ACTAVIS GROUP HF.

G04CA02 TAMSULOSINUM CAPS. ELIB. MODIF. 0.4 mg

FOKUSIN 0.4 mg ZENTIVA AS

G04CA02 TAMSULOSINUM CAPS. ELIB. PREL. 0.4 mg

CONTIFLO MR 0.4 mg RANBAXY UK LTD.

TANYZ 0.4 mg KRKA D.D. NOVO MESTO

G04CA02 TAMSULOSINUM COMPR. FILM. ELIB. 0.4 mg

PREL.

OMNIC TOCAS(R) 0,4 0.4 mg ASTELLAS PHARMA EUROPE

B.V.

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| **279** |**G04CB01**| **FINASTERIDUM\*** | |

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Prescriere limitată: **Tratamentul hiperplaziei benigne de prostată.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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G04CB01 FINASTERIDUM COMPR. FILM. 5 mg

MOSTRAFIN 5 mg PLIVA LJUBLIJANA D.O.O.

PROSCAR 5 mg 5 mg MERCK SHARP & DOHME

ROMANIA S.R.L.

TAREDOX 5 mg 5 mg DR. REDDY'S LABORATORIES

G04CB01 FINASTERIDUM COMPR. FILM. 5 mg

MOSTRAFIN 5 mg PLIVA LJUBLIJANA D.O.O.

PROSCAR 5 mg 5 mg MERCK SHARP & DOHME

ROMANIA S.R.L.

TAREDOX 5 mg 5 mg DR. REDDY'S LABORATORIES

G04CB01 FINASTERIDUM COMPR. FILM. 5 mg

FINASTERID SANDOZ 5 mg 5 mg HEXAL AG

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| **280** |**G04CB02**| **DUTASTERIDUM\*** | |

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Prescriere limitată: **Tratamentul hiperplaziei benigne de prostată.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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G04CB02 DUTASTERIDUM CAPS. MOI 0.5 mg

AVODART(R) 0.5 mg GLAXO GROUP LTD.

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| **281** |**H01AA02**| **TETRACOSACTIDUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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H01AA02 TETRACOSACTIDUM SUSP. INJ. 1 mg/ml

SYNACHTEN DEPOT 1 mg/ml NOVARTIS PHARMA GMBH

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| **282** |**H01AC01**| **SOMATROPINUM\*\*\*#** | **Protocol: H009E** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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H01AC01 SOMATROPINUM SOL. INJ. 10 mg/1.5 ml

NORDITROPIN 10 mg/1.5 ml NOVO NORD ISK A/S

SIMPLEX x 10 mg/1,5 ml

H01AC01 SOMATROPINUM SOL. INJ. 10 mg/2 ml

NUTROPINAq 10 mg/2 ml 10 mg/2 ml IPSEN LIMITED

H01AC01 SOMATROPINUM SOL. INJ. 3,3 mg/ml

OMNITROPE 3,3 mg/ml 3,3 mg/ml SANDOZ GMBH

H01AC01 SOMATROPINUM LIOF. + SOLV. PT. SOL. 4 mg (12 ui)

INJ.

ZOMACTON 4 mg (12 ui) FERING GMBH

H01AC01 SOMATROPINUM PULB. + SOLV. PT. SOL. 5.3 mg/ml (16 ui)

INJ.

GENOTROPIN(R) 16 ui (5,3 mg) 5.3 mg/ml (16 ui) PFIZER EUROPE MA EEIG

H01AC01 SOMATROPINUM SOL. INJ. 5 mg/1.5 ml

NORDITROPIN 5 mg/1.5 ml NOVO NORDISK A/S

SIMPLEX x 5 mg/1,5 ml

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| **283** |**H01CC01**| **GANIRELIXUM\*\*\*#** | **Protocol: G004N** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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H01CC01 GANIRELIXUM SOL. INJ. 0.25 mg/0.5 ml

ORGALUTRAN 0.25 mg/0.5 ml 0.25 mg/0.5 ml N.V. ORGANON

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| **284** |**H01CC02**| **CETRORELIXUM\*\*\*#** | **Protocol: H004E** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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H01CC02 CETRORELIXUM LIOF. + SOLV. PT. SOL. 0.25 mg

INJ.

CETROTIDE 0,25 mg 0.25 mg SERONO EUROPE LTD.

H01CC02 CETRORELIXUM LIOF. + SOLV. PT. SOL. 3 mg

INJ.

CETROTIDE 3 mg 3 mg SERONO EUROPE LTD.

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| **285** |**H02AA02**| **FLUDROCORTISONUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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H02AA02 FLUDROCORTISONUM COMPR. 0.1 mg

ASTONIN H 0.1 mg MERCK KGAA

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| **286** |**H02AB01**| **BETAMETHASONUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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H02AB01 BETAMETHASONUM SUSP. INJ. I.M. 7 mg/ml

DIPROPHOS(R) 7 mg/ml SCHERING PLOUGH EUROPE

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| **287** |**H02AB06**| **PREDNISOLONUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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H02AB06 PREDNISOLONUM LIOF. + SOLV. PT. SOL. 250 mg

INJ.

SOLU-DECORTIN H 250 250 mg MERCK KGAA

H02AB06 PREDNISOLONUM LIOF. + SOLV. PT. SOL. 50 mg

INJ.

SOLU-DECORTIN H 50 50 mg MERCK KGAA

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| **288** |**H03BB02**| **THIAMAZOLUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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H03BB02 THIAMAZOLUM COMPR. FILM. 10 mg

THYROZOL(R) 10 mg 10 mg MERCK KGAA

H03BB02 THIAMAZOLUM COMPR. FILM. 20 mg

THYROZOL(R) 20 mg 20 mg MERCK KGAA

H03BB02 THIAMAZOLUM COMPR. FILM. 5 mg

THYROZOL(R) 5 mg 5 mg MERCK KGAA

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| **289** |**H05BA01**| **CALCITONINUM (SOMON)** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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H05BA01 CALCITONINUM (SOMON) SOL. INJ. 100 UI

TONOCALCIN 100 UI 100 UI ALFA WASSERMANN SPA

H05BA01 CALCITONINUM (SOMON) SPRAY NAZ., SOL. 100 ui/doza

NYLEX 100 Ul/doza 100 UI/doza PHARMACEUTICAL IND. PROEL

EPAM. G. CORONIS SA

H05BA01 CALCITONINUM (SOMON) SOL. INJ. 100 UI/ml

NYLEX(R) 100 UI/ml PROEL E.P. CORONIS SA

H05BA01 CALCITONINUM (SOMON) SPRAY NAZAL-SOL. 200 UI/doza

MIACALCIC(R) NASAL 200 200 ui/doza NOVARTIS PHARMA GMBH

NYLEX(R) 200 UI/doza PROEL E.P. CORONIS SA

H05BA01 CALCITONINUM (SOMON) SOL. INJ. 50 ui/ml

MIACALCIC(R) 50 ui/ml NOVARTIS PHARMA GMBH

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| **290** |**J01CR01**| **AMPICILLINUM + SULBACTAM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01CR01 AMPICILLINUM + PULB. PT. SOL. INJ. 1 g + 500 mg

SULBACTAM

AMPIPLUS(R) 1,5 g 1 g + 500 mg ANTIBIOTICE SA

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| **291** |**J01CR04**| **SULTAMICILLINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01CR04 SULTAMICILLINUM PULB. PT. SUSP. ORALĂ 250 mg/5 ml

UNASYN 250 mg/5 ml PFIZER EUROPE MA EEIG

J01CR04 SULTAMICILLINUM COMPR. FILM. 375 mg

UNASYN 375 mg PFIZER EUROPE MA EEIG

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| **292** |**J01DC10**| **CEFPROZILUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01DC10 CEFPROZILUM PULB. PT. SUSP. ORALĂ 125 mg/5 ml

CEFZIL 125 mg/5 ml 125 mg/5 ml BRISTOL-MYERS SQUIBB KFT.

J01DC10 CEFPROZILUM COMPR. FILM. 250 mg

CEFZIL 250 mg 250 mg BRISTOL-MYERS SQUIBB KFT.

J01DC10 CEFPROZILUM PULB. PT. SUSP. ORALĂ 250 mg/5 ml

CEFZIL 250 mg/5 ml 250 mg/5 ml BRISTOL-MYERS SQUIBB KFT.

J01DC10 CEFPROZILUM COMPR. FILM. 500 mg

CEFZIL 500 mg 500 mg BRISTOL-MYERS SQUIBB KFT.

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| **293** |**J01DD14**| **CEFTIBUTENUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01DD14 CEFTIBUTENUM PULB. PT. SUSP. ORALĂ 36 mg/ml

CEDAX 36 mg/ml SCHERING PLOUGH EUROPE

J01DD14 CEFTIBUTENUM CAPS. 400 mg

CEDAX 400 mg SCHERING PLOUGH EUROPE

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| **294** |**J01FA02**| **SPIRAMYCINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01FA02 SPIRAMYCINUM COMPR. FILM. 1.5 M ui

ROVAMYCINE(R) 1,5 Mil. UI 1.5 M ui LAB. AVENTIS

J01FA02 SPIRAMYCINUM COMPR. FILM. 3 M ui

ROVAMYCINE(R) 3 Mil. UI 3 M ui LAB. AVENTIS

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| **295** |**J01FA10**| **AZITHROMYCINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01FA10 AZITHROMYCINUM PULB. PT. SUSP. ORALĂ 100 mg/5 ml

AZITROMICINA 100 mg/5 ml SANDOZ SRL

SANDOZ 100 mg/5 ml

J01FA10 AZITHROMYCINUM COMPR. FILM. 125 mg

SUMAMED 125 mg 125 mg PLIVA LJUBLJANA D.O.O.

J01FA10 AZITHROMYCINUM PULB. PT. SUSP. ORALĂ 200 mg/5 ml

AZITROMICINA 200 mg/5 ml SANDOZ SRL

SANDOZ 200 mg/5 ml

J01FA10 AZITHROMYCINUM PULB. + SOLV. SUSP. 200 mg/5 ml

ORALĂ

AZITROX 200 mg/5 ml 200 mg/5 ml ECZACIBASI PHARMACEUTICALS

S.R.L.

J01FA10 AZITHROMYCINUM PULB. PT. SUSP. ORALĂ 200 mg/5 ml

SUMAMED FORTE 200 mg/5 ml PLIVA LJUBLIJANA D.O.O.

J01FA10 AZITHROMYCINUM CAPS. 250 mg

AZATRIL 250 mg 250 mg BALKANPHARMA RAZGRAD AD

J01FA10 AZITHROMYCINUM COMPR. FILM. 250 mg

AZITROMICINA SANDOZ 250 mg 250 mg SANDOZ S.R.L.

COMPRIMATE FILMATE

AZITROX(R) 250 250 mg ZENTIVA AS

J01FA10 AZITHROMYCINUM COMPR. FILM. 500 mg

AZITROMICINA SANDOZ 500 mg 500 mg SANDOZ S.R.L.

COMPRIMATE FILMATE

AZITROX(R) 500 500 mg ZENTIVA AS

AZRO(R) 500 mg 500 mg ECZACIBASI PHARMACEUTICALS

S.R.L.

SUMAMED 500 mg 500 mg PLIVA LJUBLJANA D.O.O.

ZITROCIN 500 mg 500 mg OZONE LABORATORIES LTD.

J01FA10 AZITHROMYCINUM GRAN. ELIB. PREL. PT. 2 g

SUSP. ORALĂ

ZMAX 2 g 2 g PFIZER EUROPE MA EEIG

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| **296** |**J01FF01**| **CLINDAMYCINUM** | |

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Prescriere limitată: **Infecţii cu coci Gram pozitivi care nu pot fi tratate**

**eficient cu peniciline.**

**Infecţii severe cu germeni anaerobi.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01FF01 CLINDAMYCINUM CAPS. 150 mg

DALACIN C 150 mg 150 mg PFIZER EUROPE MA EEIG

J01FF01 CLINDAMYCINUM CAPS. 300 mg

DALACIN C 300 mg 300 mg PFIZER EUROPE MA EEIG

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| **297** |**J01MA12**| **LEVOFLOXACINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01MA12 LEVOFLOXACINUM COMPR. FILM. 500 mg

TAVANIC(R) 500 mg AVENTIS PHARMA DEUTSCHLAND

GMBH

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| **298** |**J01MA14**| **MOXIFLOXACINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01MA14 MOXIFLOXACINUM COMPR. FILM. 400 mg

AVELOX(R) 400 mg 400 mg BAYER HEALTHCARE AG

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| **299** |**J02AC02**| **ITRACONAZOLUM\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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J02AC02 ITRACONAZOLUM CAPS. 100 mg

ITRACONAZOL 100 mg 100 mg TERAPIA S.A.

OMICRAL 100 mg 100 mg MEDICO UNO PHARMACEUTICAL

S.R.L

ORUNGAL 100 mg JANSSEN PHARMACEUTICA NV

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| **300** |**J05AB11**| **VALACYCLOVIRUM\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J05AB11 VALACYCLOVIRUM COMPR. FILM. 500 mg

VALTREX 500 mg 500 mg THE WELLCOME FOUNDATION

LTD

Prescriere limitată: **Tratamentul pacienţilor cu herpes zoster în decurs de 72 de ore de la debutul rash-ului**

Prescriere limitată: **Herpes zoster oftalmic.**

Prescriere limitată: **Herpes genital iniţial moderat/sever.**

Prescriere limitată: **Tratamentul episodic sau supresiv al herpesului genital recurent (forme moderate/severe).**

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| **301** |**J05ABN1**| **BRIVUDINUM\*#** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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Prescriere limitată: **Tratamentul pacienţilor cu herpes zoster în decurs de 72 de ore de la debutul rash-ului.**

J05ABN1 BRIVUDINUM COMPR. 125 mg

BRIVAL(R) 125 mg BERLIN CHEMIE AG MENARINI

GROUP

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| **302** |**L01AA01**| **CYCLOPHOSPHAMIDUM\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L01AA01 CYCLOPHOSPHAMIDUM DRAJ. 50 mg

ENDOXAN(R) 50 mg 50 mg BAXTER ONCOLOGY GMBH

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| **305** |**L02AE04**| **TRIPTORELINUM\*\*\*#** | **Protocol: L013E** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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Prescriere limitată: **Tratamentul de scurtă durată (până la 6 luni) al**

**endometriozei confirmate histologic.**

**Tratamentul pubertăţii precoce.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

L02AE04 TRIPTORELINUM LIOF. + SOLV. PT. 0.1 mg

SOL. INJ.

DIPHERELINE 0,1 mg 0.1 mg BEAUFOUR IPSEN PHARMA

L02AE04 TRIPTORELINUM LIOF. + SOLV. PT. SUSP. 11.25 mg

INJ. I.M. ELIB. PREL

DIPHERELINE(R) 11,25 mg 11.25 mg BEAUFOUR IPSEN PHARMA

L02AE04 TRIPTORELINUM LIOF. +SOLV. PT. SUSP. 3.75 mg

INJ. I.M. ELIB. PREL.

DIPHERELINE(R) 3,75 mg 3.75 mg BEAUFOUR IPSEN PHARMA

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| **306** |**L04AX01**| **AZATHIOPRINUM\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L04AX01 AZATHIOPRINUM COMPR. FILM. 50 mg

IMURAN(R) 50 mg THE WELLCOME FOUNDATION

LTD.

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| **307** |**M01AC01**| **PIROXICAMUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A se administra cu precauţie la pacienţii cu istoric de factori de risc sau afecţiuni gastrointestinale.

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

M01AC01 PIROXICAMUM COMPR. 20 mg

FLAMEXIN 20 mg CHIESI FARMACEUTICI SPA

N-PIROXICAM MEDUMAN 20 mg 20 mg MEDUMAN S.A.

PIROXICAM 20 mg 20 mg ARENA GROUP SA

PIROXICAM LPH 20 mg 20 mg LABORMED PHARMA SA

PIROXSAL 20 mg SLAVIA PHARM SRL

M01AC01 PIROXICAMUM COMPR. EFF. 20 mg

FLAMEXIN 20 mg CHIESI FARMACEUTICI S.P.A.

M01AC01 PIROXICAMUM SUPOZ. 20 mg

PIROXICAM 20 mg 20 mg SINTOFARM SA

M01AC01 PIROXICAMUM SOL. INJ. 20 mg/ml

FELDENE(R) 20 mg/ml 20 mg/ml PFIZER EUROPE MA EEIG

HOTEMIN 20 mg/ml EGIS PHARMACEUTICALS PLC

M01AC01 PIROXICAMUM PULB. PT. SOL. ORALĂ 20 mg/plic

FLAMEXIN(R) 20 mg/plic CHIESI FARMACEUTICI SPA

M01AC01 PIROXICAMUM SUPOZ. 40 mg

PIROXICAM 40 mg 40 mg ANTIBIOTICE SA

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| **308** |**M01AC05**| **LORNOXICAMUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A se administra cu precauţie la pacienţii cu istoric de factori de risc sau afecţiuni gastrointestinale.

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

M01AC05 LORNOXICAMUM COMPR. FILM. 4 mg

XEFO(R) 4 mg 4 mg NYCOMED AUSTRIA GMBH

M01AC05 LORNOXICAMUM COMPR. FILM. 8 mg

XEFO(R) 8 mg 8 mg NYCOMED AUSTRIA GMBH

M01AC05 LORNOXICAMUM PULB. + SOLV. PT. 8 mg/2 ml

SOL. INJ.

XEFO 8 mg/2 ml 8 mg/2 ml NYCOMED AUSTRIA GMBH

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| **309** |**M01AE17**| **DEXKETOPROFENUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A se administra cu precauţie la pacienţii cu istoric de factori de risc sau afecţiuni gastrointestinale.

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

M01AE17 DEXKETOPROFENUM COMPR. FILM. 25 mg

TADOR 25 mg BERLIN CHEMIE AG MENARINI

GROUP

M01AE17 DEXKETOPROFENUM SOL. INJ./CONC. 50 mg/2 ml

PT. SOL. PERF.

TADOR INJECT 50 mg/2 ml MENARINI INTERNATIONAL

OPERATIONS S.A.

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| **310** |**M01AH01**| **CELECOXIBUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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Prescriere limitată: Tratamentul simptomatic antiinflamator la pacienţii cu intoleranţă la AINS neselective.

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

M01AH01 CELECOXIBUM CAPS. 100 mg

CELEBREX 100 mg 100 mg PFIZER EUROPE MA EEIG

M01AH01 CELECOXIBUM CAPS. 200 mg

CELEBREX 200 mg 200 mg PFIZER EUROPE MA EEIG

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| **311** |**M01AH05**| **ETORICOXIBUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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Prescriere limitată: **Tratamentul simptomatic antiinflamator la pacienţii cu intoleranţă la AINS neselective.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

M01AH05 ETORICOXIBUM COMPR. FILM. 120 mg

ARCOXIA(R) 120 mg 120 mg MERCK SHARP & DOHME

ROMANIA S.R.L

M01AH05 ETORICOXIBUM COMPR. FILM. 60 mg

ARCOXIA(R) 60 mg 60 mg MERCK SHARP & DOHME

ROMANIA S.R.L

M01AH05 ETORICOXIBUM COMPR. FILM. 90 mg

ARCOXIA(R) 90 mg 90 mg MERCK SHARP & DOHME

ROMANIA S.R.L

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| **312** |**M01AX05**| **GLUCOSAMINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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M01AX05 GLUCOSAMINUM PULB. PT. SOL. ORALĂ 150 mg/plic

DONA(R) 150 mg/plic ROTTAPHARM SPA

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| **313** |**M01AX17**| **NIMESULIDUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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A se administra cu precauţie la pacienţii cu istoric de factori de risc sau afecţiuni gastrointestinale.

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

M01AX17 NIMESULIDUM COMPR. 100 mg

APONIL 100 mg MEDOCHEMIE LTD

AULIN(R) 100 mg 100 mg CSC PHARMACEUTICALS

HANDELS GMBH

COXTRAL 100 mg ZENTIVA AS

LEMESIL 100 mg ANFARM HELLAS S.A.

PHARMACEUTICALS

NIMESULID LPH 100 mg 100 mg LABORMED PHARMA SA

NIMESULID 100 mg 100 mg MAGISTRA C & C

NIMESULID ARENA 100 mg 100 mg ARENA GROUP S.A.

NIMESULID SLAVIA 100 mg SLAVIA PHARM SRL

NISE 100 mg 100 mg DR. REDDY'S LABORATORIES

M01AX17 NIMESULIDUM PULB. PT. SUSP. ORALĂ 100 mg

SULIDAMOR 100 mg FARMACEUTICI DAMOR SPA

M01AX17 NIMESULIDUM GRAN. PT. SUSP. ORALĂ 100 mg/plic

AULIN(R) 100 mg/plic CSC PHARMACEUTICALS

HANDELS GMBH

NIMESIL 100 mg/plic LAB. GUIDOTTI SPA

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| **314** |**M03BX01**| **BACLOFENUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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M03BX01 BACLOFENUM COMPR. 10 mg

LIORESAL(R) 10 mg NOVARTIS PHARMA GMBH

M03BX01 BACLOFENUM COMPR. 25 mg

LIORESAL(R) 25 mg NOVARTIS PHARMA GMBH

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| **315** |**M05BA04**| **ACIDUM ALENDRONICUM\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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**Cod restricţie 3001: Tratamentul osteoporozei la pacienţi cu scor T </= - 2,5 măsurat DEXA (coloană vertebrală sau şold).**

**Cod restricţie 3002: Tratamentul osteoporozei la pacienţi cu scor T </= - 2 măsurat DEXA (coloană vertebrală sau şold) şi istoric de fracturi pe structuri osoase fragile.**

**Cod restricţie 3003: Tratamentul osteoporozei la paciente în postmenopauză care au suferit fracturi vertebrale osteoporotice în antecedente.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

M05BA04 ACIDUM ALENDRONICUM COMPR. 10 mg

FOSAMAX 10 mg 10 mg MERCK SHARP & DOHME S.R.L

M05BA04 ACIDUM ALENDRONICUM COMPR. 70 mg

FOSAMAX 70 mg 70 mg MERCK SHARP & DOHME S.R.L

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| **316** |**M05BA06**| **ACIDUM IBANDRONICUM\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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**Cod restricţie 3001: Tratamentul osteoporozei la pacienţi cu scor T </= - 2,5 măsurat DEXA (coloană vertebrală sau şold).**

**Cod restricţie 3002: Tratamentul osteoporozei la pacienţi cu scor T </= - 2 măsurat DEXA (coloană vertebrală sau şold) şi istoric de fracturi pe structuri osoase fragile.**

**Cod restricţie 3003: Tratamentul osteoporozei la paciente în postmenopauză care au suferit fracturi vertebrale osteoporotice în antecedente.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

M05BA06 ACIDUM IBANDRONICUM COMPR. FILM. 150 mg

BONVIVA 150 mg 150 mg ROCHE REGISTRATION LTD.

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| **317** |**M05BA07**| **ACIDUM RISEDRONICUM\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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**Cod restricţie 3001: Tratamentul osteoporozei la pacienţi cu scor T </= - 2,5 măsurat DEXA (coloană vertebrală sau şold).**

**Cod restricţie 3002: Tratamentul osteoporozei la pacienţi cu scor T </= - 2 măsurat DEXA (coloană vertebrală sau şold) şi istoric de fracturi pe structuri osoase fragile.**

**Cod restricţie 3003: Tratamentul osteoporozei la paciente în postmenopauză care au suferit fracturi vertebrale osteoporotice în antecedente.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

M05BA07 ACIDUM RISEDRONICUM COMPR. FILM. 35 mg

ACTONEL(R) SAPTAMANAL 35 mg AVENTIS PHARMA AB

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| **318** |**M05BX03**| **STRONTIUM RANELATUM\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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M05BX03 STRONTIUM RANELATUM GRAN. PT. SUSP. ORALĂ 2 g

OSSEOR 2 g 2 g LES LAB. SERVIER

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| **319** |**M05BB03**| **COMBINATII (ACIDUM ALENDRONICUM +** | |

| | | **COLECALCIFEROLUM)\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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**Cod restricţie 3001: Tratamentul osteoporozei la pacienţi cu scor T </= - 2,5 măsurat DEXA (coloană vertebrală sau şold).**

**Cod restricţie 3002: Tratamentul osteoporozei la pacienţi cu scor T </= - 2 măsurat DEXA (coloană vertebrală sau şold) şi istoric de fracturi pe structuri osoase fragile.**

**Cod restricţie 3003: Tratamentul osteoporozei la paciente în postmenopauză care au suferit fracturi vertebrale osteoporotice în antecedente.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

M05BB03 COMBINATII (ACIDUM COMPR. 70 mg/2800 UI

ALENDRONICUM +

COLECALCIFEROLUM)

FOSAVANCE 70 mg/2800 UI 70 mg/2800 UI MERCK SHARP & DOHME LTD.

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| **320** |**N02AA05**| **OXYCODONUM\*#** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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Prescriere limitată: **Durere severă, invalidantă, care nu răspunde la**

**analgezice non-opioide.**

**Durere cronică severă, invalidantă, care nu răspunde la**

**analgezice non-opioide, unde durata totală a**

**tratamentului opioid este mai scurtă de 12 luni.**

Risc înalt de apariţie a dependenţei.

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

N02AA05 OXYCODONUM COMPR. FILM. ELIB. 10 mg

MODIF.

OXYCONTIN(R) 10 mg 10 mg MUNDIPHARMA GMBH

N02AA05 OXYCODONUM COMPR. FILM. ELIB. 20 mg

MODIF.

OXYCONTIN(R) 20 mg 20 mg MUNDIPHARMA GMBH

N02AA05 OXYCODONUM COMPR. FILM. ELIB. 40 mg

MODIF.

OXYCONTIN(R) 40 mg 40 mg MUNDIPHARMA GMBH

N02AA05 OXYCODONUM COMPR. FILM. ELIB. 80 mg

MODIF.

OXYCONTIN(R) 80 mg 80 mg MUNDIPHARMA GMBH

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| **321** |**N02AA08**| **DIHYDROCODEINUM\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N02AA08 DIHYDROCODEINUM COMPR. ELIB. PREL. 120 mg

DHC CONTINUS 120 mg 120 mg MUNDIPHARMA GMBH

N02AA08 DIHYDROCODEINUM COMPR. ELIB. PREL. 60 mg

DHC CONTINUS 60 mg 60 mg MUNDIPHARMA GMBH

N02AA08 DIHYDROCODEINUM COMPR. ELIB. PREL. 90 mg

DHC CONTINUS 90 mg 90 mg MUNDIPHARMA GMBH

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| **322** |**N02AX52**| **COMBINATII (TRAMADOLUM + PARACETAMOLUM)** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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Prescriere limitată: **Durere severă, care nu răspunde la analgezice**

**non-opioide.**

**Pentru durere acută la care tratamentul cu aspirină**

**şi/sau paracetamol este contraindicat sau nu a dat**

**rezultate.**

N02AX52 COMBINATII COMPR. FILM. 37,5 mg + 325 mg

(TRAMADOLUM +

PARACETAMOLUM)

ZALDIAR(R) 37,5 mg + 325 mg GRUNENTHAL GMBH

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| **323** |**N03AE01**| **CLONAZEPAMUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N03AE01 CLONAZEPAMUM COMPR. 0.5 mg

RIVOTRIL 0.5 mg ROCHE ROMANIA S.R.L

N03AE01 CLONAZEPAMUM COMPR. 2 mg

RIVOTRIL(R) 2 mg ROCHE ROMANIA S.R.L.

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| **324** |**N03AX16**| **PREGABALINUM\*\*#** | **Protocol: N025G;**|

| | | | **N032G** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N03AX16 PREGABALINUM CAPS. 150 mg

LYRICA 150 mg 150 mg PFIZER LTD.

N03AX16 PREGABALINUM CAPS. 300 mg

LYRICA 300 mg 300 mg PFIZER LTD.

N03AX16 PREGABALINUM CAPS. 75 mg

LYRICA 75 mg 75 mg PFIZER LTD.

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| **326** |**N04BC05**| **PRAMIPEXOLUM\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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Prescriere limitată: **Tratamentul simptomatic al sindromului idiopatic al**

**picioarelor neliniştite, forme moderate/severe.**

La acest medicament au fost raportate episoade de instalare bruscă a somnului fără avertizare în timpul activităţii.

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

N04BC05 PRAMIPEXOLUM COMPR. 0.18 mg

MIRAPEXIN 0,18 mg 0.18 mg BOEHRINGER INGELHEIM

INTERNATIONAL GMBH

N04BC05 PRAMIPEXOLUM COMPR. 0.7 mg

MIRAPEXIN 0,7 mg 0.7 mg BOEHRINGER INGELHEIM

INTERNATIONAL GMBH

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| **327** |**N04BXN1**| **PIRIBEDILUM\*\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N04BXN1 PIRIBEDILUM DRAJ. ELIB. PREL. 50 mg

PRONORAN(R) 50 mg LP 50 mg LES LAB. SERVIER IND.

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| **328** |**N05AL03**| **TIAPRIDUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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N05AL03 TIAPRIDUM COMPR. 100 mg

TIAPRIDAL(R) 100 mg 100 mg SANOFI-SYNTHELABO FRANCE

N05AL03 TIAPRIDUM SOL. INJ. 100 mg/2 ml

TIAPRIDAL 100 mg/2 ml 100 mg/2 ml SANOFI-AVENTIS FRANCE

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| **329** |**N05BE01**| **BUSPIRONUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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Prescriere limitată: **Pentru tratamentul de scurta durata al anxietăţii.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

N05BE01 BUSPIRONUM COMPR. 10 mg

SPITOMIN 10 mg 10 mg EGIS PHARMACEUTICALS PLC

STRESSIGAL 10 mg ANFARM HELLAS S.A.

PHARMACEUTICALS

N05BE01 BUSPIRONUM COMPR. 5 mg

SPITOMIN 5 mg 5 mg EGIS PHARMACEUTICALS PLC

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| **330** |**N06AA21**| **MAPROTILINUM\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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N06AA21 MAPROTILINUM COMPR. FILM. 10 mg

LUDIOMIL(R) 10 mg 10 mg NOVARTIS PHARMA GMBH

N06AA21 MAPROTILINUM COMPR. FILM. 25 mg

LUDIOMIL(R) 25 mg 25 mg NOVARTIS PHARMA GMBH

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| **331** |**N06AB10**| **ESCITALOPRAMUM\*\*** | **Protocol: N009F** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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N06AB10 ESCITALOPRAMUM COMPR. FILM. 10 mg

CIPRALEX 10 mg 10 mg H. LUNDBECK A/S

N06AB10 ESCITALOPRAMUM COMPR. FILM. 5 mg

CIPRALEX 5 mg 5 mg H. LUNDBECK A/S

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| **332** |**N06AX05**| **TRAZODONUM\*\*** | **Protocol: N010F** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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N06AX05 TRAZODONUM COMPR. ELIB. PREL. 150 mg

TRITTICO AC 150 mg 150 mg ANGELINI FRANCESCO SPA

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| **333** |**N06AX14**| **TIANEPTINUM\*\*** | **Protocol: N011F** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N06AX14 TIANEPTINUM DRAJ. 12.5 mg

COAXIL(R) 12.5 mg LES LAB. SERVIER IND.

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| **334** |**N06AX17**| **MILNACIPRANUM\*\*** | **Protocol: N002F** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N06AX17 MILNACIPRANUM CAPS. 25 mg

IXEL 25 mg PIERRE FABRE MEDICAMENT

N06AX17 MILNACIPRANUM CAPS. 50 mg

IXEL 50 mg PIERRE FABRE MEDICAMENT

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| **335** |**N06AX21**| **DULOXETINUM\*\*** | **Protocol: N014F** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N06AX21 DULOXETINUM CAPS. GASTROREZ. 30 mg

CYMBALTA 30 mg 30 mg ELI LILLY NEDERLAND BV

N06AX21 DULOXETINUM SOL. PERF. 100 mg/50 ml

CYMBALTA 60 mg 60 mg ELI LILLY NEDERLAND BV

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| **336** |**N06AXN1**| **BUPROPIONUM\*\*#** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N06AXN1 BUPROPIONUM COMPR. FILM. ELIB. PREL. 150 mg

WELLBUTRIN SR 150 mg 150 mg GLAXO WELLCOME UK LTD.

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| **337** |**N06BX16**| **PRAMIRACETAMUM\*\*#** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N06BX16 PRAMIRACETAMUM COMPR. FILM. 600 mg

PRAMISTAR 600 mg F.I.R.M.A. S.p.a.

(MENARINI GROUP)

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| **338** |**N06BX18**| **VINPOCETINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N06BX18 VINPOCETINUM COMPR. 10 mg

CAVINTON(R) FORTE 10 mg GEDEON RICHTER LTD.

N06BX18 VINPOCETINUM CAPS. 5 mg

VIMPOCETIN 5 mg 5 mg VIM SPECTRUM SRL

N06BX18 VINPOCETINUM COMPR. 5 mg

CAVINTON(R) 5 mg GEDEON RICHTER LTD.

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| **339** |**N07CA01**| **BETAHISTINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N07CA01 BETAHISTINUM COMPR. 16 mg

BETASERC(R) 16 mg 16 mg SOLVAY PHARMACEUTICALS BV

N07CA01 BETAHISTINUM COMPR. 24 mg

BETASERC(R) 24 mg 24 mg SOLVAY PHARMACEUTICALS BV

N07CA01 BETAHISTINUM COMPR. 80 mg

URUTAL 8 mg 80 mg A & G MED TRADING S.R.L.

N07CA01 BETAHISTINUM COMPR. 8 mg

BETASERC(R) 8 mg 8 mg SOLVAY PHARMACEUTICALS BV

MICROSER 8 mg PRODOTTI FORMENTI

VESTIBO 8 mg 8 mg ACTAVIS GROUP HF.

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| **340** |**N07CA52**| **COMBINATII (CINNARIZINUM + DIMENHIDRATUM)** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N07CA52 COMBINATII COMPR.

(CINNARIZINUM +

DIMENHIDRATUM)

ARLEVERT HENNIG ARZNEIMITTEL GMBH &

CO.KG

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| **341** |**N07XN01**| **HIDROLIZAT DE PROTEINA DIN CREIER DE** | **Protocol: N026F** |

| | | **PORCINA\*\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N07XN01 HIDROLIZAT DE SOL. INJ./PERF. 215.2 mg/ml

PROTEINA DIN CREIER

DE PORCINA

CEREBROLYSIN(R) 215.2 mg/ml EBEWE PHARMA GMBH NFG.KG

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| **342** |**P01BA02**| **HYDROXYCHLOROQUINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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P01BA02 HYDROXYCHLOROQUINUM COMPR. FILM. 200 mg

PLAQUENIL(R) 200 mg SANOFI-SYNTHELABO LTD.

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| **343** |**R03AC04**| **FENOTEROLUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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R03AC04 FENOTEROLUM SOL. DE INHALAT 100 µg/doză

PRESURIZATĂ

BEROTEC N-100 µg/doză 100 µg/doză BOEHRINGER INGELHEIM

INT. GMBH

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| **344** |**R01AD05**| **BUDESONIDUM\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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Prescriere limitată: **Profilaxia şi tratamentul rinitei alergice.**

R01AD05 BUDESONIDUM SPRAY NAZAL SUSP. 32 µg/doză

RHINOCORT(R) AQUA 32 µg/doză ASTRAZENECA AB

R01AD05 BUDESONIDUM SPRAY NAZ. SUSP. 50 µg/doză

TAFEN NASAL 50 µg/doză LEK PHARMACEUTICALS D.D.

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| **345** |**R01AD08**| **FLUTICASONUM\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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R01AD08 FLUTICASONUM SPRAY NAZAL SUSP. 50 µg/doză

FLIXONASE(R) 50 µg/doză GLAXOWELLCOME UK LTD.

Prescriere limitată: **Profilaxia şi tratamentul rinitei alergice**

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| **346** |**R01AD09**| **MOMETASONUM\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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R01AD09 MOMETASONUM SPRAY NAZAL SUSP. 50 µg/doză

NASONEX 50 µg/doză SCHERING PLOUGH EUROPE

Prescriere limitată: **Profilaxia şi tratamentul rinitei alergice.**

Prescriere limitată: **Tratamentul polipozelor nazale a adultului.**

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| **347** |**R03AK03**| **COMBINATII (FENOTEROLUM + IPRATROPIUM)\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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R03AK03 COMBINATII AEROSOL SOL. INHAL. 0,020 mg + 0,050 mg

(FENOTEROLUM +

IPRATROPIUM)

BERODUAL(R) N 0,020 mg + 0,050 mg BOEHRINGER INGELHEIM

INT. GMBH

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| **348** |**R03AK06**| **COMBINATII (SALMETEROLUM + FLUTICASONUM)\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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Prescriere limitată: **Tratament simptomatic al bolii pulmonare cronice**

**obstructive (BPOC) la pacienţii cu FEV1 mai mică decât**

**50% faţă de normal şi cu istoric de exacerbări repetate**

**şi simptome importante în timpul tratamentului**

**bronhodilatator cu agonişti ai receptorilor beta-2**

**adrenergici.**

**Tratamentul astmului bronşic care nu este controlat**

**adecvat cu corticosteroizi inhalatori şi**

**beta-2-agonişti inhalatori de scurtă durată.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

R03AK06 COMBINATII AEROSOL SUSP. INHAL. 25 mg/125 mg

(SALMETEROLUM +

FLUTICASONUM)

SERETIDE(R) 25/125 µg 25 mg/125 mg GLAXOWELLCOME UK LTD.

INHALER CFC FREE

R03AK06 COMBINATII AEROSOL SUSP. INHAL. 25 mg/250 mg

(SALMETEROLUM +

FLUTICASONUM)

SERETIDE(R) 25/250 µg 25 mg/250 mg GLAXOWELLCOME UK LTD.

NHALER CFC FREE

R03AK06 COMBINATII AEROSOL SUSP. INHAL. 25 mg/50 mg

(SALMETEROLUM +

FLUTICASONUM)

SERETIDE(R) 25/50 µg 25 mg/50 mg GLAXOWELLCOME UK LTD.

INHALER CFC FREE

R03AK06 COMBINATII PULB. INHAL. 50 mg/100 mg

(SALMETEROLUM +

FLUTICASONUM)

SERETIDE DISKUS 50/100 50 mg/100 mg GLAXO WELLCOME UK LIMITED

R03AK06 COMBINATII PULB. INHAL. 50 mg/250 mg

(SALMETEROLUM +

FLUTICASONUM)

SERETIDE DISKUS 50/250 50 mg/250 mg GLAXOWELLCOME UK LTD.

R03AK06 COMBINATII PULB. INHAL. 50 mg/500 mg

(SALMETEROLUM +

FLUTICASONUM)

SERETIDE DISKUS 50/500 50 mg/500 mg GLAXOWELLCOME UK LTD.

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| **349** |**R03AK07**| **COMBINATII (BUDESONIDUM + FORMOTEROLUM)\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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Prescriere limitată: **Tratament simptomatic al bolii pulmonare cronice**

**obstructive (BPCO) la pacienţii cu FEV1 mai mică decât**

**50% faţă de normal şi cu istoric de exacerbări repetate**

**şi simptome importante în timpul tratamentului**

**bronhodilatator cu agonişti ai receptorilor beta-2**

**adrenergici.**

**Tratamentul astmului bronşic care nu este controlat**

**adecvat cu corticosteroizi inhalatori şi**

**beta-2-agonişti inhalatori de scurtă durată.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

R03AK07 COMBINATII PULB. INHAL. 160/4.5 µg

(BUDESONIDUM +

FORMOTEROLUM)

SYMBIOCORT(R) TURBUHALER(R) 160/4.5 µg ASTRAZENECA AB

160/4,5 µg

R03AK07 COMBINATII PULB. INHAL. 320/9 µg

(BUDESONIDUM +

FORMOTEROLUM)

SYMBIOCORT(R) TURBUHALER(R) 320/9 µg ASTRAZENECA AB

320/9 µg

R03AK07 COMBINATII PULB. INHAL. 80/4.5 µg

(BUDESONIDUM +

FORMOTEROLUM)

SYMBIOCORT(R) TURBUHALER(R) 80/4.5 µg ASTRAZENECA AB

80/4,5 µg

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| **350** |**R03BA05**| **FLUTICASONUM\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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Prescriere limitată: **Tratamentul de control al astmului bronşic persistent.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

R03BA05 FLUTICASONUM SUSP. INHAL. 0.5 mg/2 ml

FLIXOTIDE(R) NEBULES(R) 0.5 mg/2 ml GLAXO WELLCOME UK LTD.

0.5 mg/2 ml

R03BA05 FLUTICASONUM SUSP. INHAL. 125 µg/doză

PRESURIZATĂ

FLIXOTIDE 125 INHALER 125 µg/doză GLAXO WELLCOME UK LTD.

CFC - Free

R03BA05 FLUTICASONUM SUSP. INHAL. 2 mg/2 ml

FLIXOTIDE(R) NEBULES(R) 2 mg/2 ml GLAXO WELLCOME UK LTD.

2 mg/2 ml

R03BA05 FLUTICASONUM SUSP. INHAL. 50 µg/doză

PRESURIZATĂ

FLIXOTIDE(R) 50 INHALER 50 µg/doză GLAXO WELLCOME UK LTD.

CFC - Free

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| **352** |**R03BA08**| **CICLESONIDUM\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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Prescriere limitată: **Tratamentul de fond al astmului bronşic persistent.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

R03BA08 CICLESONIDUM SOL. DE INHALAT 160 µg/doză

PRESURIZATĂ

ALVESCO 160 INHALER 160 µg/doză ALTANA PHARMA AG

R03BA08 CICLESONIDUM SOL. DE INHALAT 80 µg/doză

PRESURIZATĂ

ALVESCO 80 INHALER 80 µg/doză ALTANA PHARMA AG

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| **353** |**R03BB04**| **TIOTROPIUM\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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R03BB04 TIOTROPIUM CAPS. CU PULB. INHAL. 18 µg

SPIRIVA(R) 18 µg 18 µg BOEHRINGER INGELHEIM

PHARMA GMBH & CO.KG

Prescriere limitată: **Pentru tratamentul de întreţinere pe termen lung al bronhospasmului şi dispneei asociate bolii pulmonare obstructive cronice**

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| **354** |**R03DA05**| **AMINOPHYLLINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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R03DA05 AMINOPHYLLINUM CAPS. 100 mg

MIOFILIN 100 mg 100 mg ZENTIVA SA

R03DA05 AMINOPHYLLINUM COMPR. 100 mg

AMINOFILINA EEL 100 mg BIO EEL SRL

R03DA05 AMINOPHYLLINUM COMPR. 200 mg

AMINOFILINA 200 mg 200 mg ARENA GROUP SA

R03DA05 AMINOPHYLLINUM SOL. INJ. 24 mg/ml

MIOFILIN 24 mg/ml ZENTIVA S.A.

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| **355** |**R03DC03**| **MONTELUKASTUM\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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R03DC03 MONTELUKASTUM COMPR. FILM. 10 mg

SINGULAIR(R) 10 mg MERCK SHARP & DOHME

ROMANIA S.R.L.

Prescriere limitată: **Tratamentul combinat al astmului bronşic persistent la pacienţii cu simptomatologie necontrolată corespunzător cu corticosteroizi inhalatori şi beta-2-agonişti cu durată scurtă de acţiune.**

R03DC03 MONTELUKASTUM COMPR. MAST. 4 mg

SINGULAIR 4 mg MERCK SHARP & DOHME S.R.L.

Prescriere limitată: **Tratamentul combinat al astmului bronşic persistent la pacienţii cu simptomatologie necontrolată corespunzător cu corticosteroizi inhalatori şi beta-2-agonişti cu durată scurtă de acţiune.**

Cod restricţie 2617: **Tratamentul astmului bronşic persistent la copii cu vârste cuprinse între 2 şi 5 ani la care nu se poate administra terapie cu corticosteroizi inhalatori.**

R03DC03 MONTELUKASTUM GRANULE 4 mg/plic

SINGULAIR(R) 4 mg/plic MERCK SHARP & DOHME

ROMANIA S.R.L.

Prescriere limitată: **Tratamentul combinat al astmului bronşic persistent la pacienţii cu simptomatologie necontrolată corespunzător cu corticosteroizi inhalatori şi beta-2-agonişti cu durată scurtă de acţiune.**

Cod restricţie 2617: **Tratamentul astmului bronşic persistent la copii cu vârste cuprinse între 2 şi 5 ani la care nu se poate administra terapie cu corticosteroizi inhalatori.**

R03DC03 MONTELUKASTUM COMPR. MAST. 5 mg

SINGULAIR(R) 5 mg MERCK SHARP & DOHME

ROMANIA S.R.L.

Prescriere limitată: **Tratamentul combinat al astmului bronşic persistent la pacienţii cu simptomatologie necontrolată corespunzător cu corticosteroizi inhalatori şi beta-2-agonişti cu durată scurtă de acţiune.**

Cod restricţie 2617: **Tratamentul astmului bronşic persistent la copii cu vârste cuprinse între 6 şi 14 ani la care nu se poate administra terapie cu corticosteroizi inhalatori.**

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| **356** |**R03DX03**| **FENSPIRIDUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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R03DX03 FENSPIRIDUM SIROP 0.2%

EURESPAL(R) 0.2% LES LAB. SERVIER IND.

R03DX03 FENSPIRIDUM COMPR. FILM. 80 mg

EURESPAL 80 mg 80 mg LES LAB. SERVIER IND.

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| **357** |**R05CB15**| **ERDOSTEINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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R05CB15 ERDOSTEINUM PULB. PT. SUSP. ORALĂ 175 mg/5 ml

ERDOMED(R) 175 175 mg/5 ml CSC PHARMACEUTICALS

HANDELS GMBH

R05CB15 ERDOSTEINUM CAPS. 300 mg

ERDOMED 300 mg MEDICOM INTERNATIONAL SRO

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| **358** |**R05DA09**| **DEXTROMETHORPHANUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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R05DA09 DEXTROMETHORPHANUM SIROP 0.1%

HUMEX 0.1% LAB. URGO SA

TUSSIN SIROP 0.1% GLOBAL PHARMACEUTICALS

S.R.L.

R05DA09 DEXTROMETHORPHANUM SIROP 0.13%

HUMEX 0.13% LAB. URGO SA

R05DA09 DEXTROMETHORPHANUM COMPR. 10 mg

TUSSIN 10 mg EUROPHARM SA

R05DA09 DEXTROMETHORPHANUM SIROP 15 mg/5 ml

ROFEDEX 15 mg/5 ml BIOFARM SA

R05DA09 DEXTROMETHORPHANUM COMPR. 20 mg

TUSSIN FORTE 20 mg EUROPHARM SA

R05DA09 DEXTROMETHORPHANUM SOL. ORALĂ 3.75 mg/5 ml

ROBITUSSIN JUNIOR 3.75 mg/5 ml WYETH WHITEHALL EXPORT

GMBH

R05DA09 DEXTROMETHORPHANUM SOL. ORALĂ 7.5 mg/5 ml

ROBITUSSIN ANTITUSSICUM 7.5 mg/5 ml WYETH WHITEHALL EXPORT

GMBH

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| **359** |**R06AE09**| **LEVOCETIRIZINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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R06AE09 LEVOCETIRIZINUM COMPR. FILM. 5 mg

XYZAL(R) 5 mg U.C.B. GMBH

R06AE09 LEVOCETIRIZINUM PIC. ORALE, SOL. 5 mg/ml

XYZAL 5 mg/ml U.C.B. GMBH

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| **360** |**R06AX26**| **FEXOFENADINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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R06AX26 FEXOFENADINUM COMPR. FILM. 120 mg

ALTIVA 120 mg 120 mg RANBAXY UK LTD.

TELFAST(R) 120 mg 120 mg AVENTIS PHARMA DEUTSCHLAND

GMBH

R06AX26 FEXOFENADINUM COMPR. FILM. 180 mg

ALTIVA 180 mg 180 mg RANBAXY UK LTD.

TELFAST(R) 180 mg 180 mg AVENTIS PHARMA DEUTSCHLAND

GMBH

R06AX26 FEXOFENADINUM COMPR. FILM. 30 mg

TELFAST(R) 30 mg 30 mg AVENTIS PHARMA DEUTSCHLAND

GMBH

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| **361** |**R06AX27**| **DESLORATADINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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R06AX27 DESLORATADINUM SIROP 0.5 mg/ml

AERIUS 0.5 mg/ml 0.5 mg/ml SP EUROPE

R06AX27 DESLORATADINUM COMPR. FILM. 5 mg

AERIUS 5 mg 5 mg SP EUROPE

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| **362** |**S01AA11**| **GENTAMICINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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S01AA11 GENTAMICINUM PICĂTURI OFT. - SOL. 0.3%

OPHTAGRAM(R) 0,3% 0.3% LAB. CHAUVIN

S01AA11 GENTAMICINUM SOL. OFT. 0.3%

GENTICOL 0.3% S.I.F.I. SPA

S01AA11 GENTAMICINUM UNG. OFT. 0.3%

GENTICOL 0.3% S.I.F.I. SPA

OPHTAGRAM(R) 0,3% 0.3% LAB. CHAUVIN

S01AA11 GENTAMICINUM PIC. OFT., SOL. 0.3%

GENTAMICIN SULPHATE 0.3% E.I.P.I.CO. MED S.R.L.

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| **363** |**S01AA12**| **TOBRAMYCINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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S01AA12 TOBRAMYCINUM UNG. OFT. 0.3%

TOBREX(R) 0.3% ALCON COUVREUR NV

S01AA12 TOBRAMYCINUM PIC. OFT., SOL. 0.3%

TOBISOL 0.3% E.I.P.I.CO. MED S.R.L.

S01AA12 TOBRAMYCINUM PIC. OFT., SOL. 3 mg/ml

TOBREX 3 mg/ml ALCON COUVREUR NV

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| **364** |**S01AA23**| **NETILMICINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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S01AA23 NETILMICINUM PICĂTURI OFT. - SOL. 0.3%

NETTACIN(R) 0.3% S.I.F.I. SPA

S01AA23 NETILMICINUM UNG. OFT. 3 mg/g

NETTAVISC 3 mg/g 3 mg/g S.I.F.I. SPA

S01AA23 NETILMICINUM PIC. OFT., SOL. 0.3%

NETTACIN(R) 0.3% S.I.F.I. SPA

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| **365** |**S01AX11**| **OFLOXACINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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S01AX11 OFLOXACINUM PICĂTURI OFT. - SOL. 0.3%

FLOXAL(R) 0.3% DR. GERHARD MANN

CHEM-PHARM. FABRIK GMBH

S01AX11 OFLOXACINUM UNG. OFT. 0.3%

FLOXAL(R) 0.3% DR. GERHARD MANN

CHEM-PHARM. FABRIK GMBH

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| **366** |**S01BA01**| **DEXAMETHASONUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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S01BA01 DEXAMETHASONUM PICĂTURI OFT. - SUSP. 0.1%

MAXIDEX(R) 0.1% ALCON COUVREUR NV

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| **367** |**S01BA06**| **BETAMETHASONUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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S01BA06 BETAMETHASONUM SOL. OFT. 0.1%

OPHTAMESONE 0.1% DAR AL DAWA PHARMA S.R.L.

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| **368** |**S01CA01**| **COMBINAŢII (NETILMICINUM + DEXAMETHASONUM)** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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S01CA01 COMBINAŢII PIC. OFT., SOL.

(NETILMICINUM +

DEXAMETHASONUM)

NETILDEX S.I.F.I. SPA

S01CA01 COMBINAŢII PIC. OFT. SOL. UNIDOZĂ

(NETILMICINUM +

DEXAMETHASONUM)

NETILDEX S.I.F.I. SPA

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| **369** |**S01CA01**| **COMBINAŢII (TOBRAMYCINUM + DEXAMETHASONUM)** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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S01CA01 COMBINAŢII UNG. OFT. 1 mg + 3 mg

(TOBRAMYCINUM +

DEXAMETHASONUM)

TOBRADEX(R) 1 mg + 3 mg ALCON COUVREUR NV

S01CA01 COMBINAŢII PICĂTURI OFT. - SUSP. 1 mg + 3 mg

(TOBRAMYCINUM +

DEXAMETHASONUM)

TOBRADEX(R) 1 mg + 3 mg ALCON COUVREUR NV

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| **370** |**S01CA01**| **COMBINAŢII (CHLORAMPHENICOLUM +** | |

| | | **DEXAMETHASONUM)**| | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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S01CA01 COMBINAŢII PICĂTURI OFT. - SOL. 5 mg/ml + 1 mg/ml

(CHLORAMPHENICOLUM +

DEXAMETHASONUM)

SPERSADEX COMP 5 mg/ml + 1 mg/ml NOVARTIS PHARMA GMBH

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| **371** |**S01GX09**| **OLOPATADINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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S01GX09 OLOPATADINUM PIC. OFT., SOL. 1 mg/ml

OPATANOL 1 mg/ml 1 mg/ml ALCON LABORATORIES LTD.

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| **372** |**S01XA02**| **RETINOLUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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S01XA02 RETINOLUM GEL OFT. 10 mg/g

OCULOTECT 10 mg/g NOVARTIS PHARMA GMBH

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| **1219** |**H03BB01**| **CARBIMAZOLUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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H03BB01 CARBIMAZOLUM COMPR. FILM. 5 mg

CARBIMAZOLE 5 5 mg REMEDICA LTD.

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**SUBLISTA C1 - G1 INSUFICIENŢA CARDIACĂ CRONICĂ (CLASA III SAU IV NYHA).**

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| **373** |**B01AA07**| **ACENOCUMAROLUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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B01AA07 ACENOCUMAROLUM COMPR. 2 mg

TROMBOSTOP 2 mg 2 mg TERAPIA SA

B01AA07 ACENOCUMAROLUM COMPR. 4 mg

SINTROM(R) 4 mg NOVARTIS PHARMA GMBH

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| **374** |**C01AA05**| **DIGOXINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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C01AA05 DIGOXINUM SOL. ORALĂ 0.05 mg/ml

LANOXIN SOLUŢIE ORALĂ 0.05 mg/ml THE WELLCOME FOUNDATION

LTD.

C01AA05 DIGOXINUM COMPR. 0.25 mg

DIGOXIN 0.25 mg 0.25 mg ZENTIVA S.A.

C01AA05 DIGOXINUM SOL. INJ. 0.5 mg/ml

DIGOXIN 0.5 mg/2 ml 0.5 mg/ml ZENTIVA S.A.

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| **375** |**C03AA03**| **HYDROCHLOROTHIAZIDUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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C03AA03 HYDROCHLOROTHIAZIDUM COMPR. 25 mg

NEFRIX 25 mg 25 mg ZENTIVA SA

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| **376** |**C03CA01**| **FUROSEMIDUM** | |

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Electroliţii serici trebuie să fie verificaţi periodic.

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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C03CA01 FUROSEMIDUM SOL. INJ. 10 mg/ml

FUROSEMID 20 mg/2 ml 10 mg/ml ZENTIVA SA

C03CA01 FUROSEMIDUM COMPR. 40 mg

FUROSEMID ARENA 40 mg 40 mg ARENA GROUP SA

FUROSEMID EEL 40 mg BIO EEL SRL

FUROSEMID LPH 40 mg 40 mg LABORMED PHARMA SA

FUROSEMID MCC 40 mg 40 mg MAGISTRA C & C SRL

FUROSEMID SLAVIA 40 mg SLAVIA PHARM SRL

FUROSEMID ZENTIVA 40 mg ZENTIVA SA

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| **377** |**C03DA01**| **SPIRONOLACTONUM** | |

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Electroliţii serici trebuie să fie verificaţi periodic.

Femeile la vârsta fertilă la care s-a iniţiat tratament cu spironolactonă trebuie să ia măsuri adecvate de contracepţie.

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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C03DA01 SPIRONOLACTONUM CAPS. 100 mg

VEROSPIRON 100 mg GEDEON RICHTER LTD.

C03DA01 SPIRONOLACTONUM COMPR. 25 mg

SPIRONOLACTONA 25 mg 25 mg BIO EEL SRL

C03DA01 SPIRONOLACTONUM COMPR. FILM. 25 mg

ALSPIRON 25 mg 25 mg AC HELCOR PHARMA SRL

SPIRONOLACTONA 25 mg 25 mg TERAPIA SA

C03DA01 SPIRONOLACTONUM CAPS. 50 mg

VEROSPIRON 50 mg GEDEON RICHTER LTD.

C03DA01 SPIRONOLACTONUM COMPR. FILM. 50 mg

ALSPIRON 50 mg 50 mg AC HELCOR PHARMA SRL

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| **378** |**C07AB02**| **METOPROLOLUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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C07AB02 METOPROLOLUM COMPR. 100 mg

BETAPROL 100 mg 100 mg AC HELCOR PHARMA SRL

BLOXAN 100 mg KRKA D.D. NOVO MESTO

EGILOK 100 mg 100 mg EGIS PHARMACEUTICALS

P.L.C.

METOPRO TAD 100 100 mg TAD PHARMA GMBH

METOPROLOL 100 mg 100 mg OZONE LABORATORIES LTD.

METOPROLOL AL 100 100 mg ALIUD(R) PHARMA GMBH &

CO.KG

METOPROLOL LPH 100 mg 100 mg LABORMED PHARMA SA

METOPROLOL MEDICO UNO 100 mg 100 mg MEDICO UNO PHARMACEUTICAL

S.R.L.

METOPROLOL TERAPIA 100 mg 100 mg TERAPIA SA

VASOCARDIN(R) 100 100 mg SLOVAKOFARMA

C07AB02 METOPROLOLUM COMPR. ELIB. PREL. 100 mg

METOPROLOL RETARD 100 mg 100 mg TERAPIA S.A.

C07AB02 METOPROLOLUM COMPR. FILM. ELIB. 100 mg

PREL.

BETALOC(R) ZOC 100 mg 100 mg ASTRAZENECA AB

C07AB02 METOPROLOLUM COMPR. FILM. ELIB. 190 mg

MOD.

METOSUCCINAT SANDOZ 190 mg 190 mg HEXAL AG

C07AB02 METOPROLOLUM SOL. INJ. 1 mg/ml

BETALOC 1 mg/ml ASTRAZENECA AB

C07AB02 METOPROLOLUM COMPR. ELIB. PREL. 200 mg

VASOCARDIN(R) SR 200 200 mg ZENTIVA AS

C07AB02 METOPROLOLUM COMPR. 25 mg

EGILOK 25 mg 25 mg EGIS PHARMACEUTICALS

P.L.C.

METOPROLOL 25 mg 25 mg ARENA GROUP S.A.

METOPROLOL LPH 25 mg 25 mg LABORMED PHARMA SA

METOPROLOL MEDICO UNO 25 mg 25 mg MEDICO UNO PHARMACEUTICAL

S.R.L.

C07AB02 METOPROLOLUM COMPR. FILM. ELIB. 47.5 mg

MOD.

METOSUCCINAT SANDOZ 47,5 mg 47.5 mg HEXAL AG

C07AB02 METOPROLOLUM COMPR. 50 mg

BETAPROL 50 mg 50 mg AC HELCOR PHARMA SRL

EGILOK 50 mg 50 mg EGIS PHARMACEUTICALS

P.L.C.

METOPRO TAD 50 50 mg TAD PHARMA GMBH

METOPROLOL 50 mg 50 mg OZONE LABORATORIES LTD.

METOPROLOL AL 50 50 mg ALIUD PHARMA GMBH & CO.KG

METOPROLOL LPH 50 mg 50 mg LABORMED PHARMA SA

METOPROLOL MEDICO UNO 50 mg 50 mg MEDICO UNO PHARMACEUTICAL

S.R.L.

METOPROLOL TERAPIA 50 mg 50 mg TERAPIA SA

C07AB02 METOPROLOLUM COMPR. FILM. ELIB. 50 mg

PREL.

BETALOC(R) ZOC 50 mg 50 mg ASTRAZENECA AB

C07AB02 METOPROLOLUM COMPR. FILM. ELIB. MOD. 95 mg

METOSUCCINAT SANDOZ 95 mg 95 mg HEXAL AG

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| **379** |**C07AB07**| **BISOPROLOLUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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C07AB07 BISOPROLOLUM COMPR. FILM. 2.5 mg

CONCOR COR 2,5 mg 2.5 mg MERCK KGAA

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| **380** |**C07AB12**| **NEBIVOLOLUM\*\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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C07AB12 NEBIVOLOLUM COMPR. 5 mg

NEBILET(R) 5 mg BERLIN CHEMIE AG MENARINI

GROUP

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| **381** |**C07AG02**| **CARVEDILOLUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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C07AG02 CARVEDILOLUM COMPR. 12,5 mg

CARVEDILOL SANDOZ 12,5 mg HEXAL AG

C07AG02 CARVEDILOLUM COMPR. 12.5 mg

ATRAM 12,5 12.5 mg ZENTIVA AS

CARVEDILOL 12,5 mg 12.5 mg VIM SPECTRUM SRL

CARVEDILOL HELCOR 12,5 mg 12.5 mg AC HELCOR PHARMA SRL

CARVEDILOL LPH 12,5 mg 12.5 mg LABORMED PHARMA SA

CARVEDILOL TEVA 12,5 mg 12.5 mg TEVA PHARMACEUTICAL S.R.L.

CORYOL(R) 12.5 mg KRKA D.D.

DILATREND(R) 12,5 mg 12.5 mg ROCHE ROMANIA S.R.L.

TALLITON(R) 12,5 mg 12.5 mg EGIS PHARMACEUTICALS LTD.

C07AG02 CARVEDILOLUM COMPR. FILM. 12.5 mg

CARVEDIGAMMA 12,5 mg 12.5 mg WORWAG PHARMA GMBH & CO.KG

C07AG02 CARVEDILOLUM COMPR. 25 mg

ATRAM 25 25 mg ZENTIVA AS

CARVEDILOL HELCOR 25 mg 25 mg AC HELCOR PHARMA SRL

CARVEDILOL LPH 25 mg 25 mg LABORMED PHARMA SA

CARVEDILOL SANDOZ 25 mg HEXAL AG

CARVEDILOL TEVA 25 mg 25 mg TEVA PHARMACEUTICAL S.R.L.

CORYOL(R) 25 mg KRKA D.D.

DILATREND(R) 25 mg 25 mg ROCHE ROMANIA S.R.L.

TALLITON(R) 25 mg 25 mg EGIS PHARMACEUTICALS LTD.

C07AG02 CARVEDILOLUM COMPR. FILM. 25 mg

CARVEDIGAMMA 25 mg 25 mg WORWAG PHARMA GMBH & CO.KG

C07AG02 CARVEDILOLUM COMPR. 3.125 mg

CORYOL(R) 3,125 mg 3.125 mg KRKA D.D.

C07AG02 CARVEDILOLUM COMPR. 6.25 mg

ATRAM 6,25 6.25 mg ZENTIVA AS

CARVEDILOL 6,25 mg 6.25 mg VIM SPECTRUM SRL

CARVEDILOL LPH 6,25 mg 6.25 mg LABORMED PHARMA SA

CARVEDILOL SANDOZ 6.25 mg HEXAL AG

CARVEDILOL TEVA 6,25 mg 6.25 mg TEVA PHARMACEUTICAL S.R.L.

CORYOL(R) 6.25 mg KRKA D.D.

DILATREND(R) 6,25 mg 6.25 mg ROCHE ROMANIA S.R.L.

TALLITON 6,25 mg 6.25 mg EGIS PHARMACEUTICALS LTD.

C07AG02 CARVEDILOLUM COMPR. FILM. 6.25 mg

CARVEDIGAMMA 6,25 mg 6.25 mg WORWAG PHARMA GMBH & CO.KG

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| **382** |**C09AA01**| **CAPTOPRILUM** | |

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Utilizarea inhibitorilor enzimelor de conversie a angiotensinei în timpul sarcinii este contraindicată deoarece medicamentele din această categorie au fost asociate cu moartea fătului in utero.

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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C09AA01 CAPTOPRILUM COMPR. 12,5 mg

CAPTOPRIL MCC 12,5 mg 12,5 mg MAGISTRA C & C

C09AA01 CAPTOPRILUM COMPR. 12.5 mg

CAPTOPRIL 12,5 mg 12.5 mg EGIS PHARMACEUTICALS LTD.

C09AA01 CAPTOPRILUM COMPR. 25 mg

CAPTOPRIL - AC 25 mg 25 mg AC HELCOR PHARMA SRL

CAPTOPRIL SINTOFARM 25 mg 25 mg SINTOFARM SA

CAPTOPRIL 25 EEL 25 mg BIO EEL SRL

CAPTOPRIL 25 mg 25 mg EGIS PHARMACEUTICALS LTD.

CAPTOPRIL LPH 25 mg 25 mg LABORMED PHARMA SA

CAPTOPRIL MCC 25 mg 25 mg MAGISTRA C & C

C09AA01 CAPTOPRILUM COMPR. 50 mg

CAPTOPRIL 50 mg 50 mg ARENA GROUP SA

C09AA01 CAPTOPRILUM COMPR. 50 mg

CAPTOPRIL - AC 50 mg 50 mg AC HELCOR PHARMA SRL

CAPTOPRIL 50 EEL 50 mg BIO EEL SRL

CAPTOPRIL 50 mg 50 mg EGIS PHARMACEUTICALS LTD.

CAPTOPRIL LPH 50 mg 50 mg LABORMED PHARMA SA

CAPTOPRIL MCC 50 mg 50 mg MAGISTRA C & C

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| **383** |**C09AA02**| **ENALAPRILUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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C09AA02 ENALAPRILUM SOL. INJ. 1.25 mg/ml

ENAP(R) 1.25 mg/ml KRKA D.D.

C09AA02 ENALAPRILUM COMPR. 10 mg

EDNYT(R) 10 mg 10 mg GEDEON RICHTER LTD.

ENAHEXAL(R) 10 mg 10 mg HEXAL AG

ENALA TAD 10 10 mg TAD PHARMA GMBH

ENALAP 10 mg E.I.P.I.CO. MED S.R.L.

ENALAPRIL 10 mg 10 mg MAGISTRA C & C

ENALAPRIL AL 10 10 mg ALIUD(R) PHARMA GMBH &

CO.KG

ENALAPRIL FABIOL 10 mg 10 mg FABIOL SA

ENALAPRIL LPH 10 mg 10 mg LABORMED PHARMA SA

ENALAPRIL SANDOZ 10 mg 10 mg SANDOZ SRL

ENALAPRIL TERAPIA 10 mg 10 mg TERAPIA SA

ENAM 10 mg 10 mg REPREZENTANTA DR. REDDY'S

LABORATORIES LTD.

ENAP 10 mg 10 mg KRKA D.D. NOVO MESTO

RENITEC 10 mg 10 mg MERCK SHARP & DOHME

ROMANIA S.R.L.

C09AA02 ENALAPRILUM COMPR. 2.5 mg

EDNYT(R) 2,5 mg 2.5 mg GEDEON RICHTER LTD.

C09AA02 ENALAPRILUM COMPR. 20 mg

EDNYT(R) 20 mg 20 mg GEDEON RICHTER LTD.

ENAHEXAL(R) 20 mg 20 mg HEXAL AG

ENALA TAD 20 20 mg TAD PHARMA GMBH

ENALAPRIL 20 mg OZONE LABORATORIES LTD.

ENALAPRIL 20 mg 20 mg MAGISTRA C & C

ENALAPRIL AL 20 20 mg ALIUD(R) PHARMA GMBH &

CO.KG

ENALAPRIL FABIOL 20 mg 20 mg FABIOL SA

ENALAPRIL LPH 20 mg 20 mg LABORMED PHARMA SA

ENALAPRIL SANDOZ 20 mg 20 mg SANDOZ SRL

ENALAPRIL TERAPIA 20 mg 20 mg TERAPIA SA

ENAP 20 mg 20 mg KRKA D.D. NOVO MESTO

RENITEC 20 mg 20 mg MERCK SHARP & DOHME

ROMANIA S.R.L.

C09AA02 ENALAPRILUM COMPR. 5 mg

EDNYT(R) 5 mg 5 mg GEDEON RICHTER LTD.

ENAHEXAL(R) 5 mg 5 mg HEXAL AG

ENALA TAD 5 5 mg TAD PHARMA GMBH

ENALAPRIL 5 mg 5 mg OZONE LABORATORIES LTD.

ENALAPRIL AL 5 5 mg ALIUD(R) PHARMA

GMBH & CO.KG

ENALAPRIL LPH(R) 5 mg 5 mg LABORMED PHARMA SA

ENALAPRIL SANDOZ 5 mg 5 mg SANDOZ SRL

ENAP 5 mg 5 mg KRKA D.D. NOVO MESTO

RENITEC 5 mg 5 mg MERCK SHARP & DOHME

ROMANIA S.R.L.

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| **384** |**C09AA03**| **LISINOPRILUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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C09AA03 LISINOPRILUM COMPR. 10 mg

LISIGAMMA 10 mg 10 mg WORWAG PHARMA GMBH & CO.KG

LISINOPRIL 10 MEDO 10 mg MEDOCHEMIE ROMANIA SRL

LISINOPRIL ANTIBIOTICE 10 mg 10 mg ANTIBIOTICE SA

LISINOPRIL SANDOZ 10 mg 10 mg HEXAL AG

LISIREN 10 mg 10 mg AC HELCOR SRL

MEDAPRIL 10 10 mg MEDOCHEMIE LTD.

RANOLIP 10 mg RANBAXY U.K. LIMITED

SINOPRYL(R) 10 10 mg ECZACIBASI PHARMACEUTICALS

S.R.L.

TONOLYSIN 10 mg 10 mg GEDEON RICHTER LTD.

C09AA03 LISINOPRILUM COMPR. 2.5 mg

TONOLYSIN 2,5 mg 2.5 mg GEDEON RICHTER LTD.

C09AA03 LISINOPRILUM COMPR. 20 mg

LISIGAMMA 20 mg 20 mg WORWAG PHARMA GMBH & CO.KG

LISINOPRIL 20 MEDO 20 mg MEDOCHEMIE ROMANIA SRL

LISINOPRIL ANTIBIOTICE 20 mg 20 mg ANTIBIOTICE SA

LISINOPRIL SANDOZ 20 mg 20 mg HEXAL AG

LISIREN 20 mg 20 mg AC HELCOR SRL

MEDAPRIL 20 20 mg MEDOCHEMIE LTD.

RANOLIP 20 mg RANBAXY U.K. LIMITED

TONOLYSIN 20 mg 20 mg GEDEON RICHTER LTD.

C09AA03 LISINOPRILUM COMPR. 40 mg

LISINOPRIL ANTIBIOTICE 40 mg 40 mg ANTIBIOTICE SA

C09AA03 LISINOPRILUM COMPR. 5 mg

LISIGAMMA 5 mg 5 mg WORWAG PHARMA GMBH & CO.KG

LISINOPRIL 5 MEDO 5 mg MEDOCHEMIE ROMANIA SRL

LISINOPRIL SANDOZ 5 mg 5 mg HEXAL AG

MEDAPRIL 5 5 mg MEDOCHEMIE LTD.

RANOLIP 5 mg RANBAXY U.K. LIMITED

TONOLYSIN 5 mg 5 mg GEDEON RICHTER LTD.

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| **385** |**C09AA05**| **RAMIPRILUM** | |

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Utilizarea inhibitorilor enzimelor de conversie a angiotensinei în timpul sarcinii este contraindicată deoarece medicamentele din această categorie au fost asociate cu moartea fătului in utero.

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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C09AA05 RAMIPRILUM COMPR. FILM. 1.25 mg

RAMIRAN 1,25 mg 1.25 mg RANBAXY U.K. LIMITED

C09AA05 RAMIPRILUM COMPR. 10 mg

EMREN 10 mg 10 mg GEDEON RICHTER ROMANIA

S.A.

VIVACE 10 mg 10 mg ACTAVIS GROUP HF

C09AA05 RAMIPRILUM COMPR. 10 mg

AMPRIL 10 mg 10 mg KRKA D.D. NOVO MESTO

PIRAMIL 10 mg 10 mg SANDOZ SRL

RAMIGAMMA 10 mg 10 mg WORWAG PHARMA GMBH & CO.KG

RAMIPRIL-AC 10 mg 10 mg AC HELCOR PHARMA SRL

TRITACE 10 10 mg SANOFI-AVENTIS

DEUTSCHLAND GMBH

ZENRA 10 10 mg ZENTIVA S.A.

C09AA05 RAMIPRILUM COMPR. FILM. 10 mg

RAMIRAN 10 mg 10 mg RANBAXY U.K. LIMITED

C09AA05 RAMIPRILUM COMPR. 2,5 mg

EMREN 2,5 mg 2,5 mg GEDEON RICHTER ROMANIA SA

VIVACE 2,5 mg 2,5 mg ACTAVIS GROUP HF

C09AA05 RAMIPRILUM COMPR. 2.5 mg

AMPRIL 2,5 mg 2.5 mg KRKA D.D. NOVO MESTO

PIRAMIL 2,5 mg 2.5 mg SANDOZ SRL

RAMIPRIL-AC 2,5 mg 2.5 mg AC HELCOR PHARMA SRL

TRITACE(R) 2,5 2.5 mg AVENTIS PHARMA DEUTSCHLAND

GMBH

ZENRA 2,5 2.5 mg ZENTIVA S.A.

C09AA05 RAMIPRILUM COMPR. FILM. 2.5 mg

RAMIRAN 2,5 mg 2.5 mg RANBAXY U.K. LIMITED

C09AA05 RAMIPRILUM COMPR. 5 mg

EMREN 5 mg 5 mg GEDEON RICHTER ROMANIA

S.A.

VIVACE 5 mg 5 mg ACTAVIS GROUP HF

C09AA05 RAMIPRILUM COMPR. 5 mg

AMPRIL 5 mg 5 mg KRKA D.D. NOVO MESTO

PIRAMIL 5 mg 5 mg SANDOZ SRL

RAMIGAMMA 5 mg 5 mg WORWAG PHARMA GMBH & CO.KG

RAMIPRIL-AC 5 mg 5 mg AC HELCOR PHARMA SRL

TRITACE(R) 5 5 mg AVENTIS PHARMA DEUTSCHLAND

GMBH

ZENRA 5 5 mg ZENTIVA S.A.

C09AA05 RAMIPRILUM COMPR. FILM. 5 mg

RAMIRAN 5 mg 5 mg RANBAXY U.K. LIMITED

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| **386** |**C09CA03**| **VALSARTANUM\*\*** | **Protocol: C005I** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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C09CA03 VALSARTANUM COMPR. FILM. 160 mg

DIOVAN 160 mg 160 mg NOVARTIS PHARMA GMBH

C09CA03 VALSARTANUM COMPR. FILM. 80 mg

DIOVAN 80 mg 80 mg NOVARTIS PHARMA GMBH

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| **387** |**C09CA06**| **CANDESARTANUM CILEXETIL\*\*** | **Protocol: C005I** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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C09CA06 CANDESARTANUM COMPR. 16 mg

CILEXETIL

ATACAND 16 mg ASTRAZENECA AB

C09CA06 CANDESARTANUM COMPR. 8 mg

CILEXETIL

ATACAND 8 mg ASTRAZENECA AB

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**SUBLISTA C1 - G2 BOLNAVI CU PROTEZE VALVULARE ŞI VASCULARE.**

**Protocol: BB01I**

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| **388** |**B01AA07**| **ACENOCUMAROLUM\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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B01AA07 ACENOCUMAROLUM COMPR. 2 mg

TROMBOSTOP 2 mg 2 mg TERAPIA SA

B01AA07 ACENOCUMAROLUM COMPR. 4 mg

SINTROM(R) 4 mg NOVARTIS PHARMA GMBH

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**SUBLISTA C1 - G3 BOLNAVI CU PROCEDURI INTERVENŢIONALE PERCUTANE, NUMAI DUPĂ IMPLANTAREA UNEI PROTEZE ENDOVASCULARE (STENT).**

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| **389** |**B01AC04**| **CLOPIDOGRELUM\*\*\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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B01AC04 CLOPIDOGRELUM COMPR. FILM. 75 mg

PLAVIX 75 mg 75 mg SANOFI PHARMA - BRISTOL

MYERS SQUIBB

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**SUBLISTA C1 - G4 HEPATITELE CRONICE DE ETIOLOGIE VIRALĂ B, C ŞI D.**

**Protocol: LB01B; LB02E**

**#M4**

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*|* ***390*** *| \*\*\* Abrogată |*

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*|* ***391*** *| \*\*\* Abrogată |*

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| **392** |**J05AB04**| **RIBAVIRINUM\*\*\*\*** | **Protocol: J002N** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J05AB04 RIBAVIRINUM CAPS. 200 mg

REBETOL 200 mg 200 mg SP EUROPE

J05AB04 RIBAVIRINUM COMPR. FILM. 200 mg

COPEGUS(R) 200 mg ROCHE ROMANIA SRL

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| **393** |**J05AF05**| **LAMIVUDINUM\*\*\*\*** | **Protocol: J005N** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J05AF05 LAMIVUDINUM COMPR. FILM. 100 mg

ZEFFIX 100 mg 100 mg GLAXO GROUP LTD.

J05AF05 LAMIVUDINUM SOL. ORALĂ 10 mg/ml

EPIVIR 10 mg/ml 10 mg/ml GLAXO GROUP LTD.

J05AF05 LAMIVUDINUM COMPR. FILM. 150 mg

EPIVIR 150 mg 150 mg GLAXO GROUP LTD.

J05AF05 LAMIVUDINUM SOL. ORALĂ 5 mg/ml

ZEFFIX 5 mg/ml 5 mg/ml GLAXO GROUP LTD.

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| **395** |**J05AF10**| **ENTECAVIRUM\*\*\*\*** | **Protocol: J008N** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J05AF10 ENTECAVIRUM COMPR. FILM. 0,5 mg

BARACLUDE 0,5 mg 0,5 mg BRISTOL-MYERS SQUIBB

PHARMA EEIG

J05AF10 ENTECAVIRUM COMPR. FILM. 1 mg

BARACLUDE 1 mg 1 mg BRISTOL-MYERS SQUIBB

PHARMA EEIG

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| **396** |**L03AA02**| **FILGRASTIMUM (G-CSF)\*\*** | **Protocol: B013K** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L03AA02 FILGRASTIMUM (G-CSF) SOL. INJ. 30 MU/0.5 ml

NEUPOGEN(R) 30 MU/0.5 ml AMGEN EUROPE B.V.

L03AA02 FILGRASTIMUM (G-CSF) SOL. INJ. 48 MU/0.5 ml

NEUPOGEN(R) 48 MU/0.5 ml AMGEN EUROPE B.V.

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| **397** |**L03AB04**| **INTERFERONUM ALFA 2a\*\*\*\*** | **Protocol: J007N** |

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Tratamentul cu interferon alfa a fost asociat cu depresie şi suicid la unii pacienţi. Pacienţii cu istoric de ideaţie suicidară sau boală depresivă trebuie avertizaţi de riscuri. Trebuie monitorizat statusul psihiatric în timpul tratamentului.

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L03AB04 INTERFERONUM ALFA 2a SOL. INJ. 18 Mui/0.6 ml

ROFERON A 18 Mui/0.6 ml ROCHE ROMANIA S.R.L.

L03AB04 INTERFERONUM ALFA 2a SOL. INJ. 3 Mui/0.5 ml

ROFERON A 3 Mui/0.5 ml ROCHE ROMANIA S.R.L.

L03AB04 INTERFERONUM ALFA 2a SOL. INJ. 4.5 Mui/0.5 ml

ROFERON A 4.5 Mui/0.5 ml ROCHE ROMANIA S.R.L.

L03AB04 INTERFERONUM ALFA 2a SOL. INJ. 9 Mui/0.5 ml

ROFERON A 9 Mui/0.5 ml ROCHE ROMANIA S.R.L.

L03AB04 INTERFERONUM ALFA 2a SOL. INJ. 3 Mui/0.5 ml

ROFERON A 3 Mui/0.5 ml ROCHE ROMANIA S.R.L.

L03AB04 INTERFERONUM ALFA 2a SOL. INJ. 4.5 Mui/0.5 ml

ROFERON A 4.5 Mui/0.5 ml ROCHE ROMANIA S.R.L.

L03AB04 INTERFERONUM ALFA 2a SOL. INJ. 9 Mui/0.5 ml

ROFERON A 9 Mui/0.5 ml ROCHE ROMANIA S.R.L.

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| **398** |**L03AB05**| **INTERFERONUM ALFA 2b\*\*\*\*** | **Protocol: J006N** |

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Tratamentul cu interferon alfa a fost asociat cu depresie şi suicid la unii pacienţi. Pacienţii cu istoric de ideaţie suicidară sau boală depresivă trebuie avertizaţi de riscuri. Trebuie monitorizat statusul psihiatric în timpul tratamentului.

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L03AB05 INTERFERONUM ALFA 2b SOL. INJ. PEN MULTIDOZĂ 18 milioane U.I.

INTRON A 18 milioane U.I. 18 milioane U.I. SP EUROPE

L03AB05 INTERFERONUM ALFA 2b SOL. INJ. PEN MULTIDOZĂ 30 milioane U.I.

INTRON A 30 milioane U.I. 30 milioane U.I. SP EUROPE

INTRON A 60 milioane U.I. 60 milioane U.I. SP EUROPE

L03AB05 INTERFERONUM ALFA 2b SOL. INJ. PEN MULTIDOZĂ 60 milioane U.I.

INTRON A 30 milioane U.I. 30 milioane U.I. SP EUROPE

INTRON A 60 milioane U.I. 60 milioane U.I. SP EUROPE

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| **399** |**L03AB10**| **PEGINTERFERON alfa-2b\*\*\*\*** | **Protocol: J003N** |

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Tratamentul cu interferon alfa a fost asociat cu depresie şi suicid la unii pacienţi. Pacienţii cu istoric de ideaţie suicidară sau boală depresivă trebuie avertizaţi de riscuri. Trebuie monitorizat statusul psihiatric în timpul tratamentului.

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L03AB10 PEGINTERFERON alfa-2b PULB. + SOLV. PT. SOL. 100 µg

INJ.

PEGINTRON 100 µg 100 µg SP EUROPE

L03AB10 PEGINTERFERON alfa-2b PULB. + SOLV. PT. SOL. 120 µg

INJ.

PEGINTRON 120 µg 120 µg SP EUROPE

L03AB10 PEGINTERFERON alfa-2b PULB. + SOLV. PT. SOL. 150 µg

INJ.

PEGINTRON 150 µg 150 µg SP EUROPE

L03AB10 PEGINTERFERON alfa-2b PULB. + SOLV. PT. SOL. 50 µg

INJ.

PEGINTRON 50 µg 50 µg SP EUROPE

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| **400** |**L03AB11**| **PEGINTERFERON alfa-2a\*\*\*\*** | **Protocol: J004N** |

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Tratamentul cu interferon alfa a fost asociat cu depresie şi suicid la unii pacienţi. Pacienţii cu istoric de ideaţie suicidară sau boală depresivă trebuie avertizaţi de riscuri. Trebuie monitorizat statusul psihiatric în timpul tratamentului.

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L03AB11 PEGINTERFERON alfa-2a SOL. INJ. 135 µg/ml

PEGASYS 135 µg/ml 135 µg/ml ROCHE REGISTRATION LTD.

L03AB11 PEGINTERFERON alfa-2a SOL. INJ. ÎN SERINGĂ 180 µg/0.5 ml

PREUMPLUTĂ

PEGASYS 180 µ/0,5 ml 180 µ/0.5 ml ROCHE REGISTRATION LTD.

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| **401** |**N04BB01**| **AMANTADINUM\*\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N04BB01 AMANTADINUM CAPS. 100 mg

VIREGYT(R)-K 100 mg EGIS PHARMACEUTICALS LTD.

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**SUBLISTA C1 - G5 HEPATITA AUTOIMUNĂ.**

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| **402** |**H02AB04**| **METHYLPREDNISOLONUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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H02AB04 METHYLPREDNISOLONUM LIOF. PT. SOL. INJ. 125 mg

LEMOD SOLU 125 mg 125 mg HEMOFARM S.R.L

H02AB04 METHYLPREDNISOLONUM LIOF. ŞI SOLV. PT. 125 mg/2 ml

SOL. INJ.

SOLU - MEDROL ACT-O-VIAL 125 mg/2 ml PFIZER EUROPE MA EEIG

H02AB04 METHYLPREDNISOLONUM COMPR. 16 mg

MEDROL A 16 16 mg PFIZER EUROPE MA EEIG

H02AB04 METHYLPREDNISOLONUM LIOF. PT. SOL. INJ. 20 mg

LEMOD SOLU 20 mg 20 mg HEMOFARM S.R.L.

H02AB04 METHYLPREDNISOLONUM LIOF. ŞI SOLV. PT. 250 mg/4 ml

SOL. INJ.

SOLU - MEDROL ACT-O-VIAL 250 mg/4 ml PFIZER EUROPE MA EEIG

H02AB04 METHYLPREDNISOLONUM COMPR. 32 mg

MEDROL 32 32 mg PFIZER EUROPE MA EEIG

H02AB04 METHYLPREDNISOLONUM LIOF. PT. SOL. INJ. 40 mg

LEMOD SOLU 40 mg 40 mg HEMOFARM S.R.L.

H02AB04 METHYLPREDNISOLONUM LIOF. ŞI SOLV. PT. 40 mg/1 ml

SOL. INJ.

SOLU - MEDROL ACT-O-VIAL 40 mg/1 ml PFIZER EUROPE MA EEIG

H02AB04 METHYLPREDNISOLONUM COMPR. 4 mg

MEDROL 4 mg 4 mg PFIZER EUROPE MA EEIG

H02AB04 METHYLPREDNISOLONUM LIOF. PT. SOL. INJ. 500 mg

LEMOD SOLU 500 mg 500 mg HEMOFARM S.R.L.

H02AB04 METHYLPREDNISOLONUM LIOF. + SOLV. PT. SOL. 500 mg/7.8 ml

INJ.

SOLU - MEDROL 500 mg/7,8 ml 500 mg/7.8 ml PFIZER EUROPE MA EEIG

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| **403** |**H02AB06**| **PREDNISOLONUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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H02AB06 PREDNISOLONUM LIOF. + SOLV. PT. SOL. 250 mg

INJ.

SOLU - DECORTIN H 250 250 mg MERCK KGAA

H02AB06 PREDNISOLONUM LIOF. + SOLV. PT. SOL. 50 mg

INJ.

SOLU - DECORTIN H 50 50 mg MERCK KGAA

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| **404** |**L04AX01**| **AZATHIOPRINUM\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L04AX01 AZATHIOPRINUM COMPR. FILM. 50 mg

IMURAN(R) 50 mg THE WELLCOME FOUNDATION

LTD.

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**SUBLISTA C1 - G06 CIROZA BILIARĂ PRIMARĂ, COLANGITA SCLEROZANTĂ PRIMITIVĂ, HEPATITA CRONICĂ ŞI CIROZE DE ALTE ETIOLOGII CU COLESTAZĂ.**

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| **405** |**A05AA02**| **ACIDUM URSODEOXYCHOLICUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A05AA02 ACIDUM CAPS. 300 mg

URSODEOXYCHOLICUM

URSOFALK(R) 250 mg DR. FALK PHARMA GMBH

URSOFALK(R) 250 mg DR. FALK PHARMA GMBH

URSOSAN 250 mg PRO. MED. CS PRAHA AS

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**SUBLISTA C1 - G7 CIROZA HEPATICĂ.**

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| **406** |**A06AD11**| **LACTULOSUM\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A06AD11 LACTULOSUM LICHID ORAL 66.7%

DUPHALAC(R) 66.7% SOLVAY PHARMACEUTICALS BV

A06AD11 LACTULOSUM

LACTULOSE AL SIROP 66.7% ALIUD PHARMA GMBH & CO.KG

A06AD11 LACTULOSUM

LAEVOLAC 670 mg/ml 670 mg/ml FRESENIUS KABI AUSTRIA

GMBH

A06AD11 LACTULOSUM SIROP 66.7%

LACTULOSE AL SIROP 66.7% ALIUD PHARMA GMBH & CO.KG

A06AD11 LACTULOSUM SOL. ORALĂ 670 mg/ml

LAEVOLAC 670 mg/ml 670 mg/ml FRESENIUS KABI AUSTRIA

GMBH

A06AD11 LACTULOSUM SIROP 66.7%

LACTULOSE AL SIROP 66.7% ALIUD PHARMA GMBH & CO.KG

A06AD11 LACTULOSUM SOL. ORALĂ 670 mg/ml

LAEVOLAC 670 mg/ml 670 mg/ml FRESENIUS KABI AUSTRIA

GMBH

A06AD11 LACTULOSUM LICHID ORAL 66.7%

DUPHALAC(R) 66.7% SOLVAY PHARMACEUTICALS BV

A06AD11 LACTULOSUM SIROP 65%

LACTULOSE 65% E.I.P.I.CO. MED S.R.L.

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| **407** |**A07AA11**| **RIFAXIMINUM\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A07AA11 RIFAXIMINUM COMPR. FILM. 200 mg

NORMIX 200 mg 200 mg ALFA WASSERMANN SPA

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*|* ***408*** *| \*\*\* Abrogată |*

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*|* ***409*** *| \*\*\* Abrogată |*

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| **410** |**C03CA01**| **FUROSEMIDUM** | |

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Electroliţii serici trebuie să fie verificaţi periodic.

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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C03CA01 FUROSEMIDUM SOL. INJ. 10 mg/ml

FUROSEMID 20 mg/2 ml 10 mg/ml ZENTIVA SA

C03CA01 FUROSEMIDUM COMPR. 40 mg

FUROSEMID ARENA 40 mg 40 mg ARENA GROUP S.A.

FUROSEMID EEL 40 mg BIO EEL SRL

FUROSEMID LPH 40 mg 40 mg LABORMED PHARMA SA

FUROSEMID MCC 40 mg 40 mg MAGISTRA C & C SRL

FUROSEMID SLAVIA 40 mg SLAVIA PHARM SRL

FUROSEMID ZENTIVA 40 mg ZENTIVA SA

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| **411** |**C03DA01**| **SPIRONOLACTONUM** | |

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Electroliţii serici trebuie să fie verificaţi periodic.

Femeile la vârsta fertilă la care s-a iniţiat tratament cu spironolactonă trebuie să ia măsuri adecvate de contracepţie.

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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C03DA01 SPIRONOLACTONUM CAPS. 100 mg

VEROSPIRON 100 mg GEDEON RICHTER LTD.

C03DA01 SPIRONOLACTONUM COMPR. 25 mg

SPIRONOLACTONA 25 mg 25 mg BIO EEL SRL

C03DA01 SPIRONOLACTONUM COMPR. FILM. 25 mg

ALSPIRON 25 mg 25 mg AC HELCOR PHARMA SRL

SPIRONOLACTONA 25 mg 25 mg TERAPIA SA

C03DA01 SPIRONOLACTONUM CAPS. 50 mg

VEROSPIRON 50 mg GEDEON RICHTER LTD.

C03DA01 SPIRONOLACTONUM COMPR. FILM. 50 mg

ALSPIRON 50 mg 50 mg AC HELCOR PHARMA SRL

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| **412** |**H02AB06**| **PREDNISOLONUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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H02AB06 PREDNISOLONUM LIOF. + SOLV. PT. SOL. 250 mg

INJ.

SOLU - DECORTIN H 250 250 mg MERCK KGAA

H02AB06 PREDNISOLONUM LIOF. + SOLV. PT. SOL. 50 mg

INJ.

SOLU - DECORTIN H 50 50 mg MERCK KGAA

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| **413** |**J05AB04**| **RIBAVIRINUM\*\*\*\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J05AB04 RIBAVIRINUM CAPS. 200 mg

REBETOL 200 mg 200 mg SP EUROPE

J05AB04 RIBAVIRINUM COMPR. FILM. 200 mg

COPEGUS(R) 200 mg ROCHE ROMANIA SRL

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| **414** |**J05AF05**| **LAMIVUDINUM\*\*\*\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J05AF05 LAMIVUDINUM COMPR. FILM. 100 mg

ZEFFIX 100 mg 100 mg GLAXO GROUP LTD.

J05AF05 LAMIVUDINUM SOL. ORALĂ 10 mg/ml

EPIVIR 10 mg/ml 10 mg/ml GLAXO GROUP LTD.

J05AF05 LAMIVUDINUM COMPR. FILM. 150 mg

EPIVIR 150 mg 150 mg GLAXO GROUP LTD.

J05AF05 LAMIVUDINUM SOL. ORALĂ 5 mg/ml

ZEFFIX 5 mg/ml 5 mg/ml GLAXO GROUP LTD.

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| **416** |**J05AF10**| **ENTECAVIRUM\*\*\*\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J05AF10 ENTECAVIRUM COMPR. FILM. 0,5 mg

BARACLUDE 0,5 mg 0,5 mg BRISTOL-MYERS SQUIBB

PHARMA EEIG

J05AF10 ENTECAVIRUM COMPR. FILM. 1 mg

BARACLUDE 1 mg 1 mg BRISTOL-MYERS SQUIBB

PHARMA EEIG

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| **417** |**L03AA02**| **FILGRASTIMUM (G-CSF)\*\*** | Protocol: B013K |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L03AA02 FILGRASTIMUM (G-CSF) SOL. INJ. 30 MU/0.5 ml

NEUPOGEN(R) 30 MU/0.5 ml AMGEN EUROPE B.V.

L03AA02 FILGRASTIMUM (G-CSF) SOL. INJ. 48 MU/0.5 ml

NEUPOGEN(R) 48 MU/0.5 ml AMGEN EUROPE B.V.

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| **418** |**L03AB04**| **INTERFERONUM ALFA 2a\*\*\*\*** | |

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Tratamentul cu interferon alfa a fost asociat cu depresie şi suicid la unii pacienţi. Pacienţii cu istoric de ideaţie suicidară sau boală depresivă trebuie avertizaţi de riscuri. Trebuie monitorizat statusul psihiatric în timpul tratamentului.

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L03AB04 INTERFERONUM ALFA 2a SOL. INJ. 18 Mui/0.6 ml

ROFERON A 18 Mui/0.6 ml ROCHE ROMANIA S.R.L.

L03AB04 INTERFERONUM ALFA 2a SOL. INJ. 3 Mui/0.5 ml

ROFERON A 3 Mui/0.5 ml ROCHE ROMANIA S.R.L.

L03AB04 INTERFERONUM ALFA 2a SOL. INJ. 4.5 Mui/0.5 ml

ROFERON A 4.5 Mui/0.5 ml ROCHE ROMANIA S.R.L.

L03AB04 INTERFERONUM ALFA 2a SOL. INJ. 9 Mui/0.5 ml

ROFERON A 9 Mui/0.5 ml ROCHE ROMANIA S.R.L.

L03AB04 INTERFERONUM ALFA 2a SOL. INJ. 3 Mui/0.5 ml

ROFERON A 3 Mui/0.5 ml ROCHE ROMANIA S.R.L.

L03AB04 INTERFERONUM ALFA 2a SOL. INJ. 4.5 Mui/0.5 ml

ROFERON A 4.5 Mui/0.5 ml ROCHE ROMANIA S.R.L.

L03AB04 INTERFERONUM ALFA 2a SOL. INJ. 9 Mui/0.5 ml

ROFERON A 9 Mui/0.5 ml ROCHE ROMANIA S.R.L.

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| **419** |**L03AB05**| **INTERFERONUM ALFA 2b\*\*\*\*** | |

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Tratamentul cu interferon alfa a fost asociat cu depresie şi suicid la unii pacienţi. Pacienţii cu istoric de ideaţie suicidară sau boală depresivă trebuie avertizaţi de riscuri. Trebuie monitorizat statusul psihiatric în timpul tratamentului.

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L03AB05 INTERFERONUM ALFA 2b SOL. INJ. PEN MULTIDOZĂ 18 milioane U.I.

INTRON A 18 milioane U.I. 18 milioane U.I. SP EUROPE

L03AB05 INTERFERONUM ALFA 2b SOL. INJ. PEN MULTIDOZĂ 30 milioane U.I.

INTRON A 30 milioane U.I. 30 milioane U.I. SP EUROPE

INTRON A 60 milioane U.I. 60 milioane U.I. SP EUROPE

L03AB05 INTERFERONUM ALFA 2b SOL. INJ. PEN MULTIDOZĂ 60 milioane U.I.

INTRON A 30 milioane U.I. 30 milioane U.I. SP EUROPE

INTRON A 60 milioane U.I. 60 milioane U.I. SP EUROPE

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| **420** |**L03AB10**| **PEGINTERFERON alfa-2b\*\*\*\*** | |

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Tratamentul cu interferon alfa a fost asociat cu depresie şi suicid la unii pacienţi. Pacienţii cu istoric de ideaţie suicidară sau boală depresivă trebuie avertizaţi de riscuri. Trebuie monitorizat statusul psihiatric în timpul tratamentului.

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L03AB10 PEGINTERFERON alfa-2b PULB. + SOLV. PT. SOL. 100 µg

INJ.

PEGINTRON 100 µg 100 µg SP EUROPE

L03AB10 PEGINTERFERON alfa-2b PULB. + SOLV. PT. SOL. 120 µg

INJ.

PEGINTRON 120 µg 120 µg SP EUROPE

L03AB10 PEGINTERFERON alfa-2b PULB. + SOLV. PT. SOL. 150 µg

INJ.

PEGINTRON 150 µg 150 µg SP EUROPE

L03AB10 PEGINTERFERON alfa-2b PULB. + SOLV. PT. SOL. 50 µg

INJ.

PEGINTRON 50 µg 50 µg SP EUROPE

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| **421** |**L03AB11**| **PEGINTERFERON alfa-2a\*\*\*\*** | |

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Tratamentul cu interferon alfa a fost asociat cu depresie şi suicid la unii pacienţi. Pacienţii cu istoric de ideaţie suicidară sau boală depresivă trebuie avertizaţi de riscuri. Trebuie monitorizat statusul psihiatric în timpul tratamentului.

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L03AB11 PEGINTERFERON alfa-2a SOL. INJ. 135 µg/ml

PEGASYS 135 µg/ml 135 µg/ml ROCHE REGISTRATION LTD.

L03AB11 PEGINTERFERON alfa-2a SOL. INJ. ÎN SERINGĂ 180 µg/0.5 ml

PREUMPLUTĂ

PEGASYS 180 µg/0,5 ml 180 µg/0.5 ml ROCHE REGISTRATION LTD.

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| **422** |**N04BB01**| **AMANTADINUM\*\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N04BB01 AMANTADINUM CAPS. 100 mg

VIREGYT(R)-K 100 mg EGIS PHARMACEUTICALS LTD.

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**SUBLISTA C1 - G10 LEUCEMII, LIMFOAME, APLAZIE MEDULARĂ, GAMAPATII MONOCLONALE MALIGNE, MIELOPROLIFERĂRI CRONICE ŞI TUMORI MALIGNE, SINDROAME MIELODISPLAZICE.**

**Protocol: N030C**

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| **423** |**A04AA01**| **ONDANSETRONUM\*\*** | **Protocol: A004C** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A04AA01 ONDANSETRONUM SOL. INJ. 2 mg/ml

OSETRON 4 mg 2 mg/ml DR. REDDY'S LABORATORIES

OSETRON 8 mg 2 mg/ml DR. REDDY'S LABORATORIES

A04AA01 ONDANSETRONUM SOL. INJ./PERF. 2 mg/ml

EMESET 4 mg/2 ml 2 mg/ml CIPLA (UK) LIMITED

EMESET 8 mg/4 ml 2 mg/ml CIPLA (UK) LIMITED

A04AA01 ONDANSETRONUM COMPR. FILM. 4 mg

OSETRON 4 mg 4 mg DR. REDDY'S LABORATORIES

SETRONON 4 mg 4 mg PLIVA LJUBLJANA D.O.O.

ZOFRAN 4 mg 4 mg GLAXO WELLCOME UK LTD.

A04AA01 ONDANSETRONUM COMPR. ORODISPERSABILE 4 mg

ONDARAN MD 4 mg 4 mg RANBAXY UK LTD.

A04AA01 ONDANSETRONUM SOL. INJ. 4 mg/2 ml

ZOFRAN 4 mg/2 ml 4 mg/2 ml GLAXO WELLCOME UK LIMITED

A04AA01 ONDANSETRONUM SOL. INJ./PERF. 4 mg/2 ml

SETRONON 4 mg/2 ml 4 mg/2 ml PLIVA LJUBLJANA D.O.O.

A04AA01 ONDANSETRONUM COMPR. FILM. 8 mg

OSETRON 8 mg 8 mg DR. REDDY'S LABORATORIES

(UK) LTD

SETRONON 8 mg 8 mg PLIVA LJUBLJANA D.O.O.

A04AA01 ONDANSETRONUM COMPR. ORODISPERSABILE 8 mg

ONDARAN MD 8 mg 8 mg RANBAXY UK LIMITED

A04AA01 ONDANSETRONUM SOL. INJ. 8 mg/4 ml

ZOFRAN 8 mg/4 ml 8 mg/4 ml GLAXO WELLCOME UK LIMITED

A04AA01 ONDANSETRONUM COMPR. FILM. 4 mg

OSETRON 4 mg 4 mg DR. REDDY'S LABORATORIES

SETRONON 4 mg 4 mg PLIVA LJUBLJANA D.O.O.

ZOFRAN 4 mg 4 mg GLAXO WELLCOME UK LTD.

A04AA01 ONDANSETRONUM COMPR. ORODISPERSABILE 4 mg

ONDARAN MD 4 mg 4 mg RANBAXY UK LTD.

A04AA01 ONDANSETRONUM COMPR. FILM. 8 mg

OSETRON 8 mg 8 mg DR. REDDY'S LABORATORIES

(UK) LTD

SETRONON 8 mg 8 mg PLIVA LJUBLJANA D.O.O.

A04AA01 ONDANSETRONUM COMPR. ORODISPERSABILE 8 mg

ONDARAN MD 8 mg 8 mg RANBAXY UK LIMITED

A04AA01 ONDANSETRONUM SOL. INJ./PERF. 8 mg/4 ml

SETRONON 8 mg/4 ml 8 mg/4 ml PLIVA LJUBLJANA D.O.O.

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| **424** |**A04AA02**| **GRANISETRONUM\*\*** | **Protocol: A004C** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A04AA02 GRANISETRONUM COMPR. FILM. 1 mg

KYTRIL(R) 1 mg 1 mg ROCHE ROMANIA S.R.L.

A04AA02 GRANISETRONUM COMPR. FILM. 2 mg

KYTRIL 2 mg F. HOFFMANN LA ROCHE LTD.

A04AA02 GRANISETRONUM SOL. INJ. 3 mg/3 ml

KYTRIL 3 mg/3 ml ROCHE ROMANIA SRL

A04AA02 GRANISETRONUM COMPR. FILM. 2 mg

KYTRIL 2 mg F. HOFFMANN LA ROCHE LTD.

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| **425** |**A04AA05**| **PALONOSETRONUM\*\*** | **Protocol: A002C;**|

| | | | **A004C** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A04AA05 PALONOSETRONUM SOL. INJ. 250 µg/5 ml

ALOXI 250 µg/5 ml HELSINN BIREX

PHARMACEUTICALS LTD.

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| **426** |**B03XA01**| **EPOETINUM ALFA\*\*\*** | **Protocol: L022B** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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B03XA01 EPOETINUM ALFA SOL. INJ. 10000 ui/ml

EPREX(R) 10000 UI 10000 ui/ml JOHNSON & JOHNSON D.O.O.

B03XA01 EPOETINUM ALFA SOL. INJ. 1000 UI/0.5 ml

EPOKINE 1000 UI/0,5 ml 1000 UI/0.5 ml RENAMED FARMA S.R.L.

EPREX(R) 1000 UI 1000 ui/0.5 ml JOHNSON & JOHNSON D.O.O.

B03XA01 EPOETINUM ALFA SOL. INJ. 2000 UI

EPOPHAR 2000 U.I. 2000 UI GULF PHARMACEUTICAL IND.

S.R.L.

B03XA01 EPOETINUM ALFA SOL. INJ. 2000 ui/0.5 ml

EPOKINE 2000 UI/0,5 ml 2000 UI/0.5 ml RENAMED FARMA S.R.L.

EPREX(R) 2000 UI 2000 ui/0.5 ml JOHNSON & JOHNSON D.O.O.

B03XA01 EPOETINUM ALFA SOL. INJ. 2000 UI/1 ml

EPOKINE 2000 UI/1 ml 2000 UI/1 ml RENAMED FARMA S.R.L.

B03XA01 EPOETINUM ALFA SOL. INJ. 3000 ui/0.3 ml

EPREX(R) 3000 UI 3000 ui/0.3 ml JOHNSON & JOHNSON D.O.O.

B03XA01 EPOETINUM ALFA SOL. INJ. 40000 UI

EPREX(R) 40000 UI 40000 UI JOHNSON & JOHNSON D.O.O.

B03XA01 EPOETINUM ALFA SOL. INJ. 4000 UI

EPOPHAR 4000 U.I. 4000 UI GULF PHARMACEUTICAL IND.

S.R.L.

B03XA01 EPOETINUM ALFA SOL. INJ. 4000 ui/0.4 ml

EPOKINE 4000 UI/0,4 ml 4000 UI/0.4 ml RENAMED FARMA S.R.L.

EPREX(R) 4000 UI 4000 ui/0.4 ml JOHNSON & JOHNSON D.O.O.

B03XA01 EPOETINUM ALFA SOL. INJ. 4000 UI/1 ml

EPOKINE 4000 UI/1 ml 4000 UI/1 ml RENAMED FARMA S.R.L.

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| **427** |**B03XA01**| **EPOETINUM BETA\*\*\*** | **Protocol: L022B** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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B03XA01 EPOETINUM BETA SOL. INJ. ÎN SERINGĂ

PREUMPLUTĂ

NEORECORMON 10000 UI 10000 UI/0,6 ml ROCHE REGISTRATION L

B03XA01 EPOETINUM BETA SOL. INJ. ÎN SERINGĂ

PREUMPLUTĂ

NEORECORMON 1000 UI 1000 UI/0,3 ml ROCHE REGISTRATION L

B03XA01 EPOETINUM BETA SOL. INJ. ÎN SERINGĂ

PREUMPLUTĂ

NEORECORMON 2000 UI 2000 UI/0,3 ml ROCHE REGISTRATION L

B03XA01 EPOETINUM BETA SOL. INJ. ÎN SERINGĂ 30000 UI/0,6 ml

PREUMPLUTĂ

NEORECORMON 30000 UI/0,6 ml 30000 UI/0,6 ml ROCHE REGISTRATION LTD.

B03XA01 EPOETINUM BETA SOL. INJ. ÎN SERINGĂ

PREUMPLUTĂ

NEORECORMON 4000 UI 4000 UI/0,3 ml ROCHE REGISTRATION L

B03XA01 EPOETINUM BETA SOL. INJ. ÎN SERINGĂ

PREUMPLUTĂ

NEORECORMON 5000 UI 5000 UI/0,3 ml ROCHE REGISTRATION L

B03XA01 EPOETINUM BETA SOL. INJ. ÎN SERINGĂ

PREUMPLUTĂ

NEORECORMON 500 UI 500 UI/0,3 ml ROCHE REGISTRATION L

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| **428** |**B03XA02**| **DARBEPOETINUM ALFA\*\*\*** | **Protocol: L022B** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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B03XA02 DARBEPOETINUM ALFA SOL. INJ. ÎN SERINGĂ 10 µg/0.4 ml

PREUMPLUTĂ

ARANESP 10 µg/0.4 ml 10 µg/0.4 ml AMGEN EUROPE BV

B03XA02 DARBEPOETINUM ALFA SOL. INJ. ÎN SERINGĂ 100 µg/0.5 ml

PREUMPLUTĂ

ARANESP 100 µg/0.5 ml 100 µg/0.5 ml AMGEN EUROPE BV

B03XA02 DARBEPOETINUM ALFA SOL. INJ. ÎN SERINGĂ 15 µg/0.375 ml

PREUMPLUTĂ

ARANESP 15 µg/0.375 ml AMGEN EUROPE BV

15 µg/0.375 ml

B03XA02 DARBEPOETINUM ALFA SOL. INJ. ÎN SERINGĂ 150 µg/0.3 ml

PREUMPLUTĂ

ARANESP 150 µg/0.3 ml 150 µg/0.3 ml AMGEN EUROPE BV

B03XA02 DARBEPOETINUM ALFA SOL. INJ. ÎN SERINGĂ 20 µg/0.5 ml

PREUMPLUTĂ

ARANESP 20 µg/0.5 ml 20 µg/0.5 ml AMGEN EUROPE BV

B03XA02 DARBEPOETINUM ALFA SOL. INJ. ÎN SERINGĂ 30 µg/0.3 ml

PREUMPLUTĂ

ARANESP 30 µg/0.3 ml 30 µg/0.3 ml AMGEN EUROPE BV

B03XA02 DARBEPOETINUM ALFA SOL. INJ. ÎN SERINGĂ 300 µg/0.6 ml

PREUMPLUTĂ

ARANESP 300 µg/0.6 ml 300 µg/0.6 ml AMGEN EUROPE BV

B03XA02 DARBEPOETINUM ALFA SOL. INJ. ÎN SERINGĂ 40 µg/0.4 ml

PREUMPLUTĂ

ARANESP 40 µg/0.4 ml 40 µg/0.4 ml AMGEN EUROPE BV

B03XA02 DARBEPOETINUM ALFA SOL. INJ. ÎN SERINGĂ 50 µg/0.5 ml

PREUMPLUTĂ

ARANESP 50 µg/0.5 ml 50 µg/0.5 ml AMGEN EUROPE BV

B03XA02 DARBEPOETINUM ALFA SOL. INJ. ÎN SERINGĂ 500 µg/ml

PREUMPLUTĂ

ARANESP 500 µg/ml 500 µg/ml AMGEN EUROPE BV

B03XA02 DARBEPOETINUM ALFA SOL. INJ. ÎN SERINGĂ 60 µg/0.3 ml

PREUMPLUTĂ

ARANESP 60 µg/0.3 ml 60 µg/0.3 ml AMGEN EUROPE BV

B03XA02 DARBEPOETINUM ALFA SOL. INJ. ÎN SERINGĂ 80 µg/0.4 ml

PREUMPLUTĂ

ARANESP 80 µg/0.4 ml 80 µg/0.4 ml AMGEN EUROPE BV

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| **429** |**G03HA01**| **CYPROTERONUM\*\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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G03HA01 CYPROTERONUM COMPR. 50 mg

ANDROCUR 50 mg SCHERING AG

Cod restricţie 1014: **Cancer de prostată în stadiu avansat;**

G03HA01 CYPROTERONUM

ANDROCUR 50 mg SCHERING AG

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| **430** |**H02AB02**| **DEXAMETHASONUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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H02AB02 DEXAMETHASONUM SOL. INJ. 8 mg

DEXAMETHASONE SODIUM 8 mg E.I.P.I.CO. MED S.R.L.

PHOSPHATE

H02AB02 DEXAMETHASONUM SOL. INJ. 8 mg/2 ml

DEXAMED 8 mg/2 ml MEDOCHEMIE LTD.

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| **431** |**J02AC02**| **ITRACONAZOLUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J02AC02 ITRACONAZOLUM CAPS. 100 mg

ITRACONAZOL 100 mg 100 mg TERAPIA S.A.

OMICRAL 100 mg 100 mg MEDICO UNO PHARMACEUTICAL

S.R.L.

ORUNGAL 100 mg JANSSEN PHARMACEUTICA NV

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| **432** |**J02AC03**| **VORICONAZOLUM\*\*** | **Protocol: J012B** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J02AC03 VORICONAZOLUM COMPR. FILM. 200 mg

VFEND 200 mg 200 mg PFIZER LTD.

J02AC03 VORICONAZOLUM PULB. PT. SOL. PERF. 200 mg

VFEND 200 mg 200 mg PFIZER LTD.

J02AC03 VORICONAZOLUM PULB. PT. SUSP. ORALĂ 40 mg/ml

VFEND 40 mg/ml 40 mg/ml PFIZER LTD.

J02AC03 VORICONAZOLUM COMPR. FILM. 50 mg

VFEND 50 mg 50 mg PFIZER LTD.

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| **433** |**J02AC04**| **POSACONAZOLUM\*\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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J02AC04 POSACONAZOLUM SUSP. ORALĂ 40 mg/ml

NOXAFIL SP 40 mg/ml 40 mg/ml SP EUROPE

Prescriere limitată: **Profilaxia şi infecţiilor fungice invazive la pacienţii aflaţi sub chimioterapie de inducţie-remisie pentru LAM sau pentru sindroame mielodisplazice şi care prezintă risc înalt de a dezvolta infecţii fungice masive;**

Prescriere limitată: **Profilaxia şi infecţiilor fungice invazive la pacienţii în procedura de transplant medular şi aflaţi sub terapie imunosupresoare cu doze mari, cu risc mare de a dezvolta infecţii fungice masive.**

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| **434** |**J02AX04**| **CASPOFUNGINUM\*\*** | **Protocol: J010D** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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J02AX04 CASPOFUNGINUM PULB. PT. CONC. PT. 50 mg

SOL. PERF.

CANCIDAS 50 mg 50 mg MERCK SHARP & DOHME LTD

J02AX04 CASPOFUNGINUM PULB. PT. CONC. PT. 70 mg

SOL. PERF.

CANCIDAS 70 mg 70 mg MERCK SHARP & DOHME LTD

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| **435** |**L01XX35**| **ANAGRELIDUM\*\*\*** | **Protocol: L015D** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L01XX35 ANAGRELIDUM CAPS. 0.5 mg

THROMBOREDUCTIN 0.5 mg ORPHA-DEVEL HANDELS UND

VERTRIEBS GMBH

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| **436** |**L04AA01**| **CICLOSPORINUM\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L04AA01 CICLOSPORINUM CAPS. MOI 100 mg

EQUORAL(R) 100 mg 100 mg IVAX-PHARMACEUTICALS

S.R.O.

L04AA01 CICLOSPORINUM SOL. ORALĂ 100 mg/ml

EQUORAL(R) 100 mg/ml IVAX-PHARMACEUTICALS

S.R.O.

SANDIMMUN NEORAL(R) 100 mg/ml NOVARTIS PHARMA GMBH

L04AA01 CICLOSPORINUM CAPS. MOI 25 mg

CICLORAL(R) HEXAL(R) 25 mg 25 mg HEXAL AG

EQUORAL(R) 25 mg 25 mg IVAX-PHARMACEUTICALS

S.R.O.

SANDIMMUN NEORAL(R) 25 mg NOVARTIS PHARMA GMBH

L04AA01 CICLOSPORINUM CAPS. MOI 50 mg

CICLORAL(R) HEXAL 50 mg 50 mg HEXAL AG

EQUORAL(R) 50 mg 50 mg IVAX-PHARMACEUTICALS

S.R.O.

SANDIMMUN NEORAL(R) 50 mg NOVARTIS PHARMA GMBH

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| **437** |**N02AA01**| **MORPHYNUM** | |

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Prescriere limitată: **Durere severă, invalidantă, asociată cu diagnosticul**

**de cancer.**

**Durere severă, invalidantă, indusă de cancer, care nu**

**răspunde la analgezice non-opioide.**

**Durere cronică severă, invalidantă, care nu răspunde la**

**analgezice non-opioide, unde durata totală a**

**tratamentului opioid este mai scurtă de 12 luni.**

Risc înalt de apariţie a dependenţei.

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare acestui DCI**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N02AA01 MORPHYNUM COMPR. FILM. ELIB. 100 mg

MODIF.

MST CONTINUS(R) 100 mg 100 mg MUNDIPHARMA GMBH

N02AA01 MORPHYNUM COMPR. FILM. ELIB. 100 mg

PREL.

VENDAL(R) RETARD 100 mg 100 mg LANNACHER HEILMITTEL GMBH

N02AA01 MORPHYNUM COMPR. FILM. 10 mg

SEVREDOL 10 mg 10 mg MUNDIPHARMA GMBH

N02AA01 MORPHYNUM COMPR. FILM. ELIB. 10 mg

MODIF.

MST CONTINUS(R) 10 mg 10 mg MUNDIPHARMA GMBH

N02AA01 MORPHYNUM COMPR. FILM. ELIB. 10 mg

PREL.

VENDAL(R) RETARD 10 mg 10 mg LANNACHER HEILMITTEL GMBH

N02AA01 MORPHYNUM COMPR. FILM. ELIB. 200 mg

MODIF.

MST CONTINUS(R) 200 mg 200 mg MUNDIPHARMA GMBH

N02AA01 MORPHYNUM COMPR. FILM. 20 mg

SEVREDOL 20 mg 20 mg MUNDIPHARMA GMBH

N02AA01 MORPHYNUM SOL. INJ. 20 mg/ml

MORFINA 20 mg/ml 20 mg/ml ZENTIVA S.A.

N02AA01 MORPHYNUM COMPR. FILM. ELIB. 30 mg

MODIF.

MST CONTINUS(R) 30 mg 30 mg MUNDIPHARMA GMBH

N02AA01 MORPHYNUM COMPR. FILM. ELIB. 30 mg

PREL.

VENDAL(R) RETARD 30 mg 30 mg LANNACHER HEILMITTEL GMBH

N02AA01 MORPHYNUM COMPR. FILM. ELIB. 60 mg

MODIF.

MST CONTINUS(R) 60 mg 60 mg MUNDIPHARMA GMBH

N02AA01 MORPHYNUM COMPR. FILM. ELIB. 60 mg

PREL.

VENDAL(R) RETARD 60 mg 60 mg LANNACHER HEILMITTEL GMBH

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| **438** |**N02AA05**| **OXYCODONUM** | |

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Prescriere limitată: **Durere severă, invalidantă, asociată cu diagnosticul**

**de cancer.**

**Durere severă, invalidantă, indusă de cancer, care nu**

**răspunde la analgezice non-opioide.**

**Durere cronică severă, invalidantă, care nu răspunde la**

**analgezice non-opioide, unde durata totală a**

**tratamentului opioid este mai scurtă de 12 luni.**

Risc înalt de apariţie a dependenţei.

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare acestui DCI.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N02AA05 OXYCODONUM COMPR. FILM. ELIB. 10 mg

MODIF.

OXYCONTIN(R) 10 mg 10 mg MUNDIPHARMA GMBH

N02AA05 OXYCODONUM COMPR. FILM. ELIB. 20 mg

MODIF.

OXYCONTIN(R) 20 mg 20 mg MUNDIPHARMA GMBH

N02AA05 OXYCODONUM COMPR. FILM. ELIB. 40 mg

MODIF.

OXYCONTIN(R) 40 mg 40 mg MUNDIPHARMA GMBH

N02AA05 OXYCODONUM COMPR. FILM. ELIB. 80 mg

MODIF.

OXYCONTIN(R) 80 mg 80 mg MUNDIPHARMA GMBH

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| **439** |**N02AA08**| **DIHYDROCODEINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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N02AA08 DIHYDROCODEINUM COMPR. ELIB. PREL. 120 mg

DHC CONTINUS 120 mg 120 mg MUNDIPHARMA GMBH

N02AA08 DIHYDROCODEINUM COMPR. ELIB. PREL. 60 mg

DHC CONTINUS 60 mg 60 mg MUNDIPHARMA GMBH

N02AA08 DIHYDROCODEINUM COMPR. ELIB. PREL. 90 mg

DHC CONTINUS 90 mg 90 mg MUNDIPHARMA GMBH

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| **440** |**N02AB02**| **PETHIDINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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N02AB02 PETHIDINUM SOL. INJ. 50 mg/ml

MIALGIN(R) 100 mg/2 ml 50 mg/ml ZENTIVA SA

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| **441** |**N02AB03**| **FENTANYLUM\*\*** | |

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Prescriere limitată: **Durere severă, invalidantă, asociată cu diagnosticul**

**de cancer.**

**Durere severă, invalidantă, indusă de cancer, care nu**

**răspunde la analgezice non-opioide.**

**Durere cronică severă, invalidantă, care nu răspunde la**

**analgezice non-opioide, unde durata totală a**

**tratamentului opioid este mai scurtă de 12 luni.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare acestui DCI.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N02AB03 FENTANYLUM PLASTURE TRANSDERMIC 100 µg/h

FENTANYL SANDOZ 100 µg/h SANDOZ S.R.L.

100 µg/h

N02AB03 FENTANYLUM PLASTURE TRANSDERM. 16.8 mg/42.0 cmp

DUROGESIC 100 µg/h 16.8 mg/42.0 cmp JANSSEN PHARMACEUTICA NV

N02AB03 FENTANYLUM PLASTURE TRANSDERMIC 25 µg/h

FENTANYL SANDOZ 25 µg/h SANDOZ S.R.L.

25 µg/h

N02AB03 FENTANYLUM PLASTURE TRANSDERM. 4.2 mg/10.5 cmp

DUROGESIC 25 µg/h 4.2 mg/10.5 cmp JANSSEN PHARMACEUTICA NV

N02AB03 FENTANYLUM PLASTURE TRANSDERMIC 50 µg/h

FENTANYL SANDOZ 50 µg/h SANDOZ S.R.L.

50 µg/h

N02AB03 FENTANYLUM PLASTURE TRANSDERMIC 75 µg/h

FENTANYL SANDOZ 75 µg/h SANDOZ S.R.L.

75 µg/h

N02AB03 FENTANYLUM PLASTURE TRANSDERM. 8.4 mg/21.0 cmp

DUROGESIC 50 µg/h 8.4 mg/21.0 cmp JANSSEN PHARMACEUTICA NV

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| **442** |**N02AX02**| **TRAMADOLUM** | |

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Prescriere limitată: **Durere severă, care nu răspunde la analgezice**

**non-opioide.**

**Pentru durere acută la care tratamentul cu aspirină**

**şi/sau paracetamol este contraindicat sau nu a dat**

**rezultate.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice (mai puţin formelor injectabile) şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N02AX02 TRAMADOLUM COMPR. ELIB. MODIF. 100 mg

TRAMADOLOR(R) 100 ID 100 mg HEXAL AG

N02AX02 TRAMADOLUM COMPR. ELIB. PREL. 100 mg

TRALGIT SR 100 100 mg ZENTIVA AS

TRAMADOL(R) RETARD 100 mg KRKA D.D.

N02AX02 TRAMADOLUM COMPR. FILM. ELIB. 100 mg

PREL.

TRAMAL RETARD 100 mg 100 mg GRUNENTHAL GMBH

N02AX02 TRAMADOLUM SOL. INJ. 100 mg

MABRON 100 mg MEDOCHEMIE LTD.

TRADOLAN 100 mg LANNACHER HEILMITTEL GMBH

Prescriere limitată: **Tratamentul de scurtă durată al durerii acute.**

N02AX02 TRAMADOLUM SUPOZ. 100 mg

TRADOLAN 100 mg LANNACHER HEILMITTEL GMBH

TRAMADOL 100 mg KRKA D.D.

TRAMAG 100 100 mg MAGISTRA C & C

TRAMAL(R) 100 mg GRUNENTHAL GMBH

N02AX02 TRAMADOLUM SOL. INJ. 100 mg/2 ml

TRALGIT 100 100 mg/2 ml ZENTIVA A.S.

Prescriere limitată: **Tratamentul de scurtă durată al durerii acute.**

N02AX02 TRAMADOLUM PIC. ORALE, SOL. 100 mg/ml

TRALGIT 100 mg/ml ZENTIVA A.S.

N02AX02 TRAMADOLUM SOL. ORALĂ 100 mg/ml

TRADOLAN 100 mg/ml LANNACHER HEILMITTEL GMBH

N02AX02 TRAMADOLUM COMPR. ELIB. PREL. 150 mg

TRALGIT SR 150 150 mg ZENTIVA AS

N02AX02 TRAMADOLUM COMPR. FILM. ELIB. 150 mg

PREL.

TRAMADOL RETARD 150 mg 150 mg KRKA D.D. NOVO MESTO

TRAMAL RETARD 150 mg 150 mg GRUNENTHAL GMBH

N02AX02 TRAMADOLUM COMPR. ELIB. PREL. 200 mg

TRALGIT SR 200 200 mg ZENTIVA AS

N02AX02 TRAMADOLUM COMPR. FILM. ELIB. 200 mg

PREL.

TRAMADOL RETARD 200 mg 200 mg KRKA D.D. NOVO MESTO

TRAMAL RETARD 200 mg 200 mg GRUNENTHAL GMBH

N02AX02 TRAMADOLUM CAPS. 50 mg

K-ALMA(R) 50 mg ANTIBIOTICE SA

MABRON 50 mg 50 mg MEDOCHEMIE LTD.

TRALGIT 50 50 mg ZENTIVA A.S.

TRAMACALM 50 mg AC HELCOR SRL

TRAMADOL 50 mg KRKA D.D.

TRAMADOL LPH 50 mg 50 mg LABORMED PHARMA SA

TRAMADOL AL 50 50 mg ALIUD(R) PHARMA GMBH &

CO.KG

TRAMADOL ARENA 50 mg ARENA GROUP SA

TRAMAL(R) 50 mg GRUNENTHAL GMBH

URGENDOL 50 mg MEDICAROM GROUP SRL

N02AX02 TRAMADOLUM COMPR. 50 mg

TRAMADOL 50 mg 50 mg OZONE LABORATORIES LTD.

TRAMADOL EEL 50 mg BIO EEL SRL

TRAMAG 50 50 mg MAGISTRA C & C

N02AX02 TRAMADOLUM COMPR. FILM. 50 mg

TRADOLAN 50 mg 50 mg LANNACHER HEILMITTEL GMBH

N02AX02 TRAMADOLUM SOL. INJ. 50 mg

TRADOLAN 50 mg 50 mg LANNACHER HEILMITTEL GMBH

Prescriere limitată: **Tratamentul de scurtă durată al durerii acute.**

N02AX02 TRAMADOLUM SOL. INJ. 50 mg/ml

TRALGIT 50 50 mg/ml ZENTIVA A.S.

TRAMADOL 50 mg/ml KRKA D.D.

TRAMADOL(R) AL 100 Fiole 50 mg/ml ALIUD(R) PHARMA

GMBH & CO.KG

TRAMAL(R) 100 50 mg/ml GRUNENTHAL GMBH

TRAMAL(R) 50 50 mg/ml GRUNENTHAL GMBH

URGENDOL 50 mg/ml MEDICAROM GROUP SRL

Prescriere limitată: **Tratamentul de scurtă durată al durerii acute.**

N02AX02 TRAMADOLUM PIC. ORALE, SOL.

TRAMADOL AL PICĂTURI ALIUD PHARMA GMBH & CO.KG

N02AX02 TRAMADOLUM PICĂTURI ORALE - SOL 100 mg/ml

TRAMAL(R) 100 mg/ml GRUNENTHAL GMBH

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| **443** |**N07BC02**| **METHADONUM** | |

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Risc înalt de apariţie a dependenţei.

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N07BC02 METHADONUM COMPR. 2.5 mg

SINTALGON 2,5 mg 2.5 mg ZENTIVA SA

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| **444** |**R05DA04**| **CODEINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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R05DA04 CODEINUM COMPR. 15 mg

CODEINA FOSFAT 15 mg SLAVIA PHARM SRL

CODEINA FOSFAT 15 mg 15 mg OZONE LABORATORIES LTD.

CODEINA FOSFAT LPH 15 mg 15 mg LABORMED PHARMA SA

CODEINA FOSFORICA 15 mg BIO EEL SRL

CODEINA FOSFORICA 15 mg 15 mg MAGISTRA C & C

FARMACOD 15 mg FARMACOM SA

FOSFAT DE CODEINA 15 mg 15 mg SINTOFARM SA

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| **445** |**V03AC01**| **DEFEROXAMINUM\*\*(3)** | **Protocol: V001D** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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V03AC01 DEFEROXAMINUM LIOF. PT. SOL. 500 mg

INJ./PERF.

DESFERAL 500 mg NOVARTIS PHARMA GMBH

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| **446** |**V03AC03**| **DEFERASIROXUM\*\*\*** | **Protocol: V002D** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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V03AC03 DEFERASIROXUM COMPR. DISP. 125 mg

EXJADE 125 mg 125 mg NOVARTIS EUROPHARM LTD.

V03AC03 DEFERASIROXUM COMPR. DISP. 250 mg

EXJADE 250 mg 250 mg NOVARTIS EUROPHARM LTD.

V03AC03 DEFERASIROXUM COMPR. DISP. 500 mg

EXJADE 500 mg 500 mg NOVARTIS EUROPHARM LTD.

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**SUBLISTA C1 - G11 EPILEPSIE.**

**Protocol: NG01G**

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| **447** |**N03AA02**| **PHENOBARBITALUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N03AA02 PHENOBARBITALUM COMPR. 100 mg

FENOBARBITAL 100 mg 100 mg ZENTIVA SA

Prescriere limitată: **Epilepsie**

N03AA02 PHENOBARBITALUM COMPR. 100 mg

FENOBARBITAL 100 mg 100 mg SC ARENA GROUP SA

Prescriere limitată: **Epilepsie**

N03AA02 PHENOBARBITALUM SOL. INJ. 10%

FENOBARBITAL 200 mg/2 ml 10% ZENTIVA S.A.

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| **448** |**N03AB02**| **PHENYTOINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N03AB02 PHENYTOINUM COMPR. 100 mg

FENITOIN 100 mg 100 mg GEDEON RICHTER ROMANIA SA

N03AB02 PHENYTOINUM SOL. INJ. 50 mg/ml

PHENHYDAN(R) SOLUŢIE 50 mg/ml DESITIN

INJECTABILĂ

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| **449** |**N03AE01**| **CLONAZEPAMUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N03AE01 CLONAZEPAMUM COMPR. 0.5 mg

RIVOTRIL 0.5 mg ROCHE ROMANIA S.R.L.

N03AE01 CLONAZEPAMUM COMPR. 2 mg

RIVOTRIL(R) 2 mg ROCHE ROMANIA S.R.L.

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| **450** |**N03AF01**| **CARBAMAZEPINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N03AF01 CARBAMAZEPINUM SUSP. ORALĂ 100 mg/5 ml

TIMONIL SIROP 100 mg/5 ml DESITIN ARZNEIMITTEL GMBH

N03AF01 CARBAMAZEPINUM COMPR. RET. 150 mg

TIMONIL 150 RETARD 150 mg DESITIN

N03AF01 CARBAMAZEPINUM COMPR. 200 mg

CARBAMAZEPIN 200 mg SLAVIA PHARM SRL

CARBAMAZEPIN EEL 200 mg BIO EEL SRL

CARBAMAZEPINA 200 mg OZONE LABORATORIES LTD.

CARBAMAZEPINA ARENA 200 mg 200 mg ARENA GROUP SA

CARBAMAZEPINA LPH 200 mg 200 mg LABORMED PHARMA SA

CARBAVIM 200 mg VIM SPECTRUM SRL

CARBEPSIL 200 200 mg AC HELCOR SRL

FINLEPSIN 200 mg AWD PHARMA GMBH & CO.KG

NEUROTOP 200 mg GEROT PHARMAZEUTIKA GMBH

TAVER 200 mg MEDOCHEMIE LTD.

TEGRETOL(R) 200 200 mg NOVARTIS PHARMA GMBH

N03AF01 CARBAMAZEPINUM COMPR. FILM. ELIB. 200 mg

PREL.

TEGRETOL CR 200 200 mg NOVARTIS PHARMA GMBH

N03AF01 CARBAMAZEPINUM COMPR. ELIB. PREL. 300 mg

NEUROTOP(R) RETARD 300 mg 300 mg GEROT PHARMAZEUTIKA GMBH

N03AF01 CARBAMAZEPINUM COMPR. RET. 300 mg

TIMONIL 300 RETARD 300 mg DESITIN

N03AF01 CARBAMAZEPINUM COMPR. 400 mg

CARBEPSIL 400 400 mg AC HELCOR SRL

TEGRETOL(R) 400 400 mg NOVARTIS PHARMA GMBH

N03AF01 CARBAMAZEPINUM COMPR. FILM. ELIB. 400 mg

PREL.

TEGRETOL CR 400 400 mg NOVARTIS PHARMA GMBH

N03AF01 CARBAMAZEPINUM COMPR. RET. 400 mg

FINLEPSIN 400 RETARD 400 mg AWD PHARMA GMBH & CO.KG

N03AF01 CARBAMAZEPINUM COMPR. ELIB. PREL. 600 mg

NEUROTOP(R) RETARD 600 mg 600 mg GEROT PHARMAZEUTIKA GMBH

N03AF01 CARBAMAZEPINUM COMPR. RET. 600 mg

TIMONIL 600 RETARD 600 mg DESITIN

N03AF01 CARBAMAZEPINUM COMPR. FILM. ELIB. 200 mg

PREL.

FINLEPSIN 200 RETARD 200 mg AWD PHARMA GMBH & CO.KG

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| **451** |**N03AF02**| **OXCARBAZEPINUM** | |

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**Cod restricţie 1587: Tratamentul crizelor epileptice parţiale şi al crizelor primare cu contracţii tonico-clonice generalizate, care nu pot fi suficient controlate cu alte medicamente anti-epileptice.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare acestui DCI.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N03AF02 OXCARBAZEPINUM COMPR. FILM. 300 mg

TRILEPTAL(R) 300 mg 300 mg NOVARTIS PHARMA GMBH

N03AF02 OXCARBAZEPINUM COMPR. FILM. 600 mg

TRILEPTAL(R) 600 mg 600 mg NOVARTIS PHARMA GMBH

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| **452** |**N03AG01**| **ACIDUM VALPROICUM + SĂRURI** | |

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S-au raportat cazuri de hepatotoxicitate letală, în special la copii. Se înregistrează din ce în ce mai multe dovezi cu privire la teratogenitatea legată de doză.

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare acestui DCI.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N03AG01 ACIDUM VALPROICUM + MINICOMPR. ELIB. PREL. 1000 mg

SĂRURI

ORFIRIL LONG 1000 mg 1000 mg DESITIN ARZNEIMITTEL GMBH

N03AG01 ACIDUM VALPROICUM + CAPS. ELIB. PREL. 150 mg

SĂRURI

ORFIRIL LONG 150 mg 150 mg DESITIN ARZNEIMITTEL GMBH

N03AG01 ACIDUM VALPROICUM + CAPS. MOI GASTROREZ. 150 mg

SĂRURI

CONVULEX(R) 150 mg 150 mg GEROT PHARMAZEUTIKA GMBH

N03AG01 ACIDUM VALPROICUM + COMPR. FILM. GASTROREZ. 150 mg

SĂRURI

ORFIRIL 150 150 mg DESITIN ARZNEIMITTEL GMBH

N03AG01 ACIDUM VALPROICUM + COMPR. FILM. 200 mg

SĂRURI

PETILIN 200 mg REMEDICA LTD.

N03AG01 ACIDUM VALPROICUM + COMPR. FILM. GASTROREZ. 200 mg

SĂRURI

DEPAKINE 200 mg 200 mg SANOFI-AVENTIS FRANCE

N03AG01 ACIDUM VALPROICUM + CAPS. ELIB. PREL. 300 mg

SĂRURI

ORFIRIL LONG 300 mg 300 mg DESITIN ARZNEIMITTEL GMBH

N03AG01 ACIDUM VALPROICUM + CAPS. MOI GASTROREZ. 300 mg

SĂRURI

CONVULEX(R) 300 mg 300 mg GEROT PHARMAZEUTIKA GMBH

N03AG01 ACIDUM VALPROICUM + COMPR. FILM. GASTROREZ. 300 mg

SĂRURI

ORFIRIL 300 300 mg DESITIN ARZNEIMITTEL GMBH

N03AG01 ACIDUM VALPROICUM + SIROP 300 mg/5 ml

SĂRURI

ORFIRIL SIROP 300 mg/5 ml DESITIN ARZNEIMITTEL GMBH

N03AG01 ACIDUM VALPROICUM + LIOF. + SOLV. PT. SOL. 400 mg/4 ml

SĂRURI

DEPAKINE(R) 400 mg/4 ml 400 mg/4 ml SANOFI-AVENTIS FRANCE

LIOFILIZAT ŞI SOLVENT PENTRU

SOLUŢIE INJECTABILĂ i.v.

N03AG01 ACIDUM VALPROICUM + CAPS. MOI GASTROREZ. 500 mg

SĂRURI

CONVULEX(R) 500 mg 500 mg GEROT PHARMAZEUTIKA GMBH

N03AG01 ACIDUM VALPROICUM + MINICOMPR. ELIB. PREL. 500 mg

SĂRURI

ORFIRIL LONG 500 mg 500 mg DESITIN ARZNEIMITTEL GMBH

N03AG01 ACIDUM VALPROICUM + SIROP 50 mg/ml

SĂRURI

CONVULEX(R) 50 mg/ml GEROT PHARMAZEUTIKA GMBH

N03AG01 ACIDUM VALPROICUM + SIROP 57.64 mg/ml

SĂRURI

DEPAKINE 57.64 mg/ml SANOFI - AVENTIS FRANCE

N03AG01 ACIDUM VALPROICUM + COMPR. FILM. GASTROREZ. 600 mg

SĂRURI

ORFIRIL 600 600 mg DESITIN ARZNEIMITTEL GMBH

N03AG01 ACIDUM VALPROICUM + COMPR. FILM. ELIB. 300 mg

SĂRURI PREL. DIVIZ.

DEPAKINE CHRONO 300 mg 300 mg SANOFI-AVENTIS FRANCE

N03AG01 ACIDUM VALPROICUM + COMPR. FILM. ELIB. 500 mg

SĂRURI PREL. DIVIZ.

DEPAKINE(R) CHRONO 500 mg 500 mg SANOFI-AVENTIS FRANCE

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| **453** |**N03AX09**| **LAMOTRIGINUM\*\*** | |

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**Cod restricţie 1426: Tratamentul crizelor epileptice insuficient controlate prin administrarea altor medicamente antiepileptice.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare acestui DCI.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N03AX09 LAMOTRIGINUM SOL. INJ. 0.1 mg/ml

EPIMIL 100 mg 100 mg IVAX PHARMCEUTICALS S.R.O.

EPIZOL 100 mg 100 mg KRKA D.D. NOVO MESTO

LAMICTAL 100 mg 100 mg THE WELLCOME FOUNDATION

LTD.

LAMOLEP 100 mg 100 mg GEDEON RICHTER LTD.

LAMOTIRAN 100 mg 100 mg RANBAXY UK LTD.

LAMOTRIX 100 mg 100 mg MEDOCHEMIE LTD.

PLEXXO(R) 100 mg 100 mg DESITIN ARZNEIMITTEL GMBH

N03AX09 LAMOTRIGINUM COMPR. DISP. 100 mg

LAMOTRIGIN STADA 100 mg 100 mg STADA ARZNEIMITTEL AG

LAMOTRIN 100 mg 100 mg ACTAVIS GROUP HF.

N03AX09 LAMOTRIGINUM COMPR. 200 mg

LAMOTIRAN 200 mg 200 mg RANBAXY UK LTD.

LAMOTRIX 200 mg 200 mg MEDOCHEMIE LTD.

N03AX09 LAMOTRIGINUM COMPR. 25 mg

EPIMIL 25 mg 25 mg IVAX PHARMCEUTICALS S.R.O.

EPIZOL 25 mg 25 mg KRKA D.D. NOVO MESTO

LAMICTAL 25 mg 25 mg THE WELLCOME FOUNDATION

LTD.

LAMOLEP 25 mg 25 mg GEDEON RICHTER LTD.

LAMOTIRAN 25 mg 25 mg RANBAXY UK LTD.

LAMOTRIX 25 mg 25 mg MEDOCHEMIE LTD.

PLEXXO(R) 25 mg 25 mg DESITIN ARZNEIMITTEL GMBH

N03AX09 LAMOTRIGINUM COMPR. DISP. 25 mg

LAMOTRIGIN STADA 25 mg 25 mg STADA ARZNEIMITTEL AG

LAMOTRIN 25 mg 25 mg ACTAVIS GROUP HF.

N03AX09 LAMOTRIGINUM COMPR. DISP./MAST. 25 mg

LAMICTAL 25 mg 25 mg THE WELLCOME FOUNDATION

LTD.

N03AX09 LAMOTRIGINUM COMPR. DISP./MAST. 2 mg

LAMICTAL(R) 2 mg 2 mg THE WELLCOME FOUNDATION

LTD.

N03AX09 LAMOTRIGINUM COMPR. 50 mg

EPIMIL 50 mg 50 mg IVAX PHARMCEUTICALS S.R.O.

EPIZOL 50 mg 50 mg KRKA D.D. NOVO MESTO

LAMICTAL 50 mg 50 mg THE WELLCOME FOUNDATION

LTD.

LAMOLEP 50 mg 50 mg GEDEON RICHTER LTD.

LAMOTIRAN 50 mg 50 mg RANBAXY UK LTD.

LAMOTRIX 50 mg 50 mg MEDOCHEMIE LTD.

PLEXXO(R) 50 mg 50 mg DESITIN ARZNEIMITTEL GMBH

N03AX09 LAMOTRIGINUM COMPR. DISP. 50 mg

LAMOTRIGIN STADA 50 mg 50 mg STADA ARZNEIMITTEL AG

LAMOTRIN 50 mg 50 mg ACTAVIS GROUP HF.

N03AX09 LAMOTRIGINUM COMPR. DISP./MAST. 5 mg

LAMICTAL 5 mg 5 mg THE WELLCOME FOUNDATION

LTD.

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| **454** |**N03AX11**| **TOPIRAMATUM\*\*** | |

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**Cod restricţie 2797: Tratamentul crizelor epileptice parţiale, crizelor primare cu contracţii tonico-clonice generalizate, crizelor din sindromul Lennox-Gastaut, insuficient controlate prin administrarea altor medicamente antiepileptice.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare acestui DCI.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N03AX11 TOPIRAMATUM COMPR. FILM. 100 mg

TOPAMAX 100 mg 100 mg JOHNSON & JOHNSON D.O.O.

TOPRAN 100 mg 100 mg TERAPIA S.A.

N03AX11 TOPIRAMATUM COMPR. FILM. 200 mg

TOPAMAX 200 mg 200 mg JOHNSON & JOHNSON D.O.O.

TOPRAN 200 mg 200 mg TERAPIA S.A.

N03AX11 TOPIRAMATUM COMPR. FILM. 25 mg

TOPAMAX 25 mg 25 mg JOHNSON & JOHNSON D.O.O.

TOPRAN 25 mg 25 mg TERAPIA S.A.

N03AX11 TOPIRAMATUM COMPR. FILM. 50 mg

TOPAMAX 50 mg 50 mg JOHNSON & JOHNSON D.O.O.

TOPRAN 50 mg 50 mg TERAPIA S.A.

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| **455** |**N03AX12**| **GABAPENTINUM\*\*\*** | |

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**Cod restricţie 2664: Tratamentul crizelor epileptice parţiale insuficient controlate prin administrarea altor medicamente antiepileptice.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare acestui DCI.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N03AX12 GABAPENTINUM CAPS. 100 mg

GABAGAMMA 100 mg 100 mg WORWAG PHARMA GMBH & CO.KG

GABALEPT 100 mg 100 mg PLIVA LJUBLJANA D.O.O.

N03AX12 GABAPENTINUM CAPS. 300 mg

GABAGAMMA 300 mg 300 mg WORWAG PHARMA GMBH & CO.KG

GABALEPT 300 mg 300 mg PLIVA LJUBLJANA D.O.O.

GABARAN 300 mg 300 mg RANBAXY UK LTD.

N03AX12 GABAPENTINUM CAPS. 400 mg

GABAGAMMA 400 mg 400 mg WORWAG PHARMA GMBH & CO.KG

GABALEPT 400 mg 400 mg PLIVA LJUBLJANA D.O.O.

GABARAN 400 mg 400 mg RANBAXY UK LTD.

N03AX12 GABAPENTINUM COMPR. FILM. 600 mg

GABARAN 600 mg 600 mg RANBAXY UK LTD.

N03AX12 GABAPENTINUM COMPR. FILM. 800 mg

GABARAN 800 mg 800 mg RANBAXY UK LTD.

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| **456** |**N03AX14**| **LEVETIRACETAMUM\*\*** |

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Prescriere limitată: **Tratamentul crizelor epileptice parţiale insuficient**

**controlate prin administrarea altor medicamente**

**antiepileptice.**

**Tratamentul crizelor epileptice parţiale insuficient**

**controlate prin administrarea altor medicamente**

**antiepileptice şi unde au existat reacţii adverse în**

**antecedente la alte antiepileptice.**

**Tratamentul crizelor epileptice parţiale insuficient**

**controlate prin administrarea altor medicamente**

**antiepileptice şi unde au existat interacţiuni**

**medicamentoase cu alte medicamente compensate adecvate.**

**Tratamentul crizelor epileptice parţiale insuficient**

**controlate prin administrarea altor medicamente**

**antiepileptice şi unde transferul la alt medicament**

**compensat adecvat este posibil să genereze consecinţe**

**clinice adverse.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N03AX14 LEVETIRACETAMUM COMPR. FILM. 1000 mg

KEPPRA 1000 mg 1000 mg UCB PHARMA SA

N03AX14 LEVETIRACETAMUM SOL. ORALĂ 100 mg/ml

KEPPRA 100 mg/ml 100 mg/ml UCB PHARMA SA

N03AX14 LEVETIRACETAMUM COMPR. FILM. 500 mg

KEPPRA 500 mg 500 mg UCB PHARMA LTD

N03AX14 LEVETIRACETAMUM COMPR. FILM. 1000 mg

KEPPRA 1000 mg 1000 mg UCB PHARMA SA

N03AX14 LEVETIRACETAMUM COMPR. FILM. 500 mg

KEPPRA 500 mg 500 mg UCB PHARMA LTD

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| **457** |**N03AX16**| **PREGABALINUM\*\*\*** | |

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Prescriere limitată: **Tratamentul adjuvant al epilepsiei la adulţii cu convulsii parţiale, cu sau fără generalizare secundară.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N03AX16 PREGABALINUM CAPS. 150 mg

LYRICA 150 mg 150 mg PFIZER LTD.

N03AX16 PREGABALINUM CAPS. 300 mg

LYRICA 300 mg 300 mg PFIZER LTD.

N03AX16 PREGABALINUM CAPS. 75 mg

LYRICA 75 mg 75 mg PFIZER LTD.

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**SUBLISTA C1 - G12 BOALA PARKINSON.**

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| **458** |**N04AA01**| **TRIHEXYPHENIDYLUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N04AA01 TRIHEXYPHENIDYLUM COMPR. 2 mg

ROMPARKIN(R) 2 mg 2 mg TERAPIA SA

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| **460** |**N04BA02**| **COMBINAŢII (LEVODOPUM + CARBIDOPUM)\*\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N04BA02 COMBINAŢII (LEVODOPUM CAPS. ELIB. MODIF. 100 mg + 25 mg

+ CARBIDOPUM)

MADOPAR HBS 100 mg + 25 mg ROCHE ROMANIA S.R.L

N04BA02 COMBINAŢII (LEVODOPUM COMPR. 200 mg + 50 mg

+ CARBIDOPUM)

MADOPAR 250 200 mg + 50 mg ROCHE ROMANIA SRL

MADOPAR(R) 250 200 mg + 50 mg TERAPIA SA

Cod restricţie 1257: **Boala Parkinson în care tulburările funcţiei motorii nu sunt suficient controlate cu administrări frecvente ale formulelor convenţionale de levodopa combinat cu inhibitor al decarboxylazei.**

N04BA02 COMBINAŢII (LEVODOPUM COMPR. 250 mg/25 mg

+ CARBIDOPUM)

ISICOM 250 mg/25 mg 250 mg/25 mg DESITIN ARZNEIMITTEL GMBH

N04BA02 COMBINAŢII (LEVODOPUM COMPR. 250 mg + 25 mg

+ CARBIDOPUM)

CARBIDOPA/LEVODOPA 250 mg + 25 mg TEVA PHARMACEUTICALS SRL

TEVA 25/250

CREDANIL 25/250 250 mg +25 mg REMEDICA LTD.

NAKOM 250 mg + 25 mg LEK PHARMACEUTICALS D.D.

ZIMOX 250 mg + 25 mg FARAN LABORATORIES S.A.

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| **461** |**N04BA02**| **COMBINAŢII (LEVODOPUM + BENSERAZIDUM)\*\*** | |

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**Cod restricţie 1257: Boala Parkinson în care tulburările funcţiei motorii nu sunt suficient controlate cu administrări frecvente ale formulelor convenţionale de levodopa combinat cu inhibitor al decarboxylazei.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N04BA02 COMBINAŢII (LEVODOPUM CAPS. ELIB. MODIF. 100 mg + 25 mg

+ BENSERAZIDUM)

MADOPAR HBS 100 mg + 25 mg ROCHE ROMANIA S.R.L.

N04BA02 COMBINAŢII (LEVODOPUM COMPR. 200 mg + 50 mg

+ BENSERAZIDUM)

MADOPAR 250 200 mg + 50 mg ROCHE ROMANIA SRL

MADOPAR(R) 250 200 mg + 50 mg TERAPIA SA

N04BA02 COMBINAŢII (LEVODOPUM COMPR. 250 mg/25 mg

+ BENSERAZIDUM)

ISICOM 250 mg/25 mg 250 mg/25 mg DESITIN ARZNEIMITTEL GMBH

N04BA02 COMBINAŢII (LEVODOPUM COMPR. 250 mg + 25 mg

+ BENSERAZIDUM)

CARBIDOPA/LEVODOPA 250 mg + 25 mg TEVA PHARMACEUTICALS SRL

TEVA 25/250

CREDANIL 25/250 250 mg + 25 mg REMEDICA LTD.

NAKOM 250 mg + 25 mg LEK PHARMACEUTICALS D.D.

ZIMOX 250 mg + 25 mg FARAN LABORATORIES S.A.

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| **462** |**N04BA03**| **COMBINAŢII (LEVODOPUM + CARBIDOPUM +** | |

| | | **ENTACAPONUM)\*\*\*** | |

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**Cod restricţie 2059: Boala Parkinson la pacienţi trataţi cu combinaţii de inhibitor de decarboxylase-levodopa, care prezintă tulburări ale funcţiilor motorii induse la sfârşitul perioadei de acţiune a unei doze.**

**Cod restricţie 2060: Boala Parkinson la pacienţi stabilizaţi sub tratamentul cu inhibitor de decarboxylase-levodopa în asociere cu entacapone.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N04BA03 COMBINAŢII COMPR. FILM. 100 mg/25 mg/200 mg

(LEVODOPUM +

CARBIDOPUM +

ENTACAPONUM)

STALEVO 100 mg/25 mg/200 mg 100 mg/25 mg/200 mg ORION CORPORATION

N04BA03 COMBINAŢII COMPR. FILM. 150 mg/37.5 mg/

(LEVODOPUM + 200 mg

CARBIDOPUM +

ENTACAPONUM)

STALEV0 150 mg/37,5 mg/200 mg 150 mg/37.5 mg/200 mg ORION CORPORATION

N04BA03 COMBINAŢII COMPR. FILM. 50 mg/12.5 mg/200 mg

(LEVODOPUM +

CARBIDOPUM +

ENTACAPONUM)

STALEVO 50 mg/12,5 mg/200 mg 50 mg/12.5 mg/200 mg ORION CORPORATION

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| **463** |**N04BB01**| **AMANTADINUM\*\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N04BB01 AMANTADINUM CAPS. 100 mg

VIREGYT(R)-K 100 mg EGIS PHARMACEUTICALS LTD.

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| **464** |**N04BC01**| **BROMOCRIPTINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N04BC01 BROMOCRIPTINUM DRAJ. 2.5 mg

BROCRIPTIN 2.5 mg BIOFARM SA

Prescriere limitată: **Boala Parkinson**

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| **465** |**N04BC04**| **ROPINIROLUM\*\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N04BC04 ROPINIROLUM COMPR. FILM.

REQUIP 0,25 mg SMITHKLINE BEECHAM PLC T/A

REQUIP 1 mg SMITHKLINE BEECHAM PLC T/A

REQUIP 2 mg SMITHKLINE BEECHAM PLC T/A

REQUIP 5 mg SMITHKLINE BEECHAM PLC T/A

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| **466** |**N04BC05**| **PRAMIPEXOLUM\*\*** | |

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La acest medicament au fost raportate episoade de instalare bruscă a somnului fără avertizare în timpul activităţii.

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N04BC05 PRAMIPEXOLUM COMPR. 0.18 mg

MIRAPEXIN 0,18 mg 0.18 mg BOEHRINGER INGELHEIM

INTERNATIONAL GMBH

N04BC05 PRAMIPEXOLUM COMPR. 0.7 mg

MIRAPEXIN 0,7 mg 0.7 mg BOEHRINGER INGELHEIM

INTERNATIONAL GMBH

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| **467** |**N04BC09**| **ROTIGOTINUM\*\*\*** | |

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Prescriere limitată: **Monoterapie (fără levodopa), pentru tratarea semnelor**

**şi simptomelor bolii Parkinson idiopatice, în stadiu**

**incipient.**

**Tratament în asociere cu levodopa în perioada de**

**evoluţie şi în stadiile avansate ale bolii Parkinson,**

**când efectul medicamentului levodopa diminuează sau**

**devine inconstant şi apar fluctuaţii ale efectului**

**terapeutic (fluctuaţii apărute către sfârşitul**

**intervalului dintre doze sau fluctuaţii de tip on-off).**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N04BC09 ROTIGOTINUM PLASTURE TRANSDERMIC 2 mg/24 h

NEUPRO 2 mg/24 h 2 mg/24 h SCHWARZ PHARMA LTD

N04BC09 ROTIGOTINUM PLASTURE TRANSDERMIC 4 mg/24 h

NEUPRO 4 mg/24 h 4 mg/24 h SCHWARZ PHARMA LTD

N04BC09 ROTIGOTINUM PLASTURE TRANSDERMIC 6 mg/24 h

NEUPRO 6 mg/24 h 6 mg/24 h SCHWARZ PHARMA LTD

N04BC09 ROTIGOTINUM PLASTURE TRANSDERMIC 8 mg/24 h

NEUPRO 8 mg/24 h 8 mg/24 h SCHWARZ PHARMA LTD

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| **468** |**N04BD01**| **SELEGILINUM** | |

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Prescriere limitată: **Stadiu tardiv al bolii Parkinson ca tratament complementar la pacienţii trataţi cu levodopa combinat cu inhibitor al decarboxylazei.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N04BD01 SELEGILINUM COMPR. 5 mg

ALS-SELEGILINA 5 mg 5 mg ALSIFCOM INTERMED SRL

JUMEX 5 mg 5 mg CHINOIN PRIVATE CO. LTD.

SELEGOS 5 mg MEDOCHEMIE LTD.

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| **469** |**N04BD02**| **RASAGILINUM\*\*\*** | |

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Prescriere limitată: **Tratamentul bolii Parkinson idiopatică (BP) ca**

**monoterapie (fără levodopa).**

**Tratament adjuvant (în asociere cu levodopa) la**

**pacienţii cu fluctuaţii de sfârşit de doză.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N04BD02 RASAGILINUM COMPR. 1 mg

AZILECT 1 mg 1 mg TEVA PHARMA GMBH

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| **470** |**N04BX02**| **ENTACAPONUM\*\*\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N04BX02 ENTACAPONUM COMPR. FILM. 200 mg

COMTAN 200 mg 200 mg NOVARTIS EUROPHARM LTD.

Cod restricţie 2067: **Boala Parkinson la pacienţi trataţi cu combinaţii de inhibitor de decarboxylase-levodopa, care prezintă tulburări ale funcţiilor motorii induse la sfârşitul perioadei de acţiune a unei doze.**

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| **471** |**N05AH02**| **CLOZAPINUM\*\*** | |

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Prescriere limitată: **Tulburări psihotice apărute în cursul bolii Parkinson în situaţia în care terapia standard a eşuat.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N05AH02 CLOZAPINUM COMPR. 100 mg

LEPONEX(R) 100 mg 100 mg NOVARTIS PHARMA GMBH

N05AH02 CLOZAPINUM COMPR. 25 mg

LEPONEX(R) 25 mg 25 mg NOVARTIS PHARMA GMBH

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**SUBLISTA C1 - G13 MIASTENIA GRAVIS.**

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| **472** |**H02AB07**| **PREDNISONUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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H02AB07 PREDNISONUM COMPR. 5 mg

N - PREDNISON 5 mg MEDUMAN SA

PREDNISON 5 mg 5 mg SINTOFARM SA

PREDNISON ARENA 5 mg 5 mg ARENA GROUP SA

PREDNISON GEDEON RICHTER 5 mg 5 mg GEDEON RICHTER ROMANIA SA

PREDNISON MAGISTRA 5 mg 5 mg MAGISTRA C & C

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| **473** |**L01BA01**| **METHOTREXATUM (4)** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L01BA01 METHOTREXATUM

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| **474** |**L04AX01**| **AZATHIOPRINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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L04AX01 AZATHIOPRINUM COMPR. FILM. 50 mg

IMURAN(R) 50 mg THE WELLCOME FOUNDATION

LTD.

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| **475** |**N07AA01**| **NEOSTIGMINI BROMIDUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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N07AA01 NEOSTIGMINI BROMIDUM SOL. INJ. 0.5 mg/ml

MIOSTIN 0,5 mg/ml 0.5 mg/ml ZENTIVA S.A.

N07AA01 NEOSTIGMINI BROMIDUM COMPR. 15 mg

NEOSTIGMINA LPH 15 mg 15 mg LABORMED PHARMA SA

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| **476** |**N07AA02**| **PYRIDOSTIGMINI BROMIDUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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N07AA02 PYRIDOSTIGMINI DRAJ. 60 mg

BROMIDUM

MESTINON 60 mg 60 mg ICN POLFA RZESZOW S.A.

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**SUBLISTA C1 - G14 SCLEROZA MULTIPLĂ.**

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| **477** |**H02AB04**| **METHYLPREDNISOLONUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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H02AB04 METHYLPREDNISOLONUM LIOF. PT. SOL. INJ. 125 mg

LEMOD SOLU 125 mg 125 mg HEMOFARM S.R.L.

H02AB04 METHYLPREDNISOLONUM LIOF. ŞI SOLV. PT. 125 mg/2 ml

SOL. INJ.

SOLU - MEDROL ACT-O-VIAL 125 mg/2 ml PFIZER EUROPE MA EEIG

H02AB04 METHYLPREDNISOLONUM COMPR. 16 mg

MEDROL A 16 16 mg PFIZER EUROPE MA EEIG

H02AB04 METHYLPREDNISOLONUM LIOF. PT. SOL. INJ. 20 mg

LEMOD SOLU 20 mg 20 mg HEMOFARM S.R.L.

H02AB04 METHYLPREDNISOLONUM LIOF. ŞI SOLV. PT. 250 mg/4 ml

SOL. INJ.

SOLU - MEDROL ACT-O-VIAL 250 mg/4 ml PFIZER EUROPE MA EEIG

H02AB04 METHYLPREDNISOLONUM COMPR. 32 mg

MEDROL 32 32 mg PFIZER EUROPE MA EEIG

H02AB04 METHYLPREDNISOLONUM LIOF. PT. SOL. INJ. 40 mg

LEMOD SOLU 40 mg 40 mg HEMOFARM S.R.L.

H02AB04 METHYLPREDNISOLONUM LIOF. ŞI SOLV. PT. 40 mg/1 ml

SOL. INJ.

SOLU - MEDROL ACT-O-VIAL 40 mg/1 ml PFIZER EUROPE MA EEIG

H02AB04 METHYLPREDNISOLONUM COMPR. 4 mg

MEDROL 4 mg 4 mg PFIZER EUROPE MA EEIG

H02AB04 METHYLPREDNISOLONUM LIOF. PT. SOL. INJ. 500 mg

LEMOD SOLU 500 mg 500 mg HEMOFARM S.R.L.

H02AB04 METHYLPREDNISOLONUM LIOF. + SOLV. PT. SOL. 500 mg/7.8 ml

INJ.

SOLU - MEDROL 500 mg/7,8 ml 500 mg/7.8 ml PFIZER EUROPE MA EEIG

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| **478** |**H02AB07**| **PREDNISONUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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H02AB07 PREDNISONUM COMPR. 5 mg

N - PREDNISON 5 mg MEDUMAN SA

PREDNISON 5 mg 5 mg SINTOFARM SA

PREDNISON ARENA 5 mg 5 mg ARENA GROUP SA

PREDNISON GEDEON RICHTER 5 mg 5 mg GEDEON RICHTER ROMANIA SA

PREDNISON MAGISTRA 5 mg 5 mg MAGISTRA C & C

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| **480** |**L01DB07**| **MITOXANTRONUM\*\*\*** | **Protocol: L001G** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L01DB07 MITOXANTRONUM CONC. PT. SOL. PERF. 2 mg/ml

MITOXANTRONE TEVA 2 mg/ml 2 mg/ml TEVA PHARMACEUTICALS SRL

L01DB07 MITOXANTRONUM SOL. PERF. 20 mg/10 ml

NOVANTRONE 20 mg/10 ml WYETH LEDERLE PHARMA GMBH

L01DB07 MITOXANTRONUM CONC. PT. SOL. INJ. 2 mg/ml

ONKOTRONE 2 mg/ml BAXTER ONCOLOGY GMBH

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| **481** |**L04AX01**| **AZATHIOPRINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L04AX01 AZATHIOPRINUM COMPR. FILM. 50 mg

IMURAN(R) 50 mg THE WELLCOME FOUNDATION

LTD.

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**SUBLISTA C1 - G15 BOLI PSIHICE (SCHIZOFRENIE, TULBURĂRI SCHIZOTIPALE ŞI DELIRANTE, TULBURĂRI AFECTIVE MAJORE, TULBURĂRI PSIHOTICE ACUTE ŞI BOLI PSIHICE COPII, AUTISM).**

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| **482** |**N03AG01**| **ACIDUM VALPROICUM + SĂRURI** | |

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S-au raportat cazuri de hepatotoxicitate letală, în special la copii. Se înregistrează din ce în ce mai multe dovezi cu privire la teratogenitatea legată de doză.

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N03AG01 ACIDUM VALPROICUM + MINICOMPR. ELIB. PREL. 1000 mg

SĂRURI

ORFIRIL LONG 1000 mg 1000 mg DESITIN ARZNEIMITTEL GMBH

N03AG01 ACIDUM VALPROICUM + CAPS. ELIB. PREL. 150 mg

SĂRURI

ORFIRIL LONG 150 mg 150 mg DESITIN ARZNEIMITTEL GMBH

N03AG01 ACIDUM VALPROICUM + CAPS. MOI GASTROREZ. 150 mg

SĂRURI

CONVULEX(R) 150 mg 150 mg GEROT PHARMAZEUTIKA GMBH

N03AG01 ACIDUM VALPROICUM + COMPR. FILM. GASTROREZ. 150 mg

SĂRURI

ORFIRIL 150 150 mg DESITIN ARZNEIMITTEL GMBH

N03AG01 ACIDUM VALPROICUM + COMPR. FILM. 200 mg

SĂRURI

PETILIN 200 mg REMEDICA LTD.

N03AG01 ACIDUM VALPROICUM + COMPR. FILM. GASTROREZ. 200 mg

SĂRURI

DEPAKINE 200 mg 200 mg SANOFI-AVENTIS FRANCE

N03AG01 ACIDUM VALPROICUM + CAPS. ELIB. PREL. 300 mg

SĂRURI

ORFIRIL LONG 300 mg 300 mg DESITIN ARZNEIMITTEL GMBH

N03AG01 ACIDUM VALPROICUM + CAPS. MOI GASTROREZ. 300 mg

SĂRURI

CONVULEX(R) 300 mg 300 mg GEROT PHARMAZEUTIKA GMBH

N03AG01 ACIDUM VALPROICUM + COMPR. FILM. GASTROREZ. 300 mg

SĂRURI

ORFIRIL 300 300 mg DESITIN ARZNEIMITTEL GMBH

N03AG01 ACIDUM VALPROICUM + SIROP 300 mg/5 ml

SĂRURI

ORFIRIL SIROP 300 mg/5 ml DESITIN ARZNEIMITTEL GMBH

N03AG01 ACIDUM VALPROICUM + LIOF. + SOLV. PT. SOL. 400 mg/4 ml

SĂRURI

DEPAKINE(R) 400 mg/4 ml 400 mg/4 ml SANOFI-AVENTIS FRANCE

LIOFILIZAT ŞI SOLVENT PENTRU

SOLUŢIE INJECTABILĂ i.v.

N03AG01 ACIDUM VALPROICUM + CAPS. MOI GASTROREZ. 500 mg

SĂRURI

CONVULEX(R) 500 mg 500 mg GEROT PHARMAZEUTIKA GMBH

N03AG01 ACIDUM VALPROICUM + MINICOMPR. ELIB. PREL. 500 mg

SĂRURI

ORFIRIL LONG 500 mg 500 mg DESITIN ARZNEIMITTEL GMBH

N03AG01 ACIDUM VALPROICUM + SIROP 50 mg/ml

SĂRURI

CONVULEX(R) 50 mg/ml GEROT PHARMAZEUTIKA GMBH

N03AG01 ACIDUM VALPROICUM + SIROP 57.64 mg/ml

SĂRURI

DEPAKINE 57.64 mg/ml SANOFI - AVENTIS FRANCE

N03AG01 ACIDUM VALPROICUM + COMPR. FILM. GASTROREZ. 600 mg

SĂRURI

ORFIRIL 600 600 mg DESITIN ARZNEIMITTEL GMBH

N03AG01 ACIDUM VALPROICUM + COMPR. FILM. ELIB. 300 mg

SĂRURI PREL. DIVIZ.

DEPAKINE CHRONO 300 mg 300 mg SANOFI-AVENTIS FRANCE

N03AG01 ACIDUM VALPROICUM + COMPR. FILM. ELIB. 500 mg

SĂRURI PREL. DIVIZ.

DEPAKINE(R) CHRONO 500 mg 500 mg SANOFI-AVENTIS FRANCE

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| **483** |**N03AX09**| **LAMOTRIGINUM\*\*** | **Protocol: N012F** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N03AX09 LAMOTRIGINUM COMPR. 100 mg

EPIMIL 100 mg 100 mg IVAX PHARMCEUTICALS S.R.O.

EPIZOL 100 mg 100 mg KRKA D.D. NOVO MESTO

LAMICTAL 100 mg 100 mg THE WELLCOME FOUNDATION

LTD.

LAMOLEP 100 mg 100 mg GEDEON RICHTER LTD.

LAMOTIRAN 100 mg 100 mg RANBAXY UK LTD.

LAMOTRIX 100 mg 100 mg MEDOCHEMIE LTD.

PLEXXO(R) 100 mg 100 mg DESITIN ARZNEIMITTEL GMBH

N03AX09 LAMOTRIGINUM COMPR. DISP. 100 mg

LAMOTRIGIN STADA 100 mg 100 mg STADA ARZNEIMITTEL AG

LAMOTRIN 100 mg 100 mg ACTAVIS GROUP HF.

N03AX09 LAMOTRIGINUM COMPR. 200 mg

LAMOTIRAN 200 mg 200 mg RANBAXY UK LTD.

LAMOTRIX 200 mg 200 mg MEDOCHEMIE LTD.

N03AX09 LAMOTRIGINUM COMPR. 25 mg

EPIMIL 25 mg 25 mg IVAX PHARMCEUTICALS S.R.O.

EPIZOL 25 mg 25 mg KRKA D.D. NOVO MESTO

LAMICTAL 25 mg 25 mg THE WELLCOME FOUNDATION

LTD.

LAMOLEP 25 mg 25 mg GEDEON RICHTER LTD.

LAMOTIRAN 25 mg 25 mg RANBAXY UK LTD.

LAMOTRIX 25 mg 25 mg MEDOCHEMIE LTD.

PLEXXO(R) 25 mg 25 mg DESITIN ARZNEIMITTEL GMBH

N03AX09 LAMOTRIGINUM COMPR. DISP. 25 mg

LAMOTRIGIN STADA 25 mg 25 mg STADA ARZNEIMITTEL AG

LAMOTRIN 25 mg 25 mg ACTAVIS GROUP HF.

N03AX09 LAMOTRIGINUM COMPR. DISP./MAST. 25 mg

LAMICTAL 25 mg 25 mg THE WELLCOME FOUNDATION

LTD.

N03AX09 LAMOTRIGINUM COMPR. DISP./MAST. 2 mg

LAMICTAL(R) 2 mg 2 mg THE WELLCOME FOUNDATION

LTD.

N03AX09 LAMOTRIGINUM COMPR. 50 mg

EPIMIL 50 mg 50 mg IVAX PHARMCEUTICALS S.R.O.

EPIZOL 50 mg 50 mg KRKA D.D. NOVO MESTO

LAMICTAL 50 mg 50 mg THE WELLCOME FOUNDATION

LTD.

LAMOLEP 50 mg 50 mg GEDEON RICHTER LTD.

LAMOTIRAN 50 mg 50 mg RANBAXY UK LTD.

LAMOTRIX 50 mg 50 mg MEDOCHEMIE LTD.

PLEXXO(R) 50 mg 50 mg DESITIN ARZNEIMITTEL GMBH

N03AX09 LAMOTRIGINUM COMPR. DISP. 50 mg

LAMOTRIGIN STADA 50 mg 50 mg STADA ARZNEIMITTEL AG

LAMOTRIN 50 mg 50 mg ACTAVIS GROUP HF.

N03AX09 LAMOTRIGINUM COMPR. DISP./MAST. 5 mg

LAMICTAL 5 mg 5 mg THE WELLCOME FOUNDATION

LTD.

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| **484** |**N04AA01**| **TRIHEXYPHENIDYLUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N04AA01 TRIHEXYPHENIDYLUM COMPR. 2 mg

ROMPARKIN(R) 2 mg 2 mg TERAPIA SA

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| **485** |**N05AD01**| **HALOPERIDOLUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N05AD01 HALOPERIDOLUM SOL. INJ. 50 mg/ml

HALOPERIDOL DECANOAT 50 mg/ml GEDEON RICHTER LTD.

N05AD01 HALOPERIDOLUM COMPR. 5 mg

HALDOL 5 mg JANSSEN PHARMACEUTICA NV

N05AD01 HALOPERIDOLUM SOL. INJ. 5 mg/ml

HALOPERIDOL 5 mg/ml 5 mg/ml GEDEON RICHTER LTD.

N05AD01 HALOPERIDOLUM PIC. ORALE-SOL. 2 mg/ml

HALOPERIDOL 2 mg/ml 2 mg/ml GEDEON RICHTER ROMANIA SA

N05AD01 HALOPERIDOLUM PICĂTURI ORALE-SOL. 2 mg/ml

HALOPERIDOL 2 mg/ml TERAPIA SA

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| **486** |**N05AE03**| **SERTINDOL\*\*** | **Protocol: N017F** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N05AE03 SERTINDOL COMPR. FILM. 12 mg

SERDOLECT 12 mg 12 mg H. LUNDBECK A/S

N05AE03 SERTINDOL COMPR. FILM. 16 mg

SERDOLECT 16 mg 16 mg H. LUNDBECK A/S

N05AE03 SERTINDOL COMPR. FILM. 20 mg

SERDOLECT 20 mg 20 mg H. LUNDBECK A/S

N05AE03 SERTINDOL COMPR. FILM. 4 mg

SERDOLECT 4 mg 4 mg H. LUNDBECK A/S

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| **487** |**N05AE04**| **ZIPRASIDONUM\*\*** | **Protocol: N018F** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N05AE04 ZIPRASIDONUM LIOF. PT. SOL. INJ. + 20 mg/ml

SOLV.

ZELDOX(R) 20 mg/ml 20 mg/ml PFIZER EUROPE MA EEIG

N05AE04 ZIPRASIDONUM CAPS. 40 mg

ZELDOX(R) 40 mg 40 mg PFIZER EUROPE MA EEIG

N05AE04 ZIPRASIDONUM CAPS. 60 mg

ZELDOX(R) 60 mg 60 mg PFIZER EUROPE MA EEIG

N05AE04 ZIPRASIDONUM CAPS. 80 mg

ZELDOX(R) 80 mg 80 mg PFIZER EUROPE MA EEIG

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| **488** |**N05AF01**| **FLUPENTIXOLUM\*\*** | **Protocol: N015F** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N05AF01 FLUPENTIXOLUM SOL. INJ. 20 mg/ml

FLUANXOL DEPOT 20 mg/ml H. LUNDBECK A/S

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| **489** |**N05AF05**| **ZUCLOPENTHIXOLUM\*\*** | **Protocol: N019F** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N05AF05 ZUCLOPENTHIXOLUM COMPR. FILM. 10 mg

CLOPIXOL(R) 10 mg 10 mg H. LUNDBECK A/S

N05AF05 ZUCLOPENTHIXOLUM SOL. INJ. 200 mg/ml

CLOPIXOL(R) DEPOT 200 mg/ml H. LUNDBECK A/S

N05AF05 ZUCLOPENTHIXOLUM COMPR. FILM. 25 mg

CLOPIXOL(R) 25 mg 25 mg H. LUNDBECK A/S

N05AF05 ZUCLOPENTHIXOLUM SOL. INJ. 50 mg/ml

CLOPIXOL ACUPHASE(R) 50 mg/ml H. LUNDBECK A/S

N05AF05 ZUCLOPENTHIXOLUM PIC. ORALE-SOL. 20 mg/ml

CLOPIXOL 20 mg/ml 20 mg/ml H. LUNDBECK A/S

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| **490** |**N05AH02**| **CLOZAPINUM\*\*** | **Protocol: N016F** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N05AH02 CLOZAPINUM COMPR. 100 mg

LEPONEX(R) 100 mg 100 mg NOVARTIS PHARMA GMBH

N05AH02 CLOZAPINUM COMPR. 25 mg

LEPONEX(R) 25 mg 25 mg NOVARTIS PHARMA GMBH

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| **491** |**N05AH03**| **OLANZAPINUM\*\*** | **Protocol: N003F** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N05AH03 OLANZAPINUM COMPR. FILM. 10 mg

ZYPREXA 10 mg 10 mg ELI LILLY NEDERLAND BV

N05AH03 OLANZAPINUM PULB. PT. SOL. INJ. 10 mg

ZYPREXA 10 mg 10 mg ELI LILLY NEDERLAND BV

N05AH03 OLANZAPINUM COMPR. ORODISPERSABILE 15 mg

ZYPREXA VELOTAB 15 mg 15 mg ELI LILLY NEDERLAND BV

N05AH03 OLANZAPINUM COMPR. ORODISPERSABILE 20 mg

ZYPREXA VELOTAB 20 mg 20 mg ELI LILLY NEDERLAND BV

N05AH03 OLANZAPINUM COMPR. FILM. 5 mg

ZYPREXA 5 mg 5 mg ELI LILLY NEDERLAND BV

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| **492** |**N05AH04**| **QUETIAPINUM\*\*** | **Protocol: N005F** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N05AH04 QUETIAPINUM COMPR. FILM. 100 mg

SEROQUEL 100 mg 100 mg ASTRAZENECA UK LTD.

N05AH04 QUETIAPINUM COMPR. FILM. 200 mg

SEROQUEL 200 mg 200 mg ASTRAZENECA UK LTD.

N05AH04 QUETIAPINUM COMPR. FILM. ELIB. 200 mg

PREL.

SEROQUEL XR 200 mg 200 mg ASTRAZENECA UK LTD.

N05AH04 QUETIAPINUM COMPR. FILM. 300 mg

SEROQUEL(R) 300 mg 300 mg ASTRAZENECA UK LTD.

N05AH04 QUETIAPINUM COMPR. FILM. ELIB. 300 mg

PREL.

SEROQUEL XR 300 mg 300 mg ASTRAZENECA UK LTD.

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| **493** |**N05AL01**| **SULPIRIDUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N05AL01 SULPIRIDUM COMPR. 200 mg

EGLONYL(R) 200 mg 200 mg SANOFI-SYNTHELABO FRANCE

N05AL01 SULPIRIDUM CAPS. 50 mg

EGLONYL(R) 50 mg 50 mg SANOFI-SYNTHELABO FRANCE

N05AL01 SULPIRIDUM SOL. INJ. 50 mg/ml

EGLONYL 100 mg/2 ml 50 mg/ml SANOFI-AVENTIS FRANCE

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| **494** |**N05AL05**| **AMISULPRIDUM\*\*** | **Protocol: N006F** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N05AL05 AMISULPRIDUM COMPR. DIVIZ. 200 mg

SOLIAN 200 mg 200 mg SANOFI-AVENTIS FRANCE

N05AL05 AMISULPRIDUM COMPR. FILM. 400 mg

SOLIAN(R) 400 mg 400 mg SANOFI-AVENTIS FRANCE

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| **495** |**N05AX08**| **RISPERIDONUM\*\*** | **Protocol: N004F** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N05AX08 RISPERIDONUM COMPR. FILM. 1 mg

RISSET 1 mg 1 mg PLIVA LJUBLJANA D.O.O.

N05AX08 RISPERIDONUM COMPR. FILM. 1 mg

RILEPTID 1 mg 1 mg EGIS PHARMACEUTICALS

P.L.C.

RISPEN 1 1 mg ZENTIVA AS

RISPERIDONA 1 mg 1 mg ARENA GROUP S.A.

RISPERIDONE TEVA 1 mg 1 mg TEVA PHARMACEUTICAL S.R.L

RISPOLEPT(R) 1 mg 1 mg JANSSEN PHARMACEUTICA NV

TORENDO 1 mg 1 mg KRKA D.D. NOVO MESTO

N05AX08 RISPERIDONUM COMPR. ORODISPERSABILE 1 mg

RISPOLEPT QUICKLET 1 mg JANSSEN PHARMACEUTICA NV

TORENDO Q-TAB 1 mg 1 mg KRKA D.D. NOVO MESTO

N05AX08 RISPERIDONUM SOL. ORALĂ 1 mg/ml

RISPOLEPT 1 mg/ml JANSSEN PHARMACEUTICA NV

N05AX08 RISPERIDONUM COMPR. FILM. 2 mg

RISPEN 2 2 mg ZENTIVA AS

RISSET 2 mg 2 mg PLIVA LJUBLJANA D.O.O.

N05AX08 RISPERIDONUM PULB. + SOLV. PT. SOL. 25 mg

INJ.

RISPOLEPT CONSTA(R) 25 mg 25 mg JANSSEN PHARMACEUTICA NV

N05AX08 RISPERIDONUM COMPR. FILM. 2 mg

RILEPTID 2 mg 2 mg EGIS PHARMACEUTICALS

P.L.C.

RISON 2 mg 2 mg ACTAVIS GROUP HF.

RISPERIDONA 2 mg 2 mg ARENA GROUP S.A.

RISPERIDONE TEVA 2 mg 2 mg TEVA PHARMACEUTICALS SRL

RISPOLEPT(R) 2 mg 2 mg JANSSEN PHARMACEUTICA NV

TORENDO 2 mg 2 mg KRKA D.D. NOVO MESTO

N05AX08 RISPERIDONUM COMPR. ORODISPERSABILE 2 mg

RISPOLEPT QUICKLET 2 mg JANSSEN PHARMACEUTICA NV

TORENDO Q-TAB 2 mg 2 mg KRKA D.D. NOVO MESTO

N05AX08 RISPERIDONUM PULB. + SOLV. PT. SOL. 37.5 mg

INJ.

RISPOLEPT CONSTA(R) 37,5 mg 37.5 mg JANSSEN PHARMACEUTICA NV

N05AX08 RISPERIDONUM COMPR. FILM. 3 mg

RILEPTID 3 mg 3 mg EGIS PHARMACEUTICALS

P.L.C.

RISON 3 mg 3 mg ACTAVIS GROUP HF.

RISPEN 3 3 mg ZENTIVA AS

RISPERIDONA 3 mg 3 mg ARENA GROUP S.A.

RISPERIDONE TEVA 3 mg 3 mg TEVA PHARMACEUTICALS SRL

RISPOLEPT(R) 3 mg 3 mg JANSSEN PHARMACEUTICA NV

RISSET 3 mg 3 mg PLIVA LJUBLJANA D.O.O.

TORENDO 3 mg 3 mg KRKA D.D. NOVO MESTO

N05AX08 RISPERIDONUM COMPR. FILM. 4 mg

RISPEN 4 4 mg ZENTIVA AS

N05AX08 RISPERIDONUM COMPR. FILM. 4 mg

RILEPTID 4 mg 4 mg EGIS PHARMACEUTICALS

P.L.C.

RISON 4 mg 4 mg ACTAVIS GROUP HF.

RISPERIDONA 4 mg 4 mg ARENA GROUP S.A.

RISPERIDONE TEVA 4 mg 4 mg TEVA PHARMACEUTICALS SRL

RISPOLEPT(R) 4 mg 4 mg JANSSEN PHARMACEUTICA NV

RISSET 4 mg 4 mg PLIVA LJUBLJANA D.O.O.

TORENDO 4 mg 4 mg KRKA D.D. NOVO MESTO

N05AX08 RISPERIDONUM PULB. + SOLV. PT. SOL. 50 mg

INJ.

RISPOLEPT CONSTA(R) 50 mg 50 mg JANSSEN PHARMACEUTICA NV

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| **496** |**N05AX12**| **ARIPIPRAZOLUM\*\*** | **Protocol: N007F** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N05AX12 ARIPIPRAZOLUM COMPR. 10 mg

ABILIFY 10 mg 10 mg OTSUKA PHARMACEUTICAL

EUROPE LTD.

N05AX12 ARIPIPRAZOLUM COMPR. 15 mg

ABILIFY 15 mg 15 mg OTSUKA PHARMACEUTICAL

EUROPE LTD.

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| **498** |**N06AB04**| **CITALOPRAMUM\*\*** | **Protocol: N008F** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N06AB04 CITALOPRAMUM COMPR. FILM. 10 mg

CITALORAN 10 mg 10 mg RANBAXY UK LIMITED

LINISAN 10 mg 10 mg GEDEON RICHTER ROMANIA

S.A.

N06AB04 CITALOPRAMUM COMPR. FILM. 20 mg

CITALORAN 20 mg 20 mg RANBAXY UK LIMITED

LINISAN 20 mg 20 mg GEDEON RICHTER ROMANIA

S.A.

N06AB04 CITALOPRAMUM COMPR. FILM. 40 mg

CITALORAN 40 mg 40 mg RANBAXY UK LIMITED

LINISAN 40 mg 40 mg GEDEON RICHTER ROMANIA

S.A.

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| **499** |**N06AB10**| **ESCITALOPRAMUM\*\*** | **Protocol: N009F** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N06AB10 ESCITALOPRAMUM COMPR. FILM. 10 mg

CIPRALEX 10 mg 10 mg H. LUNDBECK A/S

N06AB10 ESCITALOPRAMUM COMPR. FILM. 5 mg

CIPRALEX 5 mg 5 mg H. LUNDBECK A/S

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| **500** |**N06AX05**| **TRAZODONUM\*\*** | **Protocol: N010F** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N06AX05 TRAZODONUM COMPR. ELIB. PREL. 150 mg

TRITTICO AC 150 mg 150 mg ANGELINI FRANCESCO SPA

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| **501** |**N06AX14**| **TIANEPTINUM\*\*** | **Protocol: N011F** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N06AX14 TIANEPTINUM DRAJ. 12.5 mg

COAXIL(R) 12.5 mg LES LAB. SERVIER IND.

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| **502** |**N06AX16**| **VENLAFAXINUM\*\*** | **Protocol: N013F** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N06AX16 VENLAFAXINUM CAPS. ELIB. PREL. 150 mg

EFECTIN ER 150 mg 150 mg WYETH LEDERLE PHARMA GMBH

VELAXIN 150 mg 150 mg EGIS PHARMACEUTICALS

P.L.C.

N06AX16 VENLAFAXINUM COMPR. 37.5 mg

VELAXIN 37,5 mg 37.5 mg EGIS PHARMACEUTICALS PLC

VENLAFAXINA LPH 37,5 mg 37.5 mg LABORMED PHARMA SA

N06AX16 VENLAFAXINUM CAPS. ELIB. PREL. 75 mg

EFECTIN ER 75 mg 75 mg WYETH LEDERLE PHARMA GMBH

VELAXIN 75 mg 75 mg EGIS PHARMACEUTICALS

P.L.C.

N06AX16 VENLAFAXINUM COMPR. 75 mg

VELAXIN 75 mg 75 mg EGIS PHARMACEUTICALS PLC

VENLAFAXINA LPH 75 mg 75 mg LABORMED PHARMA SA

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| **503** |**N06AX17**| **MILNACIPRANUM\*\*** | **Protocol: N002F** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N06AX17 MILNACIPRANUM CAPS. 25 mg

IXEL 25 mg PIERRE FABRE MEDICAMENT

N06AX17 MILNACIPRANUM CAPS. 50 mg

IXEL 50 mg PIERRE FABRE MEDICAMENT

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| **504** |**N06AX21**| **DULOXETINUM\*\*** | **Protocol: N014F** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N06AX21 DULOXETINUM CAPS. GASTROREZ. 30 mg

CYMBALTA 30 mg 30 mg ELI LILLY NEDERLAND BV

N06AX21 DULOXETINUM CAPS. GASTROREZ. 60 mg

CYMBALTA 60 mg 60 mg ELI LILLY NEDERLAND BV

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**SUBLISTA C1 - G16 DEMENŢE (DEGENERATIVE, VASCULARE, MIXTE).**

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| **505** |**N06DA02**| **DONEPEZILUM\*\*\*** | **Protocol: N020G** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N06DA02 DONEPEZILUM COMPR. FILM. 10 mg

ARICEPT(R) 10 mg 10 mg PFIZER EUROPE MA EEIG

N06DA02 DONEPEZILUM COMPR. ORODISPERSABILE 10 mg

ARICEPT EVESS 10 mg PFIZER EUROPE MA EEIG

N06DA02 DONEPEZILUM COMPR. FILM. 5 mg

ARICEPT(R) 5 mg 5 mg PFIZER EUROPE MAEEIG

N06DA02 DONEPEZILUM COMPR. ORODISPERSABILE 5 mg

ARICEPT EVESS 5 mg PFIZER EUROPE MA EEIG

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| **506** |**N06DA03**| **RIVASTIGMINUM\*\*\*** | **Protocol: N021G** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N06DA03 RIVASTIGMINUM CAPS. 1.5 mg

EXELON 1.5 mg 1.5 mg NOVARTIS EUROPHARM LTD.

N06DA03 RIVASTIGMINUM CAPS. 3 mg

EXELON 3 mg 3 mg NOVARTIS EUROPHARM LTD.

N06DA03 RIVASTIGMINUM CAPS. 4.5 mg

EXELON 4.5 mg 4.5 mg NOVARTIS EUROPHARM LTD.

N06DA03 RIVASTIGMINUM PLASTURE TRANSDERMIC 4.6 mg/24 h

EXELON 4.6 mg/24 h 4.6 mg/24 h NOVARTIS EUROPHARM LTD.

N06DA03 RIVASTIGMINUM CAPS. 6 mg

EXELON 6 mg 6 mg NOVARTIS EUROPHARM LTD.

N06DA03 RIVASTIGMINUM PLASTURE TRANSDERMIC 9.5 mg/24 h

EXELON 9.5 mg/24 h 9.5 mg/24 h NOVARTIS EUROPHARM LTD.

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| **507** |**N06DA04**| **GALANTAMINUM\*\*\*** | **Protocol: N022G** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N06DA04 GALANTAMINUM COMPR. FILM. 12 mg

REMINYL(R) 12 mg 12 mg JANSSEN-PHARMACEUTICA NV

N06DA04 GALANTAMINUM CAPS. ELIB. PREL. 16 mg

REMINYL 16 mg 16 mg JANSSEN PHARMACEUTICA NV

N06DA04 GALANTAMINUM CAPS. ELIB. PREL. 24 mg

REMINYL 24 mg 24 mg JANSSEN PHARMACEUTICA NV

N06DA04 GALANTAMINUM COMPR. FILM. 4 mg

REMINYL(R) 4 mg 4 mg JANSSEN-PHARMACEUTICA NV

N06DA04 GALANTAMINUM SOL. ORALĂ 4 mg/ml

REMINYL(R) 4 mg/ml 4 mg/ml JANSSEN-PHARMACEUTICA NV

N06DA04 GALANTAMINUM CAPS. ELIB. PREL. 8 mg

REMINYL 8 mg 8 mg JANSSEN PHARMACEUTICA NV

N06DA04 GALANTAMINUM COMPR. FILM. 8 mg

REMINYL(R) 8 mg 8 mg JANSSEN-PHARMACEUTICA NV

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| **508** |**N06DX01**| **MEMANTINUM\*\*\*** | **Protocol: N001F** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N06DX01 MEMANTINUM COMPR. FILM. 10 mg

EBIXA(R) 10 mg 10 mg H. LUNDBECK A/S

N06DX01 MEMANTINUM PIC. ORALE, SOL. 10 mg/g

EBIXA(R) 10 mg/g 10 mg/g H. LUNDBECK A/S

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**SUBLISTA C1 - G17 COLAGENOZE MAJORE (LUPUS ERITEMATOS SISTEMIC, SCLERODERMIE, POLI/DERMATOMIOZITĂ, VASCULITE SISTEMICE).**

**Protocol: L045M**

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| **509** |**H02AB04**| **METHYLPREDNISOLONUM (5)** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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H02AB04 METHYLPREDNISOLONUM COMPR. 16 mg

MEDROL A 16 16 mg PFIZER EUROPE MA EEIG

H02AB04 METHYLPREDNISOLONUM COMPR. 32 mg

MEDROL 32 32 mg PFIZER EUROPE MA EEIG

H02AB04 METHYLPREDNISOLONUM COMPR. 4 mg

MEDROL 4 mg 4 mg PFIZER EUROPE MA EEIG

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| **510** |**L01AA01**| **CYCLOPHOSPHAMIDUM\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L01AA01 CYCLOPHOSPHAMIDUM PULB. PT. SOL. 1 g

INJ./PERF.

ENDOXAN(R) 1 g 1 g BAXTER ONCOLOGY GMBH

L01AA01 CYCLOPHOSPHAMIDUM PULB. PT. SOL. 200 mg

PERF./INJ. I.V.

ENDOXAN 200 mg 200 mg ACTAVIS S.R.L.

L01AA01 CYCLOPHOSPHAMIDUM PULB. PT. SOL. 500 mg

INJ./PERF.

ENDOXAN(R) 500 mg 500 mg BAXTER ONCOLOGY GMBH

L01AA01 CYCLOPHOSPHAMIDUM DRAJ. 50 mg

ENDOXAN(R) 50 mg 50 mg BAXTER ONCOLOGY GMBH

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| **511** |**L04AX01**| **AZATHIOPRINUM\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L04AX01 AZATHIOPRINUM COMPR. FILM. 50 mg

IMURAN(R) 50 mg THE WELLCOME FOUNDATION

LTD.

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| **512** |**P01BA02**| **HYDROXYCHLOROQUINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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P01BA02 HYDROXYCHLOROQUINUM COMPR. FILM. 200 mg

PLAQUENIL(R) 200 mg SANOFI-SYNTHELABO LTD.

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SUBLISTA C1 - G18 POLIARTRITA REUMATOIDĂ, ARTROPATIA PSORIAZICĂ ŞI ARTRITA JUVENILĂ.

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| **513** |**A07EC01**| **SULFASALAZINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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A07EC01 SULFASALAZINUM COMPR. FILM. 500 mg

SALAZIDIN 500 mg AC HELCOR SRL

A07EC01 SULFASALAZINUM COMPR. FILM. GASTROREZ. 500 mg

SULFASALAZIN EN 500 mg KRKA D.D. NOVO MESTO

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| **514** |**H02AB01**| **BETAMETHASONUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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H02AB01 BETAMETHASONUM SUSP. INJ. I.M. 7 mg/ml

DIPROPHOS(R) 7 mg/ml SCHERING PLOUGH EUROPE

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| **515** |**H02AB04**| **METHYLPREDNISOLONUM (5)** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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H02AB04 METHYLPREDNISOLONUM COMPR. 16 mg

MEDROL A 16 16 mg PFIZER EUROPE MA EEIG

H02AB04 METHYLPREDNISOLONUM COMPR. 32 mg

MEDROL 32 32 mg PFIZER EUROPE MA EEIG

H02AB04 METHYLPREDNISOLONUM COMPR. 4 mg

MEDROL 4 mg 4 mg PFIZER EUROPE MA EEIG

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| **516** |**L01BA01**| **METHOTREXATUM (4)** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L01BA01 METHOTREXATUM

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| **517** |**L04AA01**| **CICLOSPORINUM\*** | |

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Prescriere limitată: **Terapie de menţinere ulterioară iniţierii şi stabilizării tratamentului cu ciclosporina, la pacienţii cu poliartrită reumatoidă severă pentru care agenţii antireumatici clasici cu acţiune lentă (inclusiv methotrexat) sunt ineficienţi sau inadecvaţi.**

Monitorizarea atentă a pacienţilor este obligatorie.

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L04AA01 CICLOSPORINUM CAPS. MOI 100 mg

EQUORAL(R) 100 mg 100 mg IVAX - PHARMACEUTICALS

S.R.O.

L04AA01 CICLOSPORINUM SOL. ORALĂ 100 mg/ml

EQUORAL(R) 100 mg/ml IVAX - PHARMACEUTICALS

S.R.O.

SANDIMMUN NEORAL(R) 100 mg/ml NOVARTIS PHARMA GMBH

L04AA01 CICLOSPORINUM CAPS. MOI 25 mg

CICLORAL(R) HEXAL(R) 25 mg 25 mg HEXAL AG

EQUORAL(R) 25 mg 25 mg IVAX - PHARMACEUTICALS

S.R.O.

SANDIMMUN NEORAL(R) 25 mg NOVARTIS PHARMA GMBH

L04AA01 CICLOSPORINUM CAPS. MOI 50 mg

CICLORAL(R) HEXAL 50 mg 50 mg HEXAL AG

EQUORAL(R) 50 mg 50 mg IVAX - PHARMACEUTICALS

S.R.O.

SANDIMMUN NEORAL(R) 50 mg NOVARTIS PHARMA GMBH

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| **518** |**L04AA13**| **LEFLUNOMIDUM\*\*** | |

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**Cod restricţie 2643: Tratamentul iniţial al poliartritei reumatoide active severe în condiţiile în care alte medicamente remisive standard (inclusiv methotrexat) sunt ineficiente şi/sau**

**Cod restricţie 2681: Tratamentul iniţial al poliartritei reumatoide active severe în condiţiile în care alte medicamente remisive standard (inclusiv methotrexat) sunt ineficiente şi/sau**

Leflunomide este un medicament care nu trebuie administrat la gravide. Sarcina trebuie evitată timp de doi ani după întreruperea tratamentului.

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L04AA13 LEFLUNOMIDUM COMPR. FILM. 100 mg

ARAVA 100 mg 100 mg SANOFI-AVENTIS DEUTSCHLAND

GMBH

L04AA13 LEFLUNOMIDUM COMPR. FILM. 10 mg

ARAVA 10 mg 10 mg SANOFI-AVENTIS DEUTSCHLAND

GMBH

L04AA13 LEFLUNOMIDUM COMPR. FILM. 20 mg

ARAVA 20 mg 20 mg SANOFI-AVENTIS DEUTSCHLAND

GMBH

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| **519** |**L04AX01**| **AZATHIOPRINUM\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L04AX01 AZATHIOPRINUM COMPR. FILM. 50 mg

IMURAN(R) 50 mg THE WELLCOME FOUNDATION

LTD.

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| **520** |**M01AB05**| **DICLOFENACUM** | |

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A se administra cu precauţie la pacienţii cu istoric de factori de risc sau afecţiuni gastrointestinale.

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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M01AB05 DICLOFENACUM COMPR. FILM. ELIB. 100 mg

PREL.

DICLOTARD(R) 100 mg 100 mg TERAPIA SA

REFEN(R) RETARD 100 mg HEMOFARM S.R.L.

VOLTAREN(R) RETARD 100 mg NOVARTIS PHARMA GMBH

M01AB05 DICLOFENACUM SUPOZ. 100 mg

CLAFEN 100 mg 100 mg ANTIBIOTICE SA

DICLOFENAC 100 mg 100 mg SINTOFARM SA

DICLOFENAC SODIC 100 mg 100 mg MAGISTRA C & C

DICLOGESIC 100 SUPOZITOARE 100 mg DAR AL DAWA PHARMA SRL

EPIFENAC 100 mg E.I.P.I.CO. MED S.R.L.

VOLTAREN(R) 100 mg NOVARTIS PHARMA GMBH

M01AB05 DICLOFENACUM SUPOZ. 120 mg

TRATUL 120 120 mg GEROT PHARMAZEUTIKA GMBH

M01AB05 DICLOFENACUM CAPS. ELIB. PREL. 150 mg

DICLOREUM 150 mg 150 mg ALFA WASSERMANN SPA

M01AB05 DICLOFENACUM COMPR. FILM. GASTROREZ. 25 mg

RHEUMAVEK 25 mg FARAN LABORATORIES S.A.

VOLTAREN(R) 25 25 mg NOVARTIS PHARMA GMBH

M01AB05 DICLOFENACUM COMPR. GASTROREZ. 25 mg

EPIFENAC 25 mg E.I.P.I.CO. MED S.R.L.

M01AB05 DICLOFENACUM DRAJ. GASTROREZ. 25 mg

DICLOFENAC 25 mg 25 mg ARENA GROUP SA

M01AB05 DICLOFENACUM SOL. INJ. 25 mg/ml

RHEUMAVEK 25 mg/ml FARAN LABORATORIES S.A.

VOLTAREN(R) 25 mg/ml NOVARTIS PHARMA GMBH

M01AB05 DICLOFENACUM SOL. INJ. 30 mg/ml

TRATUL(R) 30 mg/ml GEROT PHARMAZEUTIKA GMBH

M01AB05 DICLOFENACUM CAPS. GASTROREZ. 50 mg

TRATUL 50 50 mg GEROT PHARMAZEUTIKA GMBH

M01AB05 DICLOFENACUM COMPR. FILM. GASTROREZ. 50 mg

CLAFEN 50 mg 50 mg ANTIBIOTICE SA

DICLOFENAC 50 mg 50 mg TERAPIA SA

VOLTAREN(R) 50 50 mg NOVARTIS PHARMA GMBH

M01AB05 DICLOFENACUM DRAJ. 50 mg

VOLTAREN RAPID(R) 50 mg NOVARTIS PHARMA GMBH

M01AB05 DICLOFENACUM DRAJ. GASTROREZ. 50 mg

DICLOFENAC 50 mg 50 mg ARENA GROUP SA

M01AB05 DICLOFENACUM SUPOZ. 50 mg

VOLTAREN(R) 50 mg NOVARTIS PHARMA GMBH

M01AB05 DICLOFENACUM SUPOZ. 60 mg

TRATUL 60 60 mg GEROT PHARMAZEUTIKA GMBH

M01AB05 DICLOFENACUM COMPR. ELIB. MODIF. 75 mg

DICLAC(R) 75 ID 75 mg HEXAL AG

M01AB05 DICLOFENACUM SOL. INJ. 75 mg

DICLAC 75 mg HEXAL AG

VURDON 75 mg HELP S.A. PHARMACEUTICALS

M01AB05 DICLOFENACUM SOL. INJ. 75 mg/3 ml

ALMIRAL 75 mg/3 ml MEDOCHEMIE LTD.

DICLOFENAC 75 mg 75 mg/3 ml TERAPIA SA

DICLOFENAC AL I.M. 75 mg/3 ml ALIUD PHARMA GMBH & CO.KG

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| **521** |**P01BA02**| **HYDROXYCHLOROQUINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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P01BA02 HYDROXYCHLOROQUINUM COMPR. FILM. 200 mg

PLAQUENIL(R) 200 mg SANOFI-SYNTHELABO LTD.

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**SUBLISTA C1 - G19 SPONDILITA ANKILOZANTA.**

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| **522** |**A07EC01**| **SULFASALAZINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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A07EC01 SULFASALAZINUM COMPR. FILM. 500 mg

SALAZIDIN 500 mg AC HELCOR SRL

A07EC01 SULFASALAZINUM COMPR. FILM. GASTROREZ. 500 mg

SULFASALAZIN EN 500 mg KRKA D.D. NOVO MESTO

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| **523** |**H02AB01**| **BETAMETHASONUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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H02AB01 BETAMETHASONUM SUSP. INJ. I.M. 7 mg/ml

DIPROPHOS(R) 7 mg/ml SCHERING PLOUGH EUROPE

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| **524** |**M01AB05**| **DICLOFENACUM** | |

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A se administra cu precauţie la pacienţii cu istoric de factori de risc sau afecţiuni gastrointestinale.

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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M01AB05 DICLOFENACUM COMPR. FILM. ELIB. PREL 100 mg

DICLOTARD(R) 100 mg 100 mg TERAPIA SA

REFEN(R) RETARD 100 mg HEMOFARM S.R.L

VOLTAREN(R) RETARD 100 mg NOVARTIS PHARMA GMBH

M01AB05 DICLOFENACUM SUPOZ. 100 mg

CLAFEN 100 mg 100 mg ANTIBIOTICE SA

DICLOFENAC 100 mg 100 mg SINTOFARM SA

DICLOFENAC SODIC 100 mg 100 mg MAGISTRA C & C

DICLOGESIC 100 SUPOZITOARE 100 mg DAR AL DAWA PHARMA SRL

EPIFENAC 100 mg E.I.P.I.CO. MED S.R.L.

VOLTAREN(R) 100 mg NOVARTIS PHARMA GMBH

M01AB05 DICLOFENACUM SUPOZ. 120 mg

TRATUL 120 120 mg GEROT PHARMAZEUTIKA GMBH

M01AB05 DICLOFENACUM CAPS. ELIB. PREL. 150 mg

DICLOREUM 150 mg 150 mg ALFA WASSERMANN SPA

M01AB05 DICLOFENACUM COMPR. FILM. GASTROREZ. 25 mg

RHEUMAVEK 25 mg FARAN LABORATORIES S.A.

VOLTAREN(R) 25 25 mg NOVARTIS PHARMA GMBH

M01AB05 DICLOFENACUM COMPR. GASTROREZ. 25 mg

EPIFENAC 25 mg E.I.P.I.CO. MED S.R.L.

M01AB05 DICLOFENACUM DRAJ. GASTROREZ. 25 mg

DICLOFENAC 25 mg 25 mg ARENA GROUP SA

M01AB05 DICLOFENACUM SOL. INJ. 25 mg/ml

RHEUMAVEK 25 mg/ml FARAN LABORATORIES S.A.

VOLTAREN(R) 25 mg/ml NOVARTIS PHARMA GMBH

M01AB05 DICLOFENACUM SOL. INJ. 30 mg/ml

TRATUL(R) 30 mg/ml GEROT PHARMAZEUTIKA GMBH

M01AB05 DICLOFENACUM CAPS. GASTROREZ. 50 mg

TRATUL 50 50 mg GEROT PHARMAZEUTIKA GMBH

M01AB05 DICLOFENACUM COMPR. FILM. GASTROREZ. 50 mg

CLAFEN 50 mg 50 mg ANTIBIOTICE SA

DICLOFENAC 50 mg 50 mg AC HELCOR PHARMA SRL

VOLTAREN(R) 50 50 mg NOVARTIS PHARMA GMBH

M01AB05 DICLOFENACUM DRAJ. 50 mg

VOLTAREN RAPID(R) 50 mg NOVARTIS PHARMA GMBH

M01AB05 DICLOFENACUM DRAJ. GASTROREZ. 50 mg

DICLOFENAC 50 mg 50 mg ARENA GROUP SA

M01AB05 DICLOFENACUM SUPOZ. 50 mg

VOLTAREN(R) 50 mg NOVARTIS PHARMA GMBH

M01AB05 DICLOFENACUM SUPOZ. 60 mg

TRATUL 60 60 mg GEROT PHARMAZEUTIKA GMBH

M01AB05 DICLOFENACUM COMPR. ELIB. MODIF. 75 mg

DICLAC(R) 75 ID 75 mg HEXAL AG

M01AB05 DICLOFENACUM SOL. INJ. 75 mg

DICLAC 75 mg HEXAL AG

VURDON 75 mg HELP S.A. PHARMACEUTICALS

M01AB05 DICLOFENACUM SOL. INJ. 75 mg/3 ml

ALMIRAL 75 mg/3 ml MEDOCHEMIE LTD.

DICLOFENAC 75 mg 75 mg/3 ml TERAPIA SA

DICLOFENAC AL I.M. 75 mg/3 ml ALIUD PHARMA GMBH & CO.KG

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**SUBLISTA C1 - G22 BOLI ENDOCRINE (GUŞA ENDEMICĂ, INSUFICIENŢA SUPRARENALĂ CRONICĂ, DIABETUL INSIPID, MIXEDEMUL ADULTULUI, TUMORI HIPOFIZARE CU EXPANSIUNE SUPRASELARĂ ŞI TUMORI NEUROENDOCRINE).**

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| **525** |**G02CB03**| **CABERGOLINUM\*\*** | **Protocol: G001C** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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G02CB03 CABERGOLINUM COMPR. 0.5 mg

DOSTINEX 0.5 mg PFIZER EUROPE MA EEG

G02CB03 CABERGOLINUM COMPR. 0.5 mg

DOSTINEX 0.5 mg PFIZER EUROPE MA EEG

Prescriere limitată: **Prevenirea apariţiei lactaţiei în lăuzie din motive medicale**

Cod restricţie 2659: **Hiperprolactinemia patologică pentru care nu este indicată intervenţia chirurgicală**

Cod restricţie 2660: **Hiperprolactinemia patologică pentru care a fost utilizat tratament chirurgical dar cu rezultate incomplete**

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| **526** |**H01AX01**| **PEGVISOMANTUM\*\*\*\*** | **Protocol: H012E** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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H01AX01 PEGVISOMANTUM LIOF. + SOLV. PT. SOL. 10 mg

INJ.

SOMAVERT 10 mg 10 mg PFIZER LTD.

H01AX01 PEGVISOMANTUM LIOF. + SOLV. PT. SOL. 20 mg

INJ.

SOMAVERT 20 mg 20 mg PFIZER LTD.

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| **527** |**H01BA02**| **DESMOPRESSINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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H01BA02 DESMOPRESSINUM COMPR. 0.2 mg

MINIRIN 0,2 mg 0.2 mg FERRING AB

Cod restricţie 1678: **Diabet insipid.**

H01BA02 DESMOPRESSINUM

MINIRIN 0,2 mg 0.2 mg FERRING AB

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| **528** |**H01CB02**| **OCTREOTIDUM\*\*\*\*** | **Protocol: H008E** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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H01CB02 OCTREOTIDUM COMPR. 100 mg

SANDOSTATIN(R) 0.1 mg/ml NOVARTIS PHARMA GMBH

H01CB02 OCTREOTIDUM PULB. + SOLV. PT. SUSP. 10 mg

INJ. (I.M.) CU ELIB.

PRELUNG.

SANDOSTATIN LAR 10 mg 10 mg NOVARTIS PHARMA GMBH

H01CB02 OCTREOTIDUM PULB. + SOLV. PT. SUSP. 20 mg

INJ. (I.M.) CU ELIB.

PRELU

SANDOSTATIN LAR 20 mg 20 mg NOVARTIS PHARMA GMBH

H01CB02 OCTREOTIDUM PULB. + SOLV. PT. SUSP. 30 mg

INJ. (I.M.) CU ELIB.

PRELUNG.

SANDOSTATIN LAR 30 mg 30 mg NOVARTIS PHARMA GMBH

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| **529** |**H01CB03**| **LANREOTIDUM\*\*\*\*** | **Protocol: H005E;**|

| | | | **H006C** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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H01CB03 LANREOTIDUM LIOF. PT. SOL. INJ. + 30 mg

SOLV.

SOMATULINE(R) PR 30 mg 30 mg BEAUFOUR IPSEN PHARMA

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| **530** |**H02AA02**| **FLUDROCORTISONUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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H02AA02 FLUDROCORTISONUM COMPR. 0.1 mg

ASTONIN H 0.1 mg MERCK KGAA

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| **531** |**H02AB06**| **PREDNISOLONUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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H02AB06 PREDNISOLONUM LIOF. + SOLV. PT. SOL. 250 mg

INJ.

SOLU - DECORTIN H 250 250 mg MERCK KGAA

H02AB06 PREDNISOLONUM LIOF. + SOLV. PT. SOL. 50 mg

INJ.

SOLU - DECORTIN H 50 50 mg MERCK KGAA

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| **532** |**H02AB07**| **PREDNISONUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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H02AB07 PREDNISONUM COMPR. 5 mg

N - PREDNISON 5 mg MEDUMAN SA

PREDNISON 5 mg 5 mg SINTOFARM SA

PREDNISON ARENA 5 mg 5 mg ARENA GROUP SA

PREDNISON GEDEON RICHTER 5 mg 5 mg GEDEON RICHTER ROMANIA SA

PREDNISON MAGISTRA 5 mg 5 mg MAGISTRA C & C

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| **533** |**H02AB09**| **HYDROCORTISONUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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H02AB09 HYDROCORTISONUM LIOF. + SOLV. PT. SOL. 100 mg

INJ.

HYDROCORTISONE 100 mg 100 mg HEMOFARM S.R.L

HYDROCORTISONE SUCCINAT SODIC 100 mg E.I.P.I.CO. MED S.R.L.

H02AB09 HYDROCORTISONUM SOL. INJ. I.V. 25 mg/5 ml

HIDROCORTIZON HEMISUCCINAT 25 mg/5 ml ZENTIVA S.A.

H02AB09 HYDROCORTISONUM LIOF. PT. SOL. INJ. + 500 mg

SOLV.

HYDROCORTISONE 500 mg 500 mg HEMOFARM S.R.L.

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| **534** |**H03AA01**| **LEVOTHYROXINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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H03AA01 LEVOTHYROXINUM COMPR. 100 µg

EUTHYROX(R) 100 100 µg MERCK KGAA

L-THYROXIN 100 BERLIN-CHEMIE 100 µg BERLIN CHEMIE AG MENARINI

GROUP

H03AA01 LEVOTHYROXINUM COMPR. 200 µg

EUTHYROX(R) 200 200 µg MERCK KGAA

H03AA01 LEVOTHYROXINUM COMPR. 25 µg

EUTHYROX(R) 25 25 µg MERCK KGAA

H03AA01 LEVOTHYROXINUM COMPR. 50 µg

EUTHYROX(R) 50 50 µg MERCK KGAA

L-THYROXIN 50 50 µg BERLIN CHEMIE AG MENARINI

GROUP

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| **535** |**H03CA01**| **KALII IODIDUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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H03CA01 KALII IODIDUM COMPR. 100 µg

JODID 100 100 µg MERCK KGAA

H03CA01 KALII IODIDUM COMPR. 200 µg

JODID 200 200 µg MERCK KGAA

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| **536** |**G02CB01**| **BROMOCRIPTINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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G02CB01 BROMOCRIPTINUM DRAJ. 2.5 mg

BROCRIPTIN 2.5 mg BIOFARM SA

Prescriere limitată: **Hiperprolactinemia patologică pentru care nu este indicată intervenţia chirurgicală**

Prescriere limitată: **Hiperprolactinemia patologică pentru care tratamentul chirurgical utilizat a dus la rezultate incomplete;**

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**SUBLISTA C1 - G23 BOALA WILSON.**

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| **537** |**M01CC01**| **PENICILLAMINUM\*\*(4)** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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M01CC01 PENICILLAMINUM

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**SUBLISTA C1 - G25 BOALA CRONICA DE RINICHI - FAZA PREDIALIZA.**

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| **538** |**A11CC07**| **PARICALCITOLUM\*\*** | **Protocol: A005E** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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A11CC07 PARICALCITOLUM SOL. INJ. 5 µg/ml

ZEMPLAR 5 µg/ml ABBOTT LABORATORIES S.A.

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| **539** |**B03AC02**| **COMPLEX DE HIDROXID DE FER (III) SUCROZA\*\*** | **Protocol: A010N** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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B03AC02 COMPLEX DE HIDROXID SOL. INJ./PERF. 20 mg/ml

DE FER (III) SUCROZA

VENOFER(R) 20 mg/ml VIFOR FRANCE S.A.

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| **540** |**B03XA01**| **EPOETINUM ALFA\*\*** | **Protocol: B010N** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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B03XA01 EPOETINUM ALFA SOL. INJ. 10000 ui/ml

EPREX(R) 10000 UI 10000 ui/ml JOHNSON & JOHNSON D.O.O.

B03XA01 EPOETINUM ALFA SOL. INJ. 1000 UI/0.5 ml

EPOKINE 1000 UI/0,5 ml 1000 UI/0.5 ml RENAMED FARMA S.R.L.

EPREX(R) 1000 UI 1000 ui/0.5 ml JOHNSON & JOHNSON D.O.O.

B03XA01 EPOETINUM ALFA SOL. INJ. 2000 UI

EPOPHAR 2000 U.I. 2000 UI GULF PHARMACEUTICAL IND.

S.R.L.

B03XA01 EPOETINUM ALFA SOL. INJ. 2000 ui/0.5 ml

EPOKINE 2000 UI/0,5 ml 2000 UI/0.5 ml RENAMED FARMA S.R.L.

EPREX(R) 2000 UI 2000 ui/0.5 ml JOHNSON & JOHNSON D.O.O.

B03XA01 EPOETINUM ALFA SOL. INJ. 2000 UI/1 ml

EPOKINE 2000 UI/1 ml 2000 UI/1 ml RENAMED FARMA S.R.L.

B03XA01 EPOETINUM ALFA SOL. INJ. 3000 ui/0.3 ml

EPREX(R) 3000 UI 3000 ui/0.3 ml JOHNSON & JOHNSON D.O.O.

B03XA01 EPOETINUM ALFA SOL. INJ. 40000 UI

EPREX(R) 40000 UI 40000 UI JOHNSON & JOHNSON D.O.O.

B03XA01 EPOETINUM ALFA SOL. INJ. 4000 UI

EPOPHAR 4000 U.I. 4000 UI GULF PHARMACEUTICAL IND.

S.R.L.

B03XA01 EPOETINUM ALFA SOL. INJ. 4000 ui/0.4 ml

EPOKINE 4000 UI/0,4 ml 4000 UI/0.4 ml RENAMED FARMA S.R.L.

EPREX(R) 4000 UI 4000 ui/0.4 ml JOHNSON & JOHNSON D.O.O.

B03XA01 EPOETINUM ALFA SOL. INJ. 4000 UI/1 ml

EPOKINE 4000 UI/1 ml 4000 UI/1 ml RENAMED FARMA S.R.L.

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| **541** |**B03XA01**| **EPOETINUM BETA\*\*** | **Protocol: B009N** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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B03XA01 EPOETINUM BETA SOL. INJ. ÎN SERINGĂ

PREUMPLUTĂ

NEORECORMON 10000 UI 10000 UI/0,6ml ROCHE REGISTRATION L

B03XA01 EPOETINUM BETA SOL. INJ. ÎN SERINGĂ

PREUMPLUTĂ

NEORECORMON 1000 UI 1000 UI/0,3 ml ROCHE REGISTRATION L

B03XA01 EPOETINUM BETA SOL. INJ. ÎN SERINGĂ

PREUMPLUTĂ

NEORECORMON 2000 UI 2000 UI/0,3 ml ROCHE REGISTRATION L

B03XA01 EPOETINUM BETA SOL. INJ. ÎN SERINGĂ 30000 UI/0,6ml

PREUMPLUTĂ

NEORECORMON 30000 UI/0,6 ml 30000 UI/0,6 ml ROCHE REGISTRATION LTD.

B03XA01 EPOETINUM BETA SOL. INJ. ÎN SERINGĂ

PREUMPLUTĂ

NEORECORMON 4000 UI 4000 UI/0,3 ml ROCHE REGISTRATION L

B03XA01 EPOETINUM BETA SOL. INJ. ÎN SERINGĂ

PREUMPLUTĂ

NEORECORMON 5000 UI 5000 UI/0,3 ml ROCHE REGISTRATION L

B03XA01 EPOETINUM BETA SOL. INJ. ÎN SERINGĂ

PREUMPLUTĂ

NEORECORMON 500 UI 500 UI/0,3 ml ROCHE REGISTRATION L

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| **542** |**B03XA02**| **DARBEPOETINUM ALFA\*\*** | **Protocol: B011N** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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B03XA02 DARBEPOETINUM ALFA SOL. INJ. ÎN SERINGĂ 10 µg/0.4 ml

PREUMPLUTĂ

ARANESP 10 µg/0.4 ml 10 µg/0.4 ml AMGEN EUROPE BV

B03XA02 DARBEPOETINUM ALFA SOL. INJ. ÎN SERINGĂ 100 µg/0.5 ml

PREUMPLUTĂ

ARANESP 100 µg/0.5 ml 100 µg/0.5 ml AMGEN EUROPE BV

B03XA02 DARBEPOETINUM ALFA SOL. INJ. ÎN SERINGĂ 15 µg/0.375 ml

PREUMPLUTĂ

ARANESP 15 µg/0.375 ml 15 µg/0.375 ml AMGEN EUROPE BV

B03XA02 DARBEPOETINUM ALFA SOL. INJ. ÎN SERINGĂ 150 µg/0.3 ml

PREUMPLUTĂ

ARANESP 150 µg/0.3 ml 150 µg/0.3 ml AMGEN EUROPE BV

B03XA02 DARBEPOETINUM ALFA SOL. INJ. ÎN SERINGĂ 20 µg/0.5 ml

PREUMPLUTĂ

ARANESP 20 µg/0.5 ml 20 µg/0.5 ml AMGEN EUROPE BV

B03XA02 DARBEPOETINUM ALFA SOL. INJ. ÎN SERINGĂ 30 µg/0.3 ml

PREUMPLUTĂ

ARANESP 30 µg/0.3 ml 30 µg/0.3 ml AMGEN EUROPE BV

B03XA02 DARBEPOETINUM ALFA SOL. INJ. ÎN SERINGĂ 300 µg/0.6 ml

PREUMPLUTĂ

ARANESP 300 µg/0.6 ml 300 µg/0.6 ml AMGEN EUROPE BV

B03XA02 DARBEPOETINUM ALFA SOL. INJ. ÎN SERINGĂ 40 µg/0.4 ml

PREUMPLUTĂ

ARANESP 40 µg/0.4 ml 40 µg/0.4 ml AMGEN EUROPE BV

B03XA02 DARBEPOETINUM ALFA SOL. INJ. ÎN SERINGĂ 50 µg/0.5 ml

PREUMPLUTĂ

ARANESP 50 µg/0.5 ml 50 µg/0.5 ml AMGEN EUROPE BV

B03XA02 DARBEPOETINUM ALFA SOL. INJ. ÎN SERINGĂ 500 µg/ml

PREUMPLUTĂ

ARANESP 500 µg/ml 500 µg/ml AMGEN EUROPE BV

B03XA02 DARBEPOETINUM ALFA SOL. INJ. ÎN SERINGĂ 60 µg/0.3 ml

PREUMPLUTĂ

ARANESP 60 µg/0.3 ml 60 µg/0.3 ml AMGEN EUROPE BV

B03XA02 DARBEPOETINUM ALFA SOL. INJ. ÎN SERINGĂ 80 µg/0.4 ml

PREUMPLUTĂ

ARANESP 80 µg/0.4 ml 80 µg/0.4 ml AMGEN EUROPE BV

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| **544** |**C09CA04**| **IRBESARTANUM\*\*** | **Protocol: C008N** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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C09CA04 IRBESARTANUM COMPR. FILM. 150 mg

APROVEL 150 mg 150 mg SANOFI PHARMA - BRISTOL

MYERS SQUIBB

C09CA04 IRBESARTANUM COMPR. FILM. 300 mg

APROVEL 300 mg 300 mg SANOFI PHARMA - BRISTOL

MYERS SQUIBB

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| **545** |**H02AB07**| **PREDNISONUM** | **Protocol: H002N** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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H02AB07 PREDNISONUM COMPR. 5 mg

N-PREDNISON 5 mg MEDUMAN SA

PREDNISON 5 mg 5 mg SINTOFARM SA

PREDNISON ARENA 5 mg 5 mg ARENA GROUP SA

PREDNISON GEDEON RICHTER 5 mg 5 mg GEDEON RICHTER ROMANIA SA

PREDNISON MAGISTRA 5 mg 5 mg MAGISTRA C & C

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| **546** |**L01AA01**| **CYCLOPHOSPHAMIDUM** | **Protocol: L027N** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L01AA01 CYCLOPHOSPHAMIDUM DRAJ. 50 mg

ENDOXAN(R) 50 mg 50 mg BAXTER ONCOLOGY GMBH

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| **547** |**L04AA01**| **CICLOSPORINUM\*** | **Protocol: L028N** |

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Monitorizarea atentă a pacienţilor este obligatorie.

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L04AA01 CICLOSPORINUM CAPS. MOI 100 mg

EQUORAL(R) 100 mg 100 mg IVAX-PHARMACEUTICALS

S.R.O.

L04AA01 CICLOSPORINUM SOL. ORALĂ 100 mg/ml

EQUORAL(R) 100 mg/ml IVAX-PHARMACEUTICALS

S.R.O.

SANDIMMUN NEORAL(R) 100 mg/ml NOVARTIS PHARMA GMBH

L04AA01 CICLOSPORINUM CAPS. MOI 25 mg

CICLORAL(R) HEXAL(R) 25 mg 25 mg HEXAL AG

EQUORAL(R) 25 mg 25 mg IVAX-PHARMACEUTICALS

S.R.O.

SANDIMMUN NEORAL(R) 25 mg NOVARTIS PHARMA GMBH

L04AA01 CICLOSPORINUM CAPS. MOI 50 mg

CICLORAL(R) HEXAL 50 mg 50 mg HEXAL AG

EQUORAL(R) 50 mg 50 mg IVAX-PHARMACEUTICALS

S.R.O.

SANDIMMUN NEORAL(R) 50 mg NOVARTIS PHARMA GMBH

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| **548** |**L04AX01**| **AZATHIOPRINUM\*** | **Protocol: L029N** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L04AX01 AZATHIOPRINUM COMPR. FILM. 50 mg

IMURAN(R) 50 mg THE WELLCOME FOUNDATION

LTD.

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| **549** |**V06DDN1**| **AMINOACIZI INCLUSIV COMBINAŢII CU** | **Protocol: V004N** |

| | | **POLIPEPTIDE\*\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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V06DDN1 AMINOACIZI INCLUSIV COMPR. FILM.

COMBINAŢII CU

POLIPEPTIDE

KETOSTERIL(R) FRESENIUS KABI DEUTSCHLAND

GMBH

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**SUBLISTA C1 - G26 GLAUCOM.**

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| **550** |**S01EC03**| **DORZOLAMIDUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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S01EC03 DORZOLAMIDUM SOL. OFT. 20 mg/ml

TRUSOPT 20 mg/ml MERCK SHARP & DOHME S.R.L

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| **551** |**S01EC04**| **BRINZOLAMIDUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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S01EC04 BRINZOLAMIDUM PICĂTURI OFT. - SUSP. 10 mg/ml

AZOPT 10 mg/ml 10 mg/ml ALCON LABORATORIES LTD.

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| **552** |**S01ED01**| **TIMOLOLUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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S01ED01 TIMOLOLUM PICĂTURI OFT. - SOL 0.25%

TIMO-COMOD(R) 0.25% URSAPHARM ARZNEIMITTEL

GMBH&CO.KG

TIMOLOL 0.25% 0.25% E.I.P.I. CO. MED S.R.L

S01ED01 TIMOLOLUM PICĂTURI OFT. - SOL. 0.5%

TIMO-COMOD(R) 0.5% URSAPHARM ARZNEIMITTEL

GMBH&CO.KG

TIMO-GAL(R) 0.5% TERAPIA SA

TIMOLOL 0.5% 0.5% E.I.P.I.CO. MED S.R.L.

S01ED01 TIMOLOLUM GEL OFT. 1 mg/g

NYOLOL GEL 1 mg/g NOVARTIS PHARMA GMBH

S01ED01 TIMOLOLUM PIC. OFT. - SOL. 2.5 mg/ml

TIMOPTIC 2.5 mg/ml MERCK SHARP & DOHME

ROMANIA S.R.L.

S01ED01 TIMOLOLUM PICĂTURI OFT. - SOL. 2.5 mg/ml

ARUTIMOL 0.25% 2.5 mg/ml CHAUVIN ANKERPHARM GMBH

S01ED01 TIMOLOLUM PIC. OFT. - SOL. 5 mg/ml

TIMOPTIC 5 mg/ml MERCK SHARP & DOHME

ROMANIA S.R.L.

S01ED01 TIMOLOLUM PICĂTURI OFT. - SOL. 5 mg/ml

ARUTIMOL 0.5% 5 mg/ml CHAUVIN ANKERPHARM GMBH

S01ED01 TIMOLOLUM PIC. OFT., SOL. 2.5 mg/ml

TIMOLOL RPH 0.25% 2.5 mg/ml ROMPHARM COMPANY SRL

S01ED01 TIMOLOLUM PIC. OFT. SOL. 2.5 mg/ml

TIMABAK 2,5 mg/ml 2.5 mg/ml LABORATOIRES THEA

S01ED01 TIMOLOLUM PIC. OFT. SOL. 5 mg/ml

TIMABAK 5 mg/ml 5 mg/ml LABORATORIES THEA

TIMOLOL RPH 0.5% 5 mg/ml ROMPHARM COMPANY SRL

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| **553** |**S01ED02**| **BETAXOLOLUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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S01ED02 BETAXOLOLUM PICĂTURI OFT. - SUSP. 0.25%

BETOPTIC-S 0.25% ALCON COUVREUR NV

S01ED02 BETAXOLOLUM PIC. OFT. - SOL. 5 mg/ml

BETAX 5 mg/ml ROMPHARM SRL

S01ED02 BETAXOLOLUM PIC. OFTALMICE. SOL 5 mg/ml

BETOPTIC 5 mg/ml ALCON COUVREUR NV

S01ED02 BETAXOLOLUM PIC. OFT. SOL. 5 mg/ml

BETAXOLOL 5 mg/ml TERAPIA SA

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| **554** |**S01ED05**| **CARTEOLOLUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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S01ED05 CARTEOLOLUM PICĂTURI OFT. - SOL. 20 mg/ml

CARTEOL 2% 20 mg/ml S.I.F.I. SPA

S01ED05 CARTEOLOLUM PIC. OFTALMICE CU ELIB. 20 mg/ml

PREL

FORTINOL EP 2% 20 mg/ml DR. GERHARD MANN

CHEM-PHARM. FABRIK GMBH

S01ED05 CARTEOLOLUM PICĂTURI OFT. - SOL. 2%

CARTEOL 2% 2% S.I.F.I. SPA

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| **555** |**S01ED51**| **COMBINAŢII (BIMATOPROSTUM + TIMOLOLUM)** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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S01ED51 COMBINAŢII PIC. OFT.. SOL. 300 µg/ml + 5 mg/ml

(BIMATOPROSTUM +

TIMOLOLUM)

GANFORT 300 µg/ml + 5 mg/ml ALLERGAN PHARMACEUTICALS

IRELAND

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| **556** |**S01ED51**| **COMBINAŢII (DORZOLAMIDUM + TIMOLOLUM)** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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S01ED51 COMBINAŢII PIC. OFT. - SOL.

(DORZOLAMIDUM +

TIMOLOLUM)

COSOPT FĂRĂ MERCK SHARP & DOHME

CONCENTRAŢIE

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| **557** |**S01ED51**| **COMBINAŢII (LATANOPROSTUM + TIMOLOLUM)** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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S01ED51 COMBINAŢII SOL. OFT.

(LATANOPROSTUM +

TIMOLOLUM)

XALCOM(R) FĂRĂ PFIZER EUROPE MA EEI

CONCENTRAŢIE

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| **558** |**S01EE01**| **LATANOPROSTUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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S01EE01 LATANOPROSTUM PICĂTURI OFT. - SOL. 5,00%

XALATAN(R) 0.005% PFIZER EUROPE MA EEIG

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| **559** |**S01EE03**| **BIMATOPROSTUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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S01EE03 BIMATOPROSTUM PIC. OFT. SOL. 0,3 mg/ml

LUMIGAN 0,3 mg/ml 0.3 mg/ml ALLERGAN PHARMACEUTICALS

IRELAND

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| **561** |**S01EE04**| **TRAVOPROSTUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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S01EE04 TRAVOPROSTUM PICĂTURI OFT. SOL. 40 µg/ml

TRAVATAN 40 µg/ml 40 µg/ml ALCON LABORATORIES LTD.

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**SUBLISTA C1 - G27 PEMFIGUS.**

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| **562** |**H02AB02**| **DEXAMETHASONUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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H02AB02 DEXAMETHASONUM SOL. INJ. 8 mg

DEXAMETHASONE SODIUM 8 mg E.I.P.I.CO. MED S.R.L

PHOSPHATE

H02AB02 DEXAMETHASONUM SOL. INJ. 8 mg/2 ml

DEXAMED 8 mg/2 ml MEDOCHEMIE LTD.

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| **563** |**H02AB04**| **METHYLPREDNISOLONUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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H02AB04 METHYLPREDNISOLONUM

H02AB04 METHYLPREDNISOLONUM COMPR.

MEDROL 32 32 mg PFIZER EUROPE MA EEI

H02AB04 METHYLPREDNISOLONUM COMPR.

MEDROL 4 mg 4 mg PFIZER EUROPE MA EEI

H02AB04 METHYLPREDNISOLONUM COMPR.

MEDROL A 16 16 mg PFIZER EUROPE MA EEI

H02AB04 METHYLPREDNISOLONUM LIOF. + SOLV. PT. SOL.

INJ.

SOLU-MEDROL 500 mg/7,8 ml 500 mg/7.8 ml PFIZER EUROPE MA EEI

H02AB04 METHYLPREDNISOLONUM LIOF. ŞI SOLV. PT. SOL.

INJ.

SOLU-MEDROL ACT-O-VIAL 125 mg/2 ml PFIZER EUROPE MA EEI

H02AB04 METHYLPREDNISOLONUM LIOF. ŞI SOLV. PT. SOL.

INJ.

SOLU-MEDROL ACT-O- VIAL 250 mg/4 ml PFIZER EUROPE MA EEI

H02AB04 METHYLPREDNISOLONUM LIOF. ŞI SOLV. PT. SOL.

INJ.

SOLU-MEDROL ACT-O-VIAL 40 mg/1 ml PFIZER EUROPE MA EEI

H02AB04 METHYLPREDNISOLONUM LIOF. PT. SOL. INJ.

LEMOD SOLU 125 mg 125 mg HEMOFARM S.R.L.

H02AB04 METHYLPREDNISOLONUM LIOF. PT. SOL. INJ.

LEMOD SOLU 40 mg 40 mg HEMOFARM S.R.L.

H02AB04 METHYLPREDNISOLONUM LIOF. PT. SOL. INJ.

LEMOD SOLU 20 mg 20 mg HEMOFARM S.R.L.

H02AB04 METHYLPREDNISOLONUM LIOF. PT. SOL. INJ.

LEMOD SOLU 500 mg 500 mg HEMOFARM S.R.L.

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| **564** |**H02AB07**| **PREDNISONUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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H02AB07 PREDNISONUM COMPR. 5 mg

N-PREDNISON 5 mg MEDUMAN SA

PREDNISON 5 mg 5 mg SINTOFARM SA

PREDNISON ARENA 5 mg 5 mg ARENA GROUP SA

PREDNISON GEDEON RICHTER 5 mg 5 mg GEDEON RICHTER ROMANIA SA

PREDNISON MAGISTRA 5 mg 5 mg MAGISTRA C & C

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| **565** |**J04BA02**| **DAPSONUM (4)** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J04BA02 DAPSONUM

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| **566** |**L01AA01**| **CYCLOPHOSPHAMIDUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L01AA01 CYCLOPHOSPHAMIDUM PULB. PT. SOL. INJ./ 1 g

PERF.

ENDOXAN(R) 1 g 1 g BAXTER ONCOLOGY GMBH

L01AA01 CYCLOPHOSPHAMIDUM PULB. PT. SOL. PERF./ 200 mg

INJ. I.V.

ENDOXAN 200 mg 200 mg ACTAVIS S.R.L.

L01AA01 CYCLOPHOSPHAMIDUM PULB. PT. SOL. INJ./ 500 mg

PERF.

ENDOXAN(R) 500 mg 500 mg BAXTER ONCOLOGY GMBH

L01AA01 CYCLOPHOSPHAMIDUM DRAJ. 50 mg

ENDOXAN(R) 50 mg 50 mg BAXTER ONCOLOGY GMBH

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| **568** |**L04AA01**| **CICLOSPORINUM\*** | |

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Monitorizarea atentă a pacienţilor este obligatorie.

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L04AA01 CICLOSPORINUM CAPS. MOI 100 mg

EQUORAL(R) 100 mg 100 mg IVAX-PHARMACEUTICALS

S.R.O.

L04AA01 CICLOSPORINUM SOL. ORALĂ 100 mg/ml

EQUORAL(R) 100 mg/ml IVAX-PHARMACEUTICALS

S.R.O.

SANDIMMUN NEORAL(R) 100 mg/ml NOVARTIS PHARMA GMBH

L04AA01 CICLOSPORINUM CAPS. MOI 25 mg

CICLORAL(R) HEXAL(R) 25 mg 25 mg HEXAL AG

EQUORAL(R) 25 mg 25 mg IVAX-PHARMACEUTICALS

S.R.O.

SANDIMMUN NEORAL(R) 25 mg NOVARTIS PHARMA GMBH

L04AA01 CICLOSPORINUM CAPS. MOI 50 mg

CICLORAL(R) HEXAL 50 mg 50 mg HEXAL AG

EQUORAL(R) 50 mg 50 mg IVAX-PHARMACEUTICALS

S.R.O.

SANDIMMUN NEORAL(R) 50 mg NOVARTIS PHARMA GMBH

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| **569** |**L04AX01**| **AZATHIOPRINUM\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L04AX01 AZATHIOPRINUM COMPR. FILM. 50 mg

IMURAN(R) 50 mg THE WELLCOME FOUNDATION

LTD.

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**SUBLISTA C1 - G29 BOALA GAUCHER.**

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| **570** |**A16AB02**| **IMIGLUCERASUM\*\*\*\*** | **Protocol: A008E** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A16AB02 IMIGLUCERASUM PULB. PT. CONC. PT. 200 U

SOL. PERF.

CEREZYME 200 U 200 U GENZYME EUROPE BV

A16AB02 IMIGLUCERASUM PULB. PT. CONC. PT. 400 U

SOL. PERF.

CEREZYME 400 U 400 U GENZYME EUROPE BV

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| **571** |**A16AX06**| **MIGLUSTATUM\*\*\*\*** | |

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Prescriere limitată: **Tratamentul pe cale orală al bolii Gaucher de tip I, uşoară până la moderată, numai la pacienţii care nu pot fi supuşi terapiei de substituţie enzimatică**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A16AX06 MIGLUSTATUM CAPS. 100 mg

ZAVESCA 100 mg ACTELION REGISTRATION LTD.

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**SUBLISTA C1 - G30 BOLI VENERICE (SIFILIS, GONOREE, INFECŢIA CU CHLAMIDIA).**

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| **572** |**J01AA02**| **DOXYCYCLINUM** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01AA02 DOXYCYCLINUM CAPS. 100 mg

DOXICILINA 100 mg EUROPHARM SA

DOXICILINA 100 mg 100 mg ANTIBIOTICE SA

DOXICICUNA SANDOZ 100 mg 100 mg SANDOZ SRL

J01AA02 DOXYCYCLINUM COMPR. DISP. 100 mg

UNIDOX SOLUTAB 100 mg ASTELLAS PHARMA EUROPE

B.V.

J01AA02 DOXYCYCLINUM CAPS. 100 mg

DOXICILINA 100 mg ARENA GROUP SA

DOXICILINA 100 mg 100 mg ANTIBIOTICE SA

DOXICILINA SANDOZ 100 mg 100 mg SANDOZ SRL

J01AA02 DOXYCYCLINUM COMPR. DISP. 100 mg

UNIDOX SOLUTAB 100 mg ASTELLAS PHARMA EUROPE

B.V.

J01AA02 DOXYCYCLINUM CAPS. 100 mg

DOXICICLINA 100 mg ARENA GROUP SA

DOXICICLINA 100 mg 100 mg ANTIBIOTICE SA

DOXICICLINA SANDOZ 100 mg 100 mg SANDOZ SRL

J01AA02 DOXYCYCLINUM COMPR. DISP. 100 mg

UNIDOX SOLUTAB 100 mg ASTELLAS PHARMA EUROPE

B.V.

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| **573** |**J01AA07**| **TETRACYCLINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01AA07 TETRACYCLINUM CAPS. 250 mg

TETRACICLINA 250 mg 250 mg ANTIBIOTICE SA

TETRACICLINA SANDOZ 250 mg 250 mg SANDOZ SRL

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| **574** |**J01CE02**| **PHENOXYMETHYLPENICILLINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01CE02 COMPR. 1000000 ui

PHENOXYMETHYLPENICILLINUM

PENICILINA V 1 000 000 U.I. 1000000 ui EUROPHARM SA

J01CE02 COMPR. FILM. 1000000 ui

PHENOXYMETHYLPENICILLINUM

OSPEN(R) 1000 1000000 ui SANDOZ GMBH

J01CE02 COMPR. FILM. 1500000 ui

PHENOXYMETHYLPENICILLINUM

OSPEN(R) 1500 1500000 ui SANDOZ GMBH

J01CE02 SIROP 400000 ui/5 ml

PHENOXYMETHYLPENICILLINUM

OSPEN 400 400000 ui/5 ml SANDOZ GMBH

J01CE02 COMPR. FILM. 500000 ui

PHENOXYMETHYLPENICILLINUM

OSPEN(R) 500 500000 ui SANDOZ GMBH

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| **575** |**J01CE01**| **BENZYLPENICILLINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01CE01 BENZYLPENICILLINUM PULB. PT. SOL. INJ. 1000000 ui

PENICILINA G SODICA 1000000 ui ANTIBIOTICE SA

J01CE01 BENZYLPENICILLINUM PULB. PT. SOL. INJ. 1000000 ui

PENICILINA G POTASICA 1000000 ui ANTIBIOTICE SA

J01CE01 BENZYLPENICILLINUM PULB. PT. SOL. INJ. 400000 ui

PENICILINA G SODICA 400000 ui ANTIBIOTICE SA

J01CE01 BENZYLPENICILLINUM PULB. PT. SOL. INJ. 400000 ui

PENICILINA G POTASICA 400000 ui ANTIBIOTICE SA

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| **576** |**J01CE08**| **BENZATHINI BENZYLPENICILLINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01CE08 BENZATHINI PULB. PT. SUSP. INJ. 1200000 ui

BENZYLPENICILLINUM

MOLDAMIN(R) 1200000 ui ANTIBIOTICE SA

J01CE08 BENZATHINI PULB. PT. SUSP. INJ. 600000 ui

BENZYLPENICILLINUM

MOLDAMIN(R) 600000 ui ANTIBIOTICE SA

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| **577** |**J01DD08**| **CEFIXIMUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01DD08 CEFIXIMUM GRAN. PT. SUSP. ORALĂ 100 mg/5ml

SUPRAX 100 mg/5 ml GEDEON RICHTER LTD.

J01DD08 CEFIXIMUM CAPS. 200 mg

EFICEF(R) 200 mg 200 mg ANTIBIOTICE SA

J01DD08 CEFIXIMUM COMPR. FILM. 200 mg

SUPRAX 200 mg GEDEON RICHTER LTD.

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| **578** |**J01FA01**| **ERYTHROMYCINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01FA01 ERYTHROMYCINUM COMPR. 200 mg

ERITROMAGIS 200 mg 200 mg ARENA GROUP SA

ERITROMICINA 200 mg 200 mg ANTIBIOTICE SA

ERITROMICINA EUROPHARM 200 mg 200 mg EUROPHARM SA

ERITROMICINA SANDOZ 200 mg 200 mg SANDOZ S.R.L.

COMPRIMATE

J01FA01 ERYTHROMYCINUM PULB. PT. SUSP. ORALĂ 200 mg/5 ml

ERITRO 200 200 mg/5ml LEK PHARMATECH SRL

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| **579** |**J01FA10**| **AZITHROMYCINUM** | |

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Prescriere limitată: **Infecţii genitale necomplicate cu Chlamydia trachomatis.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01FA10 AZITHROMYCINUM PULB. PT. SUSP. ORALĂ 100 mg/5ml

AZITROMICINA SANDOZ 100 mg/5ml SANDOZ SRL

100 mg/5ml

J01FA10 AZITHROMYCINUM COMPR. FILM. 125 mg

SUMAMED 125 mg 125 mg PLIVA LJUBLJANA D.O.O.

J01FA10 AZITHROMYCINUM PULB. PT. SUSP. ORALĂ 200 mg/5 ml

AZITROMICINA SANDOZ 200 mg/5 ml SANDOZ SRL

200 mg/5 ml

J01FA10 AZITHROMYCINUM PULB. + SOLV. 200 mg/5ml

SUSP. ORALĂ

AZITROX 200 mg/5 ml 200 mg/5 ml ECZACIBASI PHARMACEUTICALS

S.R.L.

J01FA10 AZITHROMYCINUM PULB. PT. SUSP. ORALĂ 200 mg/5ml

SUMAMED FORTE 200 mg/5ml PLIVA LJUBLIJANA D.O.O.

J01FA10 AZITHROMYCINUM CAPS. 250 mg

AZATRIL 250 mg 250 mg BALKANPHARMA RAZGRAD AD

J01FA10 AZITHROMYCINUM COMPR. FILM. 250 mg

AZITROMICINA SANDOZ 250 mg 250 mg SANDOZ S.R.L.

COMPRIMATE FILMATE

AZITROX(R) 250 250 mg ZENTIVA AS

J01FA10 AZITHROMYCINUM LIOF. PT. SOL. PERF. 500 mg

SUMAMED(R) 500 mg PLIVA LJUBLJANA D.O.O.

J01FA10 AZITHROMYCINUM COMPR. FILM. 500 mg

AZITROMICINA SANDOZ 500 mg 500 mg SANDOZ S.R.L.

COMPRIMATE FILMATE

AZITROX(R) 500 500 mg ZENTIVA AS

AZRO(R) 500 mg 500 mg ECZACIBASI PHARMACEUTICALS

S.R.L.

SUMAMED 500 mg 500 mg PLIVA LJUBLJANA D.O.O.

ZITROCIN 500 mg 500 mg OZONE LABORATORIES LTD.

J01FA10 AZITHROMYCINUM GRAN. ELIB. PREL PT. 2 g

SUSP. ORALĂ

ZMAX 2 g 2 g PFIZER EUROPE MA EEIG

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| **580** |**J01MA02**| **CIPROFLOXACINUM** | |

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Prescriere limitată: **Gonoreea.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01MA02 CIPROFLOXACINUM COMPR. FILM. 250 mg

CIFRAN 250 mg RANBAXY UK LIMITED

CIPHIN 250 250 mg ZENTIVA A.S.

CIPRINOL 250 mg 250 mg KRKA D.D. NOVO MESTO

CIPROCIN 250 mg 250 mg E.I.P.I.CO. MED S.R.L.

CIPROFLOXACINA ALKALOID 250 mg ALKALOID D.O.O.

250 mg

CIPROLEN(R) 250 mg 250 mg AC HELCOR SRL

CIPROLET 250 mg 250 mg DR. REDDY'S LABORATORIES

CIPROZONE 250 mg 250 mg OZONE LABORATORIES LTD.

CUMINOL 250 mg 250 mg GEDEON RICHTER ROMANIA

J01MA02 CIPROFLOXACINUM CONC. PT. SOL. PERF. 100 mg/10 ml

CIPRINOL(R) 100 mg/10 ml KRKA D.D.

CIPROFLOXACINA 100 mg/10 ml 100 mg/10 ml SICOMED SA

J01MA02 CIPROFLOXACINUM SOL. PERF. 100 mg/50 ml

CIPRINOL 100 mg/50 ml KRKA D.D. NOVO MESTO

J01MA02 CIPROFLOXACINUM SOL. PERF. 200 mg/100 ml

CIPRINOL 200 mg/100 ml KRKA D.D. NOVO MESTO

CIPROBAY(R) 200 200 mg/100 ml BAYER HEALTHCARE AG

J01MA02 CIPROFLOXACINUM CAPS. 250 mg

EUCIPRIN 250 mg EUROPHARM SA

J01MA02 CIPROFLOXACINUM COMPR. FILM. 250 mg

CIFRAN 250 mg RANBAXY UK LIMITED

CIPHIN 250 250 mg ZENTIVA A.S.

CIPRINOL 250 mg 250 mg KRKA D.D. NOVO MESTO

CIPROCIN 250 mg 250 mg E.I.P.I.CO. MED S.R.L.

CIPROFLOXACINA ALKALOID 250 mg ALKALOID D.O.O.

250 mg

CIPROLEN(R) 250 mg 250 mg AC HELCOR SRL

CIPROLET 250 mg 250 mg DR. REDDY'S LABORATORIES

CIPROZONE 250 mg 250 mg OZONE LABORATORIES LTD.

CUMINOL 250 mg 250 mg GEDEON RICHTER ROMANIA

J01MA02 CIPROFLOXACINUM SOL. PERF. 2 mg/ml

CIPROBAY(R) 400 2 mg/ml BAYER HEALTHCARE AG

UFEXIL 2 mg/ml DEMO SA

J01MA02 CIPROFLOXACINUM SOL. PERF. 400 mg/200 ml

CIPRINOL(R) 400 mg/200 ml KRKA D.D.

J01MA02 CIPROFLOXACINUM COMPR. FILM. 500 mg

CIFRAN 500 mg RANBAXY UK LIMITED

CIPHIN 500 500 mg ZENTIVA A.S.

CIPRINOL 500 mg 500 mg KRKA D.D. NOVO MESTO

CIPRO QUIN(R) 500 mg ANTIBIOTICE SA

CIPROBAY(R) 500 500 mg BAYER HEALTHCARE AG

CIPROCIN 500 mg 500 mg E.I.P.I.CO. MED S.R.L.

CIPRODAR 500 mg DAR AL DAWA PHARMA S.R.L

CIPROFLOXACINA ALKALOID 500 mg ALKALOID D.O.O.

500 mg

CIPROLEN(R) 500 mg 500 mg AC HELCOR SRL

CIPROLET 500 mg 500 mg DR. REDDY'S LABORATORIES

CIPROZONE FORTE 500 mg 500 mg OZONE LABORATORIES LTD.

CUMINOL 500 mg 500 mg GEDEON RICHTER ROMANIA

SIFLOKS(R) 500 mg ECZACIBASI ILAC SANAYI VE

TICARET AS

J01MA02 CIPROFLOXACINUM COMPR. FILM. 750 mg

CIPRINOL 750 mg 750 mg KRKA D.D. NOVOMESTO

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**SUBLISTA C1 - G31A BOALĂ CRONICĂ INFLAMATORIE INTESTINALĂ.**

**Protocol: L034K**

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| **582** |**L04AA12**| **INFLIXIMABUM\*\*\*\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L04AA12 INFLIXIMABUM PULB. PT. CONC. PT. 100 mg

SOL. PERF.

REMICADE 100 mg 100 mg CENTOCOR B.V.

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| **583** |**L04AA17**| **ADALIMUMABUM\*\*\*\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L04AA17 ADALIMUMABUM SOL. INJ. ÎN SERINGĂ 40 mg

PREUMPLUTĂ

HUMIRA 40 mg 40 mg ABBOTT LABORATORIES LTD.

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**SUBLISTA C1 - G31B POLIARTRITĂ REUMATOIDĂ.**

**Protocol: L043M**

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| **584** |**L01XC02**| **RITUXIMABUM\*\*\*\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L01XC02 RITUXIMABUM CONC. PT. SOL. PERF. 10 mg/ml

MABTHERA 100 mg 10 mg/ml ROCHE REGISTRATION LTD.

MABTHERA 500 mg 10 mg/ml ROCHE REGISTRATION LTD.

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| **585** |**L04AA11**| **ETANERCEPTUM\*\*\*\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L04AA11 ETANERCEPTUM PULB. + SOLV. PT. 25 mg

SOL. INJ.

ENBREL 25 mg 25 mg WYETH EUROPA LIMITED

L04AA11 ETANERCEPTUM PULB + SOLV. PT. 50 mg

SOL. INJ.

ENBREL 50 mg 50 mg WYETH EUROPA LIMITED

L04AA11 ETANERCEPTUM PULB. + SOLV. PT. 25 mg

SOL. INJ.

ENBREL 25 mg 25 mg WYETH EUROPA LIMITED

L04AA11 ETANERCEPTUM PULB + SOLV. PT. 50 mg

SOL. INJ.

ENBREL 50 mg 50 mg WYETH EUROPA LIMITED

L04AA11 ETANERCEPTUM SOL. INJ. ÎN SERINGĂ 25 mg

PREUMPLUTĂ

ENBREL 25 mg 25 mg WYETH EUROPA LIMITED

L04AA11 ETANERCEPTUM SOL. INJ. ÎN SERINGĂ 50 mg

PREUMPLUTĂ

ENBREL 50 mg 50 mg WYETH EUROPA LIMITED

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| **586** |**L04AA12**| **INFLIXIMABUM\*\*\*\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L04AA12 INFLIXIMABUM PULB. PT. CONC. 100 mg

PT. SOL. PERF.

REMICADE 100 mg 100 mg CENTOCOR B.V.

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| **587** |**L04AA17**| **ADALIMUMABUM\*\*\*\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L04AA17 ADALIMUMABUM SOL. INJ. ÎN SERINGĂ 40 mg

PREUMPLUTĂ

HUMIRA 40 mg 40 mg ABBOTT LABORATORIES LTD.

**SUBLISTA C1 - G31C ARTROPATIA PSORIAZICA.**

**Protocol: L040M**

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| **589** |**L04AA11**| **ETANERCEPTUM\*\*\*\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L04AA11 ETANERCEPTUM PULB. + SOLV. PT. 25 mg

SOL. INJ.

ENBREL 25 mg 25 mg WYETH EUROPA LIMITED

L04AA11 ETANERCEPTUM PULB + SOLV. PT. 50 mg

SOL. INJ

ENBREL 50 mg 50 mg WYETH EUROPA LIMITED

L04AA11 ETANERCEPTUM PULB. + SOLV. PT. 25 mg

SOL. INJ.

ENBREL 25 mg 25 mg WYETH EUROPA LIMITED

L04AA11 ETANERCEPTUM PULB + SOLV. PT. 50 mg

SOL. INJ.

ENBREL 50 mg 50 mg WYETH EUROPA LIMITED

L04AA11 ETANERCEPTUM SOL. INJ. ÎN SERINGĂ 25 mg

PREUMPLUTĂ

ENBREL 25 mg 25 mg WYETH EUROPA LIMITED

L04AA11 ETANERCEPTUM SOL. INJ. ÎN SERINGĂ 50 mg

PREUMPLUTĂ

ENBREL 50 mg 50 mg WYETH EUROPA LIMITED

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| **590** |**L04AA12**| **INFLIXIMABUM\*\*\*\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L04AA12 INFLIXIMABUM PULB. PT. CONC. PT. 100 mg

SOL. PERF.

REMICADE 100 mg 100 mg CENTOCOR B.V.

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| **591** |**L04AA17**| **ADALIMUMABUM\*\*\*\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L04AA17 ADALIMUMABUM SOL. INJ. ÎN SERINGĂ 40 mg

PREUMPLUTĂ

HUMIRA 40 mg 40 mg ABBOTT LABORATORIES LTD.

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**SUBLISTA C1 - G31D SPONDILITA ANKILOZANTA.**

**Protocol: L041M**

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| **592** |**L04AA11**| **ETANERCEPTUM\*\*\*\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L04AA11 ETANERCEPTUM PULB. + SOLV. PT. 25 mg

SOL. INJ.

ENBREL 25 mg 25 mg WYETH EUROPA LIMITED

L04AA11 ETANERCEPTUM PULB + SOLV. PT. 50 mg

SOL. INJ.

ENBREL 50 mg 50 mg WYETH EUROPA LIMITED

L04AA11 ETANERCEPTUM PULB. + SOLV. PT. 25 mg

SOL. INJ.

ENBREL 25 mg 25 mg WYETH EUROPA LIMITED

L04AA11 ETANERCEPTUM PULB + SOLV. PT. 50 mg

SOL. INJ.

ENBREL 50 mg 50 mg WYETH EUROPA LIMITED

L04AA11 ETANERCEPTUM SOL. INJ. ÎN SERINGĂ 25 mg

PREUMPLUTĂ

ENBREL 25 mg 25 mg WYETH EUROPA LIMITED

L04AA11 ETANERCEPTUM SOL. INJ. ÎN SERINGĂ 50 mg

PREUMPLUTĂ

ENBREL 50 mg 50 mg WYETH EUROPA LIMITED

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| **593** |**L04AA12**| **INFLIXIMABUM\*\*\*\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L04AA12 INFLIXIMABUM PULB. PT. CONC. PT. 100 mg

SOL. PERF.

REMICADE 100 mg 100 mg CENTOCOR B.V.

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| **594** |**L04AA17**| **ADALIMUMABUM\*\*\*\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L04AA17 ADALIMUMABUM SOL. INJ. ÎN SERINGĂ 40 mg

PREUMPLUTĂ

HUMIRA 40 mg 40 mg ABBOTT LABORATORIES LTD.

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**SUBLISTA C1 - G31E ARTRITA JUVENILA.**

**Protocol: L039M**

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| **595** |**L04AA11**| **ETANERCEPTUM\*\*\*\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L04AA11 ETANERCEPTUM PULB. + SOLV. PT. 25 mg

SOL. INJ.

ENBREL 25 mg 25 mg WYETH EUROPA LIMITED

L04AA11 ETANERCEPTUM PULB + SOLV. PT.

SOL. INJ. 50 mg

ENBREL 50 mg 50 mg WYETH EUROPA LIMITED

L04AA11 ETANERCEPTUM PULB. + SOLV. PT. 25 mg

SOL. INJ.

ENBREL 25 mg 25 mg WYETH EUROPA LIMITED

L04AA11 ETANERCEPTUM PULB + SOLV. PT. 50 mg

SOL. INJ.

ENBREL 50 mg 50 mg WYETH EUROPA LIMITED

L04AA11 ETANERCEPTUM SOL. INJ. ÎN SERINGĂ 25 mg

PREUMPLUTĂ

ENBREL 25 mg 25 mg WYETH EUROPA LIMITED

L04AA11 ETANERCEPTUM SOL. INJ. ÎN SERINGĂ 50 mg

PREUMPLUTĂ

ENBREL 50 mg 50 mg WYETH EUROPA LIMITED

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**SUBLISTA C1 - G31F PSORIAZIS CRONIC SEVER (PLACI).**

**Protocol: L044L**

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| **596** |**L04AA11**| **ETANERCEPTUM\*\*\*\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L04AA11 ETANERCEPTUM PULB. + SOLV. PT.

SOL. INJ. 25 mg

ENBREL 25 mg 25 mg WYETH EUROPA LIMITED

L04AA11 ETANERCEPTUM PULB + SOLV. PT.

SOL. INJ. 50 mg

ENBREL 50 mg 50 mg WYETH EUROPA LIMITED

L04AA11 ETANERCEPTUM PULB. + SOLV. PT.

SOL. INJ. 25 mg

ENBREL 25 mg 25 mg WYETH EUROPA LIMITED

L04AA11 ETANERCEPTUM PULB + SOLV. PT.

SOL. INJ. 50 mg

ENBREL 50 mg 50 mg WYETH EUROPA LIMITED

L04AA11 ETANERCEPTUM SOL. INJ. ÎN SERINGĂ

PREUMPLUTĂ 25 mg

ENBREL 25 mg 25 mg WYETH EUROPA LIMITED

L04AA11 ETANERCEPTUM SOL. INJ. ÎN SERINGĂ 50 mg

PREUMPLUTĂ

ENBREL 50 mg 50 mg WYETH EUROPA LIMITED

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| **597** |**L04AA12**| **INFLIXIMABUM\*\*\*\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L04AA12 INFLIXIMABUM PULB. PT. CONC. PT. 100 mg

SOL. PERF.

REMICADE 100 mg 100 mg CENTOCOR B.V.

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| **598** |**L04AA21**| **EFALIZUMABUM\*\*\*\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L04AA21 EFALIZUMABUM PULB + SOLV. PT.

SOL. INJ. 100 mg/ml

RAPTIVA 100 mg/ml 100 mg/ml SERONO EUROPE LTD.

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| **599** |**L04AA17**| **ADALIMUMABUM\*\*\*\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L04AA17 ADALIMUMABUM SOL. INJ. ÎN SERINGĂ 40 mg

PREUMPLUTĂ

HUMIRA 40 mg 40 mg ABBOTT LABORATORIES LTD.

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**SUBLISTA C2 - P1: PROGRAMUL NAŢIONAL DE BOLI TRANSMISIBILE. A) SUBPROGRAMUL DE TRATAMENT ŞI MONITORIZARE A PERSOANELOR CU INFECŢIE HIV/SIDA ŞI TRATAMENTUL POSTEXPUNERE**

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| **600** |**J05AE01**| **SAQUINAVIRUM** | |

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Prescriere limitată: **Tratamentul infecţiei HIV la pacienţii cu: celule CD4 < 500 pe mm cub sau încărcare virală > 10.000 copii per ml.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J05AE01 SAQUINAVIRUM CAPS. 200 mg

INVIRASE 200 mg 200 mg ROCHE REGISTRATION LTD.

J05AE01 SAQUINAVIRUM COMPR. FILM. 500 mg

INVIRASE 500 mg 500 mg ROCHE REGISTRATION LTD.

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| **601** |**J05AE02**| **INDINAVIRUM** | |

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Prescriere limitată: **Tratamentul infecţiei HIV la pacienţii cu: celule CD4 < 500 pe mm cub sau încărcare virală > 10.000 copii per ml.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J05AE02 INDINAVIRUM CAPS. 200 mg

CRIXIVAN 200 mg 200 mg MERCK SHARP & DOHME LTD.

J05AE02 INDINAVIRUM CAPS. 400 mg

CRIXIVAN 400 mg 400 mg MERCK SHARP & DOHME LTD.

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| **602** |**J05AE03**| **RITONAVIRUM\*\*** | |

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Prescriere limitată: **Tratamentul infecţiei HIV la pacienţii cu: celule CD4 < 500 pe mm cub sau încărcare virală > 10.000 copii per ml.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J05AE03 RITONAVIRUM CAPS. MOI 100 mg

NORVIR 100 mg 100 mg ABBOTT LABORATORIES LTD.

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| **603** |**J05AE04**| **NELFINAVIRUM** | |

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Prescriere limitată: **Tratamentul infecţiei HIV la pacienţii cu: celule CD4 < 500 pe mm cub sau încărcare virală > 10.000 copii per ml.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J05AE04 NELFINAVIRUM COMPR. FILM. 250 mg

VIRACEPT 250 mg 250 mg ROCHE REGISTRATION LTD.

J05AE04 NELFINAVIRUM PULB. PT. SOL. ORALĂ 50 mg/g

VIRACEPT 50 mg/g 50 mg/g ROCHE REGISTRATION LTD.

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| **605** |**J05AE06**| **LOPINAVIRUM + RITONAVIRUM\*\*** | |

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Prescriere limitată: **Tratamentul combinat al infecţiei HIV cu două sau mai multe antiretrovirale la pacienţii cu: celule CD4 < 500 pe mm cub sau încărcare virală > 10.000 copii per ml.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J05AE06 LOPINAVIRUM + CAPS. MOI 133.3 mg/33.3 mg

RITONAVIRUM

KALETRA 133.3 mg/33.3 mg 133.3 mg/33.3 mg ABBOTT LABORATORIES LTD.

J05AE06 LOPINAVIRUM + COMPR. FILM. 200 mg/50 mg

RITONAVIRUM

KALETRA 200 mg/50 mg 200 mg/50 mg ABBOTT LABORATORIES LTD.

J05AE06 LOPINAVIRUM + SOL. ORALĂ 80 mg/ml + 20 mg/ml

RITONAVIRUM

KALETRA 80 mg/ml + 20 mg/ml 80 mg/ml + 20 mg/ml ABBOTT LABORATORIES LTD.

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| **606** |**J05AE07**| **FOSAMPRENAVIRUM\*\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J05AE07 FOSAMPRENAVIRUM COMPR. FILM. 700 mg

TELZIR 700 mg 700 mg GLAXO GROUP LTD.

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| **607** |**J05AE08**| **ATAZANAVIRUM** | |

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Prescriere limitată: **Tratamentul combinat al infecţiei HIV cu două sau mai multe antiretrovirale la pacienţii cu: celule CD4 < 500 pe mm cub sau încărcare virală > 10.000 copii per ml.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J05AE08 ATAZANAVIRUM CAPS. 150 mg

REYATAZ 150 mg 150 mg BRISTOL - MYERS SQUIBB

PHARMA EEIG

J05AE08 ATAZANAVIRUM CAPS. 200 mg

REYATAZ 200 mg 200 mg BRISTOL - MYERS SQUIBB

PHARMA EEIG

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| **608** |**J05AE09**| **TIPRANAVIRUM\*\*** | |

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Prescriere limitată: **Tratamentul combinat al infecţiei HIV concomitent cu 200 mg ritonavir de două ori pe zi la adulţi experimentaţi cu evidenţa replicării virale (încărcare virală > 10.000 copii per ml) şi/sau celule CD4 < 500 pe mm cub. Pacienţii trebuie să fi avut eşec terapeutic sau rezistenţă la 3 regimuri ARV diferite care au inclus: cel puţin 1 inhibitor de non-nucleozid revers trasncriptaza şi cel puţin 1 inhibitor de nucleozid revers trasncriptaza şi cel puţin 2 inhibitori de protează.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J05AE09 TIPRANAVIRUM CAPS. MOI 250 mg

APTIVUS 250 mg 250 mg BOEHRINGER INGELHEIM

INTERNATIONAL GMBH

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| **609** |**J05AE10**| **DARUNAVIRUM\*\*** | |

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Prescriere limitată: **Tratamentul combinat al infecţiei HIV concomitent cu 200 mg ritonavir de două ori pe zi la adulţi experimentaţi cu evidenţa replicării virale (încărcare virală > 10.000 copii per ml) şi/sau celule CD4 < 500 pe mm cub. Pacienţii trebuie să fi avut eşec terapeutic sau rezistenţă la 3 regimuri ARV diferite care au inclus: cel puţin 1 inhibitor de non-nucleozid revers trasncriptază şi cel puţin 1 inhibitor de nucleozid revers trasncriptază şi cel puţin 2 inhibitori de protează.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J05AE10 DARUNAVIRUM COMPR. FILM. 300 mg

PREZISTA 300 mg 300 mg JANSSEN - CILAG

INTERNATIONAL NV

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| **610** |**J05AF01**| **ZIDOVUDINUM** | |

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Prescriere limitată: **Tratamentul infecţiei HIV la pacienţii cu: celule CD4 < 500 pe mm cub sau încărcare virală > 10.000 copii per ml.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J05AF01 ZIDOVUDINUM CAPS. 100 mg

RETROVIR(R) 100 mg THE WELLCOME FOUNDATION

LTD.

J05AF01 ZIDOVUDINUM SOL. ORALĂ 1%

RETROVIR(R) 1% THE WELLCOME FOUNDATION

LTD.

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| **611** |**J05AF02**| **DIDANOSINUM** | |

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Prescriere limitată: **Tratamentul infecţiei HIV la pacienţii cu: celule CD4 < 500 pe mm cub sau încărcare virală > 10.000 copii per ml.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J05AF02 DIDANOSINUM CAPS. GASTROREZ. 125 mg

VIDEX EC 125 mg 125 mg BRISTOL MYERS SQUIBB KFT

J05AF02 DIDANOSINUM CAPS. GASTROREZ. 200 mg

VIDEX EC 200 mg 200 mg BRISTOL MYERS SQUIBB KFT

J05AF02 DIDANOSINUM CAPS. GASTROREZ. 250 mg

VIDEX EC 250 mg 250 mg BRISTOL MYERS SQUIBB KFT

J05AF02 DIDANOSINUM CAPS. GASTROREZ. 400 mg

VIDEX EC 400 mg 400 mg BRISTOL MYERS SQUIBB KFT

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| **612** |**J05AF04**| **STAVUDINUM** | |

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Prescriere limitată: **Tratamentul infecţiei HIV la pacienţii cu: celule CD4 < 500 pe mm cub sau încărcare virală > 10.000 copii per ml.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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J05AF04 STAVUDINUM CAPS. 15 mg

ZERIT 15 mg 15 mg BRISTOL-MYERS SQUIBB

PHARMA EEIG

J05AF04 STAVUDINUM CAPS. 20 mg

ZERIT 20 mg 20 mg BRISTOL-MYERS SQUIBB

PHARMA EEIG

J05AF04 STAVUDINUM CAPS. 30 mg

ZERIT 30 mg 30 mg BRISTOL-MYERS SQUIBB

PHARMA EEIG

J05AF04 STAVUDINUM CAPS. 40 mg

ZERIT 40 mg 40 mg BRISTOL-MYERS SQUIBB

PHARMA EEIG

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| **613** |**J05AF05**| **LAMIVUDINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J05AF05 LAMIVUDINUM COMPR. FILM. 100 mg

ZEFFIX 100 mg 100 mg GLAXO GROUP LTD.

J05AF05 LAMIVUDINUM SOL. ORALA 10 mg/ml

EPIVIR 10 mg/ml 10 mg/ml GLAXO GROUP LTD.

J05AF05 LAMIVUDINUM COMPR. FILM. 150 mg

EPIVIR 150 mg 150 mg GLAXO GROUP LTD.

J05AF05 LAMIVUDINUM SOL. ORALA 5 mg/ml

ZEFFIX 5 mg/ml 5 mg/ml GLAXO GROUP LTD.

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| **614** |**J05AF06**| **ABACAVIRUM** | |

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Prescriere limitată: **Tratamentul infecţiei HIV la pacienţii cu: celule CD4 < 500 pe mm cub sau încărcare virală > 10.000 copii per ml.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J05AF06 ABACAVIRUM SOL. ORALA 20 mg/ml

ZIAGEN 20 mg/ml 20 mg/ml GLAXO GROUP LTD.

J05AF06 ABACAVIRUM COMPR. FILM. 300 mg

ZIAGEN 300 mg 300 mg GLAXO GROUP LTD.

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| **615** |**J05AF07**| **TENOFOVIRUM DISOPROXIL FUMARATE** | |

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Prescriere limitată: **Tratamentul infecţiei HIV la pacienţii cu: celule CD4 < 500 pe mm cub sau încărcare virală > 10.000 copii per ml.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J05AF07 TENOFOVIRUM COMPR. FILM. 245 mg

DISOPROXIL FUMARATE

VIREAD 245 mg 245 mg GILEAD SCIENCE

INTERNATIONAL LIMITED

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| **616** |**J05AF09**| **EMTRICITABINUM** | |

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Prescriere limitată: **Tratamentul infecţiei HIV la pacienţii cu: celule CD4 < 500 pe mm cub sau încărcare virală > 10.000 copii per ml.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J05AF09 EMTRICITABINUM CAPS. 200 mg

EMTRIVA 200 mg 200 mg GILEAD SCIENCE

INTERNATIONAL LIMITED

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| **617** |**J05AG01**| **NEVIRAPINUM** | |

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Prescriere limitată: **Tratamentul infecţiei HIV la pacienţii cu: celule CD4 < 500 pe mm cub sau încărcare virală > 10.000 copii per ml.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J05AG01 NEVIRAPINUM COMPR. 200 mg

VIRAMUNE 200 mg 200 mg BOEHRINGER INGELHEIM INT.

GMBH

J05AG01 NEVIRAPINUM SUSP. ORALA 50 mg/5 ml

VIRAMUNE 50 mg/ml 50 mg/5 ml BOEHRINGER INGELHEIM INT.

GMBH

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| **618** |**J05AG03**| **EFAVIRENZUM** | |

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Prescriere limitată: **Tratamentul infecţiei HIV la pacienţii cu: celule CD4 < 500 pe mm cub sau încărcare virală > 10.000 copii per ml.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J05AG03 EFAVIRENZUM CAPS. 100 mg

STOCRIN 100 mg 100 mg MERCK SHARP & DOHME LTD.

J05AG03 EFAVIRENZUM CAPS. 50 mg

STOCRIN 50 mg 50 mg MERCK SHARP & DOHME LTD.

J05AG03 EFAVIRENZUM COMPR. FILM. 50 mg

STOCRIN 50 mg 50 mg MERCK SHARP & DOHME LTD.

J05AG03 EFAVIRENZUM COMPR. FILM. 600 mg

STOCRIN 600 mg 600 mg MERCK SHARP & DOHME LTD.

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| **619** |**J05AR01**| **ZIDOVUDINUM + LAMIVUDINUM\*\*** | |

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Prescriere limitată: **Tratamentul infecţiei HIV la pacienţii cu: celule CD4 < 500 pe mm cub sau încărcare virală > 10.000 copii per ml.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J05AR01 ZIDOVUDINUM + COMPR. FILM. 150 mg/300 mg

LAMIVUDINUM

COMBIVIR 150 mg/300 mg 150 mg/300 mg GLAXO GROUP LTD.

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| **620** |**J05AR02**| **ABACAVIRUM + LAMIVUDINUM\*\*** | |

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Prescriere limitată: **Tratamentul infecţiei HIV la pacienţii în vârstă de peste 12 ani şi cu greutate corporală > de 40 kg cu celule CD4 < 500 pe mm cub sau încărcare virală > 10.000 copii per ml.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J05AR02 ABACAVIRUM + COMPR. FILM. 600 mg/300 mg

LAMIVUDINUM

KIVEXA 600 mg/300 mg 600 mg/300 mg GLAXO GROUP LTD.

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| **621** |**J05AR04**| **ABACAVIRUM + LAMIVUDINUM + ZIDOVUDINUM\*\*** | |

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Prescriere limitată: **Tratamentul infecţiei HIV la pacienţii în vârstă de peste 12 ani şi cu greutate corporală > de 40 kg cu: celule CD4 < 500 pe mm cub sau încărcare virală > 10.000 copii per ml.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J05AR04 ABACAVIRUM + COMPR. FILM. 300 mg/150 mg/300 mg

LAMIVUDINUM +

ZIDOVUDINUM

TRIZIVIR 300 mg/150 mg/300 mg 300 mg/150 mg/300 mg GLAXO GROUP LTD.

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| **622** |**J05AX07**| **ENFUVIRTIDUM\*\*** | |

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Prescriere limitată: **Tratamentul combinat al infecţiei HIV la pacienţi experimentaţi cu eşec la tratament caracterizat prin: evidenţa replicării virale în timpul terapiei antiretrovirale continue sau intoleranţei la medicamentele ARV anterior administrate. Pacienţii au avut eşec terapeutic sau rezistenţă la 3 regimuri ARV diferite care au inclus: cel puţin 1 inhibitor de non-nucleozid revers trasncriptază şi cel puţin 1 inhibitor de nucleozid revers trasncriptază şi cel puţin 2 inhibitori de protează.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J05AX07 ENFUVIRTIDUM PULB. + SOLV. PT. 90 mg/ml

SOL. INJ.

FUZEON 90 mg/ml 90 mg/ml ROCHE REGISTRATION LTD.

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| **623** |**A07AA11**| **RIFAXIMINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A07AA11 RIFAXIMINUM COMPR. FILM. 200 mg

NORMIX 200 mg 200 mg ALFA WASSERMANN SPA

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| **624** |**D01AC02**| **MICONAZOLUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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D01AC02 MICONAZOLUM CREMA 20 mg/g

MICONAL ECOBI 20 mg/g FARMACEUTICI ECOBI S.A.S.

D01AC02 MICONAZOLUM CREMA 2%

MEDACTER 2% FARAN LABORATORIES S.A.

MICONAZOL NITRAT 2% 2% SLAVIA PHARM SRL

D01AC02 MICONAZOLUM GEL 2%

DERMOZOL 2% PHARCOIMPEX 93 S.R.L.

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| **625** |**D06BB03**| **ACICLOVIRUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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D06BB03 ACICLOVIRUM CREMA 50 mg/g

ACICLOVIR HYPERION 50 mg/g HYPERION S.A.

ACIKLOVIR CREMA 50 mg/g A & G MED TRADING S.R.L.

D06BB03 ACICLOVIRUM CREMA 5%

ACICLOVIR 5% OZONE LABORATORIES LTD.

ACICLOVIR 5% 5% GEDEON RICHTER ROMANIA SA

CLOVIRAL(R) 5% 5% ANTIBIOTICE SA

ZOVIRAX 5% THE WELLCOME FOUNDATION

LTD.

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| **626** |**G01AF04**| **MICONAZOLUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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G01AF04 MICONAZOLUM CAPS. MOI VAG. 1.2 g

MICONAL ECOBI 1.2 g FARMACEUTICI ECOBI S.A.S.

G01AF04 MICONAZOLUM SUPOZ. VAG. 200 mg

MYCOHEAL 200 200 mg DAR AL DAWA PHARMA S.R.L.

G01AF04 MICONAZOLUM CREMA VAG. 20 mg/g

MICONAL ECOBI 20 mg/g FARMACEUTICI ECOBI S.A.S.

G01AF04 MICONAZOLUM SOL. VAGINALA 2 mg/ml

MICONAL ECOBI 2 mg/ml FARMACEUTICI ECOBI S.A.S.

G01AF04 MICONAZOLUM OVULE 50 mg

MICONAL ECOBI 50 mg FARMACEUTICI ECOBI S.A.S.

G01AF04 MICONAZOLUM CREMA VAG. 2%

MEDACTER 2% FARAN LABORATORIES S.A.

MYCOHEAL 2% DAR AL DAWA PHARMA S.R.L.

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| **627** |**J01CF04**| **OXACILLINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01CF04 OXACILLINUM CAPS. 250 mg

OXACILINA 250 mg FARMACOM SA

OXACILINA 250 mg 250 mg ANTIBIOTICE SA

OXACILINA ARENA 250 mg 250 mg ARENA GROUP SA

OXACILINA FARMEX 250 mg 250 mg FARMEX COMPANY SRL

OXACILINA SANDOZ 250 mg 250 mg SANDOZ SRL

J01CF04 OXACILLINUM CAPS. 500 mg

OXACILINA 500 mg 500 mg ANTIBIOTICE SA

OXACILINA ARENA 500 mg 500 mg ARENA GROUP SA

OXACILINA FORTE 500 mg 500 mg OZONE LABORATORIES LTD.

OXACILINA SANDOZ 500 mg 500 mg SANDOZ SRL

OXALIN 500 mg 500 mg EUROPHARM SA

J01CF04 OXACILLINUM PULB. PT. SOL. INJ./ 500 mg

PERF. I.M./I.V.

OXACILINA ANTIBIOTICE 500 mg 500 mg ANTIBIOTICE SA

J01CF04 OXACILLINUM PULB. PT. SOL. INJ./

PERF. I.M./I.V. 1 g

OXACILINA ANTIBIOTICE 1 g 1 g ANTIBIOTICE SA

J01CF04 OXACILLINUM PULB. PT. SOL. INJ./ 250 mg

PERF. I.M./I.V.

OXACILINA ANTIBIOTICE 250 mg 250 mg ANTIBIOTICE SA

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| **628** |**J01CR01**| **AMPICILLINUM + SULBACTAM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01CR01 AMPICILLINUM + PULB. PT. SOL. INJ. 1 g + 500 mg

SULBACTAM

AMPIPLUS(R) 1.5 g 1 g + 500 mg ANTIBIOTICE SA

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| **629** |**J01CR02**| **AMOXICILLINUM + ACIDUM CLAVULANICUM** | |

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Prescriere limitată: **Tratamentul de scurtă durată la infecţiile bacteriene atunci când este suspectată rezistenţa la amoxicilină. Infecţii la care este dovedită rezistenţa la amoxicilină.**

A fost raportată hepatotoxicitate la acest medicament.

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01CR02 AMOXICILLINUM + PULB. PT. SOL. 1.2 g

ACIDUM CLAVULANICUM INJ./PERF.

AMOXIPLUS 1.2g 1.2 g ANTIBIOTICE SA

J01CR02 AMOXICILLINUM + COMPR. FILM. 1000 mg

ACIDUM CLAVULANICUM

MEDOCLAV 1000 mg 1000 mg MEDOCHEMIE LTD.

J01CR02 AMOXICILLINUM + PULB. PT. SOL. 1000 mg + 200 mg

ACIDUM CLAVULANICUM INJ./PERF.

AUGMENTIN INTRAVENOS 1.2 g 1000 mg + 200 mg BEECHAM GROUP PLC

J01CR02 AMOXICILLINUM + COMPR. FILM. ELIB. 1062.5 mg

ACIDUM CLAVULANICUM PREL.

AUGMENTIN(TM) SR 1062.5 mg BEECHAM GROUP PLC

J01CR02 AMOXICILLINUM + PULB. PT. SUSP. ORALA 125 mg + 31.25/5 m

ACIDUM CLAVULANICUM

MEDOCLAV 156.25 mg/5 ml 125 mg + 31.25/5 ml MEDOCHEMIE LTD.

J01CR02 AMOXICILLINUM + PULB. PT. SUSP. ORALA 156.25 mg/5 ml

ACIDUM CLAVULANICUM

AMOKSIKLAV 156.25 mg/5 ml 156.25 mg/5 ml LEK PHARMACEUTICALS D.D.

BIOCLAVID 156.25 mg/5 ml 156.25 mg/5 ml SANDOZ GMBH

J01CR02 AMOXICILLINUM + PULB. PT. SOL. PERF. 2000 mg + 200 mg

ACIDUM CLAVULANICUM

AUGMENTIN INTRAVENOS 2.2 g 2000 mg + 200 mg BEECHAM GROUP PLC

J01CR02 AMOXICILLINUM + COMPR. DISP. 250/62,5 mg

ACIDUM CLAVULANICUM

FORCID SOLUTAB 250/62,5 250/62,5 mg ASTELLAS PHARMA EUROPE BV

J01CR02 AMOXICILLINUM + COMPR. FILM. 250 mg + 125 mg

ACIDUM CLAVULANICUM

MEDOCLAV 375 mg 250 mg + 125 mg MEDOCHEMIE LTD.

J01CR02 AMOXICILLINUM + PULB. PT. SUSP. ORALA 250 mg + 62.5 mg/

ACIDUM CLAVULANICUM 5 ml

MEDOCLAV FORTE 312,5 mg/5 ml 250 mg + 62.5 mg/5 ml MEDOCHEMIE LTD.

J01CR02 AMOXICILLINUM + PULB. PT. SUSP. ORALA 312.5 mg/5 ml

ACIDUM CLAVULANICUM

BIOCLAVID 312.5 mg/5 ml 312.5 mg/5 ml SANDOZ GMBH

J01CR02 AMOXICILLINUM + PULB. PT. SUSP. ORALA 312.5 mg/5 ml

ACIDUM CLAVULANICUM

AMOKSIKLAV 312.5 mg/5 ml 312.5 mg/5 ml LEK PHARMACEUTICALS D.D.

ENHANCIN 312.5 mg/5 ml 312.5 mg/5 ml RANBAXY UK LIMITED

J01CR02 AMOXICILLINUM + PULB. PT. SUSP. ORALA 400 mg + 57 mg/5 ml

ACIDUM CLAVULANICUM

AUGMENTIN BIS 400 mg + 57 mg/5 ml SMITHKLINE BEECHAM PLC

J01CR02 AMOXICILLINUM + COMPR. DISP. 500/125 mg

ACIDUM CLAVULANICUM

FORCID SOLUTAB 500/125 500/125 mg ASTELLAS PHARMA EUROPE BV

J01CR02 AMOXICILLINUM + COMPR. FILM. 500 mg + 125 mg

ACIDUM CLAVULANICUM

AUGMENTIN 625 mg 500 mg + 125 mg BEECHAM GROUP PLC

MEDOCLAV 625 mg 500 mg + 125 mg MEDOCHEMIE LTD.

J01CR02 AMOXICILLINUM + PULB. PT. SOL. INJ./ 600 mg

ACIDUM CLAVULANICUM PERF.

AMOXIPLUS 600 mg 600 mg ANTIBIOTICE SA

J01CR02 AMOXICILLINUM + COMPR. FILM. 625 mg

ACIDUM CLAVULANICUM

AMOKSIKLAV 2 x 625 mg 625 mg LEK PHARMACEUTICALS D.D.

BIOCLAVID 625 mg 625 mg SANDOZ GMBH

ENHANCIN 625 mg 625 mg RANBAXY UK LIMITED

J01CR02 AMOXICILLINUM + PULB. PT. SUSP. ORALA 642.90 mg/5 ml

ACIDUM CLAVULANICUM

AUGMENTIN(R) ES 642.90 mg/5 ml SMITHKLINE BEECHAM PLC

J01CR02 AMOXICILLINUM + COMPR. DISP. 875 mg + 125 mg

ACIDUM CLAVULANICUM

FORCID SOLUTAB 875/125 875 mg + 125 mg ASTELLAS PHARMA EUROPE BV

J01CR02 AMOXICILLINUM + COMPR. FILM. 875 mg + 125 mg

ACIDUM CLAVULANICUM

AUGMENTIN 1g 875 mg + 125 mg BEECHAM GROUP PLC

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| **630** |**J01CR05**| **PIPERACILLINUM + TAZOBACTAMUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01CR05 PIPERACILLINUM + LIOF. PT. SOL. INJ.

TAZOBACTAMUM

TAZOCIN 2,25 WYETH LEDERLE PHARMA GMBH

TAZOCIN 4,5 WYETH LEDERLE PHARMA GMBH

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| **631** |**J01CR50**| **COMBINATII (CEFOPERAZONUM + SULBACTAM)** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01CR50 COMBINATII PULB. PT. SOL. INJ. 1 g + 1 g

(CEFOPERAZONUM +

SULBACTAM)

SULPERAZON(R) 2 g 1 g + 1 g PFIZER EUROPE MA EEIG

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| **632** |**J01DD04**| **CEFTRIAXONUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01DD04 CEFTRIAXONUM PULB. PT. SOL. INJ. 0.5 g

NOVOSEF 0.5 g i.v. 0.5 g ECZACIBASI PHARMACEUTICALS

S.R.L.

J01DD04 CEFTRIAXONUM PULB. PT. SOL. INJ. 1 g

LENDACIN 1 g 1 g LEK PHARMACEUTICALS D.D.

NOVOSEF 1 g i.m. 1 g ECZACIBASI PHARMACEUTICALS

S.R.L.

NOVOSEF 1 g i.v. 1 g ECZACIBASI PHARMACEUTICALS

S.R.L.

J01DD04 CEFTRIAXONUM PULB. PT. SOL. INJ./ 1 g

PERF.

CEFORT 1 g 1 g ANTIBIOTICE SA

CEFTRIAXON 1 g 1 g OZONE LABORATORIES LTD.

J01DD04 CEFTRIAXONUM PULB. PT. SOL. INJ. 250 mg

LENDACIN 250 mg 250 mg LEK PHARMACEUTICALS D.D.

J01DD04 CEFTRIAXONUM PULB. PT. SOL. INJ./ 250 mg

PERF.

CEFORT 250 mg 250 mg ANTIBIOTICE SA

J01DD04 CEFTRIAXONUM PULB. PT. SOL. INJ./ 2 g

PERF.

CEFORT 2 g 2 g ANTIBIOTICE SA

MEDAXONE 2 g 2 g MEDOCHEMIE LTD.

J01DD04 CEFTRIAXONUM PULB. PT. SOL. PERF. 2 g

ROCEPHIN(R) 2 g ROCHE ROMANIA S.R.L.

J01DD04 CEFTRIAXONUM PULB. PT. SOL. INJ./ 500 mg

PERF.

CEFORT 500 mg 500 mg ANTIBIOTICE SA

J01DD04 CEFTRIAXONUM PULB. PT. SOL. INJ. 0.5 g

NOVOSEF 0.5 g i.v. 0.5 g ECZACIBASI PHARMACEUTICALS

S.R.L.

J01DD04 CEFTRIAXONUM PULB. PT. SOL. INJ./ 500 mg

PERF.

CEFORT 500 mg 500 mg ANTIBIOTICE SA

J01DD04 CEFTRIAXONUM PULB. + SOLV. PT. SOL. 0.5 g

INJ./PERF.

NOVOSEF 0.5 g i.m. 0.5 g ECZACIBASI PHARMACEUTICALS

S.R.L.

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| **633** |**J01DD08**| **CEFIXIMUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01DD08 CEFIXIMUM GRAN. PT. SUSP. ORALA 100 mg/5 ml

SUPRAX 100 mg/5 ml GEDEON RICHTER LTD.

J01DD08 CEFIXIMUM CAPS. 200 mg

EFICEF(R) 200 mg 200 mg ANTIBIOTICE SA

J01DD08 CEFIXIMUM COMPR. FILM. 200 mg

SUPRAX 200 mg GEDEON RICHTER LTD.

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| **634** |**J01DD12**| **CEFOPERAZONUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01DD12 CEFOPERAZONUM PULB. PT. SOL. INJ. 1 g

LYZONE 1 g 1 g MEDICAROM GROUP S.R.L.

MEDOCEF 1 g 1 g MEDOCHEMIE LTD.

J01DD12 CEFOPERAZONUM PULB. PT. SOL. INJ. 2 g

LYZONE 2g 2g MEDICAROM GROUP S.R.L.

MEDOCEF 2g 2g MEDOCHEMIE LTD.

J01DD12 CEFOPERAZONUM PULB. PT. SOL. INJ. 500 mg

CEFOZON 500 mg 500 mg E.I.P.I.CO. MED S.R.L.

J01DD12 CEFOPERAZONUM PULB. PT. SOL. INJ./ 1 g

PERF. I.M./I.V.

CEFOZON 1 g 1 g E.I.P.I.CO. MED S.R.L.

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| **635** |**J01DE02**| **CEFPIROMUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01DE02 CEFPIROMUM PULB. PT. SOL. INJ./ 1 g

PERF.

CEFROM(R) 1 g 1 g LAB. AVENTIS

J01DE02 CEFPIROMUM PULB. PT. SOL. INJ./ 2 g

PERF.

CEFROM(R) 2 g 2 g LAB. AVENTIS

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| **636** |**J01DH02**| **MEROPENEMUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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J01DH02 MEROPENEMUM PULB. PT. SOL. INJ. 1 g

I.V./PERF.

MERONEM IV 1 g 1 g ASTRAZENECA UK LTD.

J01DH02 MEROPENEMUM PULB. PT. SOL. INJ. 500 mg

I.V./PERF.

MERONEM IV 500 mg 500 mg ASTRAZENECA UK LTD.

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| **637** |**J01DH51**| **IMIPENEMUM + CILASTATINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01DH51 IMIPENEMUM + PULB. PT. SOL. PERF.

CILASTATINUM

TIENAM I.V. MERCK SHARP & DOHME

ROMANIA S.R.L.

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| **638** |**J01EE01**| **SULFAMETHOXAZOLUM + TRIMETHOPRIMUM** | |

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Există un risc crescut de reacţie adversă severă la administrarea acestui medicament la persoane în vârstă.

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01EE01 SULFAMETHOXAZOLUM + SUSP. ORALA 200 mg/40 mg/5 ml

TRIMETHOPRIMUM

EPITRIM 200 mg/40 mg/5 ml E.I.P.I.CO. MED S.R.L.

J01EE01 SULFAMETHOXAZOLUM + SIROP 25 mg/5 mg/ml

TRIMETHOPRIMUM

SUMETROLIM 25 mg/5 mg/ml EGIS PHARMACEUTICALS

P.L.C.

J01EE01 SULFAMETHOXAZOLUM + COMPR. 400 mg/80 mg

TRIMETHOPRIMUM

BISEPTRIM 400 mg/80 mg EUROPHARM SA

CO - TRIM ELL 400 mg/80 mg ARENA GROUP S.A.

SUMETROLIM 400 mg/80 mg EGIS PHARMACEUTICALS

P.L.C.

TAGREMIN 400 mg/80 mg ZENTIVA S.A.

J01EE01 SULFAMETHOXAZOLUM + SOL. PERF. 400 mg/80 mg

TRIMETHOPRIMUM

SEPTRIN 400 mg/80 mg THE WELLCOME FOUNDATION

LTD.

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| **639** |**J01FA02**| **SPIRAMYCINUM** | |

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J01FA02 SPIRAMYCINUM COMPR. FILM. 1.5 M ui

ROVAMYCINE(R) 1.5 Mil. UI 1.5 M ui LAB. AVENTIS

J01FA02 SPIRAMYCINUM COMPR. FILM. 3 M ui

ROVAMYCINE(R) 3 Mil. UI 3 M ui LAB. AVENTIS

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| **640** |**J01FA06**| **ROXITHROMYCINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01FA06 ROXITHROMYCINUM COMPR. FILM. 150 mg

ROKSOLIT 150 mg ECZACIBASI ILAC SANAYI

VE TICARET AS

ROXAMED(R) 150 150 mg DAR AL DAWA PHARMA S.R.L.

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| **641** |**J01FA09**| **CLARITHROMYCINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01FA09 CLARITHROMYCINUM GRAN. PT. SUSP. ORALA 125 mg/5 ml

FROMILID(R) 125 mg/5 ml 125 mg/5 ml KRKA D.D.

KLABAX 125 mg/5 ml 125 mg/5 ml TERAPIA S.A.

KLACID(R) 125 mg/5 ml ABBOTT SPA

LEKOKLAR 125 mg/5 ml 125 mg/5 ml SANDOZ S.R.L.

J01FA09 CLARITHROMYCINUM COMPR. FILM. 250 mg

CLAR 250 250 mg MEDICAROM GROUP S.R.L.

CLARITROMICINA 250 mg 250 mg OZONE LABORATORIES LTD.

FROMILID 250 250 mg KRKA D.D. NOVO MESTO

KLABAX 250 mg 250 mg TERAPIA S.A.

KLACID(R) 250 mg ABBOTT SPA

KLERIMED(R) 250 250 mg MEDOCHEMIE LTD.

LEKOKLAR(R) 250 mg 250 mg LEK PHARMACEUTICALS D.D.

J01FA09 CLARITHROMYCINUM GRAN. PT. SUSP. ORALA 250 mg/5 ml

KLABAX 250 mg/5 ml 250 mg/5 ml TERAPIA S.A.

LEKOKLAR 250 mg/5 ml 250 mg/5 ml SANDOZ SRL

J01FA09 CLARITHROMYCINUM COMPR. FILM. 500 mg

CLAR 500 500 mg MEDICAROM GROUP S.R.L.

CLARITROMICINA 500 mg 500 mg OZONE LABORATORIES LTD.

FROMILID 500 500 mg KRKA D.D. NOVO MESTO

KLABAX 500 mg 500 mg TERAPIA S.A.

KLERIMED(R) 500 500 mg MEDOCHEMIE LTD.

LEKOKLAR(R) 500 mg 500 mg LEK PHARMACEUTICALS D.D.

J01FA09 CLARITHROMYCINUM COMPR. FILM. ELIB. 500 mg

MODIF.

KLABAX MR 500 mg 500 mg TERAPIA S.A.

LEKOKLAR XL 500 mg 500 mg LEK PHARMACEUTICALS D.D.

J01FA09 CLARITHROMYCINUM COMPR. FILM. ELIB. 500 mg

PREL.

FROMILID(R) UNO 500 mg KRKA D.D.

KLACID SR 500 mg ABBOTT LABORATORIES LTD.

J01FA09 CLARITHROMYCINUM LIOF. PT. SOL. PERF. 500 mg

KLACID I.V. 500 mg ABBOTT LABORATORIES LTD.

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| **642** |**J01FA10**| **AZITHROMYCINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01FA10 AZITHROMYCINUM PULB. PT. SUSP. ORALA 100 mg/5 ml

AZITROMICINA SANDOZ 100 mg/5 ml SANDOZ SRL

100 mg/5 ml

J01FA10 AZITHROMYCINUM COMPR. FILM. 125 mg

SUMAMED 125 mg 125 mg PLIVA LJUBLIJANA D.O.O.

J01FA10 AZITHROMYCINUM PULB. PT. SUSP. ORALA 200 mg/5 ml

AZITROMICINA SANDOZ 200 mg/5 ml SANDOZ SRL

200 mg/5 ml

J01FA10 AZITHROMYCINUM PULB. + SOLV. SUSP. 200 mg/5 ml

ORALA

AZITROX 200 mg/5 ml 200 mg/5 ml ECZACIBASI PHARMACEUTICALS

S.R.L.

J01FA10 AZITHROMYCINUM PULB. PT. SUSP. ORALA 200 mg/5 ml

SUMAMED FORTE 200 mg/5 ml PLIVA LJUBLIJANA D.O.O.

J01FA10 AZITHROMYCINUM CAPS. 250 mg

AZATRIL 250 mg 250 mg BALKANPHARMA RAZGRAD AD

J01FA10 AZITHROMYCINUM COMPR. FILM. 250 mg

AZITROMICINA SANDOZ 250 mg 250 mg SANDOZ S.R.L.

COMPRIMATE FILMATE

AZITROX(R) 250 250 mg ZENTIVA AS

J01FA10 AZITHROMYCINUM COMPR. FILM. 500 mg

AZITROMICINA SANDOZ 500 mg 500 mg SANDOZ S.R.L.

COMPRIMATE FILMATE

AZITROX(R) 500 500 mg ZENTIVA AS

AZRO(R) 500 mg 500 mg ECZACIBASI PHARMACEUTICALS

S.R.L.

SUMAMED 500 mg 500 mg PLIVA LJUBLJANA D.O.O.

ZITROCIN 500 mg 500 mg OZONE LABORATORIES LTD.

J01FA10 AZITHROMYCINUM LIOF. PT. SOL. PERF. 500 mg

SUMAMED(R) 500 mg PLIVA LJUBLJANA D.O.O.

J01FA10 AZITHROMYCINUM GRAN. ELIB. PREL. PT. 2 g

SUSP. ORALA

ZMAX 2 g 2 g PFIZER EUROPE MA EEIG

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| **643** |**J01GB03**| **GENTAMICINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01GB03 GENTAMICINUM SOL. INJ. 40 mg/ml

GENTAMICIN KRKA 40 mg/ml KRKA D.D. NOVO MESTO

GENTAMICINA SANDOZ(R) 40 mg/ml SANDOZ GMBH

40 mg/ml

J01GB03 GENTAMICINUM SOL. INJ. 40 mg/ml

GENTAMICIN KRKA 40 mg/ml KRKA D.D. NOVO MESTO

GENTAMICINA SANDOZ(R) 40 mg/ml SANDOZ GMBH

40 mg/ml

J01GB03 GENTAMICINUM SOL. PARENT. 40 mg/ml

LYRAMYCIN 40 mg/ml MEDICAROM GROUP S.R.L.

J01GB03 GENTAMICINUM SOL. INJ. 80 mg/2 ml

GENTAMICIN KRKA 80 mg/2 ml KRKA D.D. NOVO MESTO

J01GB03 GENTAMICINUM SOL. INJ. 80 mg/2 ml

PAN-GENTAMICINE 80 mg/2 ml LAB. PANPHARMA

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| **644** |**J01GB06**| **AMIKACINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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J01GB06 AMIKACINUM SOL. INJ. 100 mg/2 ml

AMIKOZIT(R) 100 mg/2 ml 100 mg/2 ml ECZACIBASI PHARMACEUTICALS

S.R.L.

J01GB06 AMIKACINUM SOL. INJ. 250 mg/ml

AMIKIN 250 mg/ml BRISTOL MYERS SQUIBB KFT

J01GB06 AMIKACINUM SOL. INJ. 500 mg/2 ml

AMIKOZIT(R) 500 mg/2 ml 500 mg/2 ml ECZACIBASI PHARMACEUTICALS

S.R.L.

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| **645** |**J01GB07**| **NETILMICINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01GB07 NETILMICINUM SOL. INJ. 150 mg/1.5 ml

NETROMYCINE(R) 150 mg/1.5 ml SCHERING PLOUGH EUROPE

J01GB07 NETILMICINUM SOL. INJ. 200 mg/2 ml

NETROMYCINE(R) 200 mg/2 ml SCHERING PLOUGH EUROPE

J01GB07 NETILMICINUM SOL. INJ. 50 mg/2 ml

NETROMYCINE(R) 50 mg/2 ml SCHERING PLOUGH EUROPE

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| **646** |**J01MA01**| **OFLOXACINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01MA01 OFLOXACINUM COMPR. FILM. 200 mg

OFLOXACIN 200 mg 200 mg ANTIBIOTICE SA

OFLOXIN 200 200 mg ZENTIVA AS

ZANOCIN 200 mg RANBAXY UK LIMITED

J01MA01 OFLOXACINUM COMPR. FILM. ELIB. 400 mg

PREL.

ZANOCIN(R) OD 400 400 mg RANBAXY U.K. LIMITED

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| **647** |**J01MA02**| **CIPROFLOXACINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01MA02 CIPROFLOXACINUM CONC. PT. SOL. PERF. 100 mg/10 ml

CIPRINOL(R) 100 mg/10 ml KRKA D.D.

CIPROFLOXACINA 100 mg/10 ml 100 mg/10 ml SICOMED SA

J01MA02 CIPROFLOXACINUM SOL. PERF. 100 mg/50 ml

CIPRINOL 100 mg/50 ml KRKA D.D. NOVO MESTO

J01MA02 CIPROFLOXACINUM SOL. PERF. 200 mg/100 ml

CIPRINOL 200 mg/100 ml KRKA D.D. NOVO MESTO

CIPROBAY(R) 200 200 mg/100 ml BAYER HEALTHCARE AG

J01MA02 CIPROFLOXACINUM CAPS. 250 mg

EUCIPRIN 250 mg EUROPHARM SA

J01MA02 CIPROFLOXACINUM COMPR. FILM. 250 mg

CIFRAN 250 mg RANBAXY UK LIMITED

CIPHIN 250 250 mg ZENTIVA A.S.

CIPRINOL 250 mg 250 mg KRKA D.D. NOVO MESTO

CIPROCIN 250 mg 250 mg E.I.P.I.CO. MED S.R.L.

CIPROFLOXACIN 250 mg 250 mg LAROPHARM SRL

CIPROFLOXACINA ALKALOID 250 mg ALKALOID D.O.O.

250 mg

CIPROLEN(R) 250 mg 250 mg AC HELCOR SRL

CIPROLET 250 mg 250 mg DR. REDDY'S LABORATORIES

CIPROZONE 250 mg 250 mg OZONE LABORATORIES LTD.

CUMINOL 250 mg 250 mg GEDEON RICHTER ROMANIA

J01MA02 CIPROFLOXACINUM SOL. PERF. 2 mg/ml

CIPROBAY(R) 400 2 mg/ml BAYER HEALTHCARE AG

UFEXIL 2 mg/ml DEMO SA

J01MA02 CIPROFLOXACINUM SOL. PERF. 400 mg/200 ml

CIPRINOL(R) 400 mg/200 ml KRKA D.D.

J01MA02 CIPROFLOXACINUM COMPR. FILM. 500 mg

CIFRAN 500 mg RANBAXY UK LIMITED

CIPHIN 500 500 mg ZENTIVA A.S.

CIPRINOL 500 mg 500 mg KRKA D.D. NOVO MESTO

CIPRO QUIN(R) 500 mg ANTIBIOTICE SA

CIPROBAY(R) 500 500 mg BAYER HEALTHCARE AG

CIPROCIN 500 mg 500 mg E.I.P.I.CO. MED S.R.L.

CIPRODAR 500 mg DAR AL DAWA PHARMA S.R.L.

CIPROFLOXACINA ALKALOID 500 mg ALKALOID D.O.O.

500 mg

CIPROLEN(R) 500 mg 500 mg AC HELCOR SRL

CIPROLET 500 mg 500 mg DR. REDDY'S LABORATORIES

CIPROZONE FORTE 500 mg 500 mg OZONE LABORATORIES LTD.

CUMINOL 500 mg 500 mg GEDEON RICHTER ROMANIA

SIFLOKS(R) 500 mg ECZACIBASI ILAC SANAYI VE

TICARET AS

J01MA02 CIPROFLOXACINUM COMPR. FILM. 750 mg

CIPRINOL 750 mg 750 mg KRKA D.D. NOVO MESTO

J01MA02 CIPROFLOXACINUM COMPR. FILM. 250 mg

CIFRAN 250 mg RANBAXY UK LIMITED

CIPHIN 250 250 mg ZENTIVA A.S.

CIPRINOL 250 mg 250 mg KRKA D.D. NOVO MESTO

CIPROCIN 250 mg 250 mg E.I.P.I.CO. MED S.R.L.

CIPROFLOXACIN 250 mg 250 mg LAROPHARM SRL

CIPROFLOXACINA ALKALOID 250 mg ALKALOID D.O.O.

250 mg

CIPROLEN(R) 250 mg 250 mg AC HELCOR SRL

CIPROLET 250 mg 250 mg DR. REDDY'S LABORATORIES

CIPROZONE 250 mg 250 mg OZONE LABORATORIES LTD.

CUMINOL 250 mg 250 mg GEDEON RICHTER ROMANIA

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| **648** |**J01MA03**| **PEFLOXACINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01MA03 PEFLOXACINUM COMPR. FILM. 400 mg

ABAKTAL 400 mg LEK PHARMACEUTICALS D.D.

PEFLOXACIN LAROPHARM 400 mg LAROPHARM S.R.L.

J01MA03 PEFLOXACINUM CONC. PT. SOL. PERF. 400 mg/5 ml

ABAKTAL 400 mg/5 ml 400 mg/5 ml LEK PHARMACEUTICALS D.D.

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| **649** |**J01MA06**| **NORFLOXACINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01MA06 NORFLOXACINUM COMPR. FILM. 400 mg

EPINOR 400 mg E.I.P.I.CO. MED S.R.L.

H-NORFLOXACIN 400 mg 400 mg AC HELCOR SRL

NOLICIN 400 mg 400 mg KRKA D.D. NOVO MESTO

NORFLOX-400 400 mg LEK PHARMATECH SRL

NORFLOXACIN 400 mg 400 mg OZONE LABORATORIES LTD.

NORFLOXACIN OZONE 400 mg 400 mg OZONE LABORATORIES LTD.

NORFLOXACINA LPH 400 mg 400 mg LABORMED PHARMA SA

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| **650** |**J01MA12**| **LEVOFLOXACINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01MA12 LEVOFLOXACINUM COMPR. FILM. 250 mg

LEVOFLOXACINA ACTAVIS 250 mg 250 mg ACTAVIS GROUP PTC EHF.

J01MA12 LEVOFLOXACINUM COMPR. FILM. 500 mg

LEVOFLOXACINA ACTAVIS 500 mg 500 mg ACTAVIS GROUP PTC EHF.

TAVANIC(R) 500 mg AVENTIS PHARMA DEUTSCHLAND

GMBH

J01MA12 LEVOFLOXACINUM SOL. PERF. 5 mg/ml

TAVANIC(R) I.V. 500 mg 5 mg/ml AVENTIS PHARMA DEUTSCHLAND

GMBH

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| **651** |**J01MA14**| **MOXIFLOXACINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01MA14 MOXIFLOXACINUM COMPR. FILM. 400 mg

AVELOX(R) 400 mg 400 mg BAYER HEALTHCARE AG

J01MA14 MOXIFLOXACINUM SOL. PERF. 400 mg/250 ml

AVELOX(R) 400 mg/250 ml 400 mg/250 ml BAYER HEALTHCARE AG

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| **652** |**J01XA01**| **VANCOMYCINUM** | |

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Prescriere limitată: **Tratamentul este iniţiat în spital pentru infecţiile cu germeni sensibili la vancomicină.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01XA01 VANCOMYCINUM LIOF. PT. SOL. PERF. 1 g

VANCOMYCIN TEVA 1 g TEVA PHARM. WORKS PRIVATE

LTD. COMPANY

J01XA01 VANCOMYCINUM PULB. LIOF. PT. SOL. 1 g

PERF./INJ.

EDICIN 1 g LEK PHARMACEUTICALS D.D.

J01XA01 VANCOMYCINUM LIOF. PT. SOL. PERF. 500 mg

VANCOMYCIN TEVA 500 mg TEVA PHARM. WORKS PRIVATE

LTD. COMPANY

J01XA01 VANCOMYCINUM LIOF. PT. SOL. PERF. 1 g

VANCOMYCIN TEVA 1 g TEVA PHARM. WORKS PRIVATE

LTD. COMPANY

J01XA01 VANCOMYCINUM PULB. LIOF. PT. SOL. 1 g

PERF./INJ.

EDICIN 1 g LEK PHARMACEUTICALS D.D.

J01XA01 VANCOMYCINUM LIOF. PT. SOL. PERF. 500 mg

VANCOMYCIN TEVA 500 mg TEVA PHARM. WORKS PRIVATE

LTD. COMPANY

J01XA01 VANCOMYCINUM LIOF. PT. SOL. 500 mg

PERF./INJ.

EDICIN 500 mg LEK PHARMACEUTICALS D.D.

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| **653** |**J01XA02**| **TEICOPLANINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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J01XA02 TEICOPLANINUM LIOF. + SOLV. PT. SOL. 400 mg

INJ.

TARGOCID(R) 400 mg 400 mg AVENTIS PHARMA LTD.

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| **654** |**J01XB01**| **COLISTINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01XB01 COLISTINUM PULB. PT. SOL. PERF. 1000000 ui

COLISTINA ANTIBIOTICE 1000000 ui ANTIBIOTICE SA

1000000 UI

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| **655** |**J01XD01**| **METRONIDAZOLUM** | |

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Prescriere limitată: **Tratamentul infecţiilor cu anaerobi**

**Tratamentul infecţiilor cu protozoare sensibile la**

**metronidazol:**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01XD01 METRONIDAZOLUM COMPR. 250 mg

METRONIDAZOL 250 mg (J01XD01) 250 mg ARENA GROUP SA

J01XD01 METRONIDAZOLUM COMPR. FILM. 250 mg

FLAGYL 250 mg LABORATOIRE AVENTIS

J01XD01 METRONIDAZOLUM SOL. PERF. 5 g/l

METRONIDAZOL A 5 g/l 5 g/l INFOMED FLUIDS SRL

METRONIDAZOL B 5 g/l 5 g/l INFOMED FLUIDS SRL

J01XD01 METRONIDAZOLUM SOL. PERF. 5 mg/ml

METRONIDAZOL BRAUN 5 mg/ml 5 mg/ml B. BRAUN MELSUNGEN AG

J01XD01 METRONIDAZOLUM COMPR. 250 mg

METRONIDAZOL 250 mg (J01XD01) 250 mg ARENA GROUP SA

J01XD01 METRONIDAZOLUM COMPR. FILM. 250 mg

FLAGYL 250 mg LABORATOIRE AVENTIS

J01XD01 METRONIDAZOLUM SUSP. ORALA 4%

FLAGYL 4% (J01XD01) 4% LABORATOIRE AVENTIS

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| **656** |**J01XX08**| **LINEZOLIDUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01XX08 LINEZOLIDUM GRAN. PT. SUSP. ORALA 100 mg/5 ml

ZYVOXID(R) 100 mg/5 ml PFIZER EUROPE MA EEIG

J01XX08 LINEZOLIDUM SOL. PERF. 2 mg/ml

ZYVOXID(R) 2 mg/ml PFIZER EUROPE MA EEIG

J01XX08 LINEZOLIDUM COMPR. FILM. 600 mg

ZYVOXID(R) 600 mg PFIZER EUROPE MA EEIG

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| **657** |**J02AB02**| **KETOCONAZOLUM** | |

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Prescriere limitată: **Candidoza genitală simptomatică recurentă după**

**tratamentul local a cel puţin două episoade.**

**Tratamentul candidozelor muco-cutanate cronice şi**

**candidozelor orofaringiene care nu pot fi tratate cu**

**antifungice locale, la pacienţii care prezintă**

**rezistenţă sau intoleranţă la fluconazol şi**

**intraconazol.**

**Micoze sistemice la care alte forme de terapie**

**antifungică nu au avut efect.**

A fost raportată hepatotoxicitate la ketoconazol.

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J02AB02 KETOCONAZOLUM COMPR. 200 mg

KEFUNGIN 200 mg ANTIBIOTICE SA

KETOCONAZOL 200 mg 200 mg MAGISTRA C&C

KETOSTIN 200 mg 200 mg AC HELCOR SRL

NIZORAL 200 mg JANSSEN PHARMACEUTICA NV

NIZORAL 200 mg 200 mg TERAPIA SA

J02AB02 KETOCONAZOLUM COMPR. 200 mg

KEFUNGIN 200 mg ANTIBIOTICE SA

KETOCONAZOL 200 mg 200 mg SLAVIA PHARM SRL

KETOSTIN 200 mg 200 mg AC HELCOR SRL

NIZORAL 200 mg JANSSEN PHARMACEUTICA NV

NIZORAL 200 mg 200 mg TERAPIA SA

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| **658** |**J02AC01**| **FLUCONAZOLUM** | |

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Prescriere limitată: **Tratament de întreţinere la pacienţi cu meningită**

**criptococică şi imunosupresie.**

**Profilaxia secundară a candidozei orofaringiene la**

**pacienţi cu imunosupresie.**

**Tratamentul meningitei criptococice la pacienţii care**

**nu pot lua sau nu tolerează amfotericina.**

**Tratamentul candidozelor severe şi care pun în pericol**

**viaţa la pacienţi care nu tolerează amfotericina.**

**Tratamentul candidozei orofaringiene la pacienţi cu**

**imunosupresie.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J02AC01 FLUCONAZOLUM CAPS. 100 mg

DIFLAZON 100 mg 100 mg KRKA D.D.

FLUCONAZOLE TEVA 100 mg 100 mg TEVA PHARMACEUTICALS SRL

FLUCORIC 100 mg 100 mg TERAPIA S.A.

FLUCOVIM 100 100 mg VIM SPECTRUM SRL

FUNGOLON 100 mg 100 mg BALKANPHARMA RAZGRAD AD

J02AC01 FLUCONAZOLUM CAPS. 150 mg

DIFLAZON 150 mg 150 mg KRKA D.D.

DIFLUCAN 150 mg 150 mg PFIZER EUROPE MA EEIG

FLUCONAZOL 150 mg 150 mg OZONE LABORATORIES LTD.

FLUCONAZOL MEDICO UNO 150 mg 150 mg MEDICO UNO PHARMACEUTICAL

SRL

FLUCONAZOL MEDOCHEMIE 150 mg 150 mg MEDOCHEMIE ROMANIA SRL

FLUCONAZOL SANDOZ(R) 150 150 mg SANDOZ SRL

FLUCONAZOL TERAPIA 150 mg 150 mg TERAPIA SA

FLUCONAZOLE TEVA 150 mg 150 mg TEVA PHARMACEUTICALS SRL

FLUCORIC 150 mg 150 mg TERAPIA S.A.

FLUCOVIM 150 150 mg VIM SPECTRUM SRL

MYCOMAX 150 150 mg ZENTIVA AS

MYCOSYSTA(R) 150 mg 150 mg GEDEON RICHTER PLC.

J02AC01 FLUCONAZOLUM CAPS. 200 mg

DIFLAZON 200 mg 200 mg KRKA D.D.

FLUCONAZOLE TEVA 200 mg 200 mg TEVA PHARMACEUTICALS SRL

J02AC01 FLUCONAZOLUM SOL. PERF. 2 mg/ml

DIFLAZON(R) 2 mg/ml KRKA D.D.

DIFLUCAN(R) 2 mg/ml PFIZER EUROPE MA EEIG

MYCOMAX(R) INF 2 mg/ml ZENTIVA AS

J02AC01 FLUCONAZOLUM CAPS. 50 mg

DIFLAZON 50 mg 50 mg KRKA D.D.

DIFLUCAN 50 mg 50 mg PFIZER EUROPE MA EEIG

FLUCONAZOL 50 mg 50 mg ARENA GROUP SA

FLUCONAZOL MEDOCHEMIE 50 mg 50 mg MEDOCHEMIE ROMANIA SRL

FLUCONAZOL SANDOZ(R) 50 50 mg SANDOZ SRL

FLUCONAZOL TERAPIA 50 mg 50 mg TERAPIA S.A.

FLUCONAZOLE TEVA 50 mg 50 mg TEVA PHARMACEUTICALS SRL

FLUCORIC 50 mg 50 mg TERAPIA S.A.

FLUCOVIM 50 50 mg VIM SPECTRUM SRL

FUNGOLON 50 mg 50 mg BALKANPHARMA RAZGRAD AD

J02AC01 FLUCONAZOLUM PULB. PT. SUSP. ORALA 50 mg/5 ml

DIFLUCAN(R) 50 mg/5 ml 50 mg/5 ml PFIZER EUROPE MA EEIG

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| **659** |**J02AC02**| **ITRACONAZOLUM** | |

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Prescriere limitată: **Aspergiloza sistemică.**

**Histoplasmoza sistemică.**

**Tratament şi terapia de întreţinere la pacienţi cu SIDA**

**şi histoplasmoza pulmonară diseminată.**

**Tratament şi terapia de întreţinere la pacienţi cu SIDA**

**şi histoplasmoza pulmonară cronică;**

**Criptococoza sistemică inclusiv meningeală.**

**Cromoblastomicoză şi micetom.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J02AC02 ITRACONAZOLUM CAPS. 100 mg

ITRACONAZOL 100 mg 100 mg SLAVIA PHARM SRL

OMICRAL 100 mg 100 mg MEDICO UNO PHARMACEUTICAL

S.R.L.

ORUNGAL 100 mg JANSSEN PHARMACEUTICA NV

SPORIUN 100 mg 100 mg GEDEON RICHTER ROMANIA

S.A.

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| **660** |**J02AC03**| **VORICONAZOLUM\*\*** | **Protocol: J012B** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J02AC03 VORICONAZOLUM COMPR. FILM. 200 mg

VFEND 200 mg 200 mg PFIZER LTD.

J02AC03 VORICONAZOLUM PULB. PT. SOL. PERF. 200 mg

VFEND 200 mg 200 mg PFIZER LTD.

J02AC03 VORICONAZOLUM PULB. PT. SUSP. ORALA 40 mg/ml

VFEND 40 mg/ml 40 mg/ml PFIZER LTD.

J02AC03 VORICONAZOLUM COMPR. FILM. 50 mg

VFEND 50 mg 50 mg PFIZER LTD.

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| **661** |**J02AC04**| **POSACONAZOLUM\*\*** | |

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Prescriere limitată: **Aspergiloză invazivă la pacienţi cu boală rezistentă la**

**amfotericina B sau itraconazol sau la pacienţi care nu**

**tolerează aceste medicamente;**

**Fusarioză la pacienţii cu boală rezistentă la**

**amfotericina B sau la pacienţi care nu tolerează**

**amfotericina B;**

**Cromoblastomicoză şi micetom la pacienţii cu boală**

**rezistentă la itraconazol sau la pacienţi care nu**

**tolerează itraconazolul;**

**Coccidioidomicoză la pacienţi cu boală rezistentă la**

**amfotericina B, itraconazol sau fluconazol sau la**

**pacienţi care nu tolerează aceste medicamente.**

**Candidoză oro-faringiană: ca terapie de primă intenţie**

**la pacienţii cu forme severe sau la pacienţii cu**

**imunitate scăzută, la care este de aşteptat ca**

**răspunsul la tratamentul topic să fie scăzut.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J02AC04 POSACONAZOLUM SUSP. ORALA 40 mg/ml

NOXAFIL SP 40 mg/ml 40 mg/ml SP EUROPE

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| **662** |**J02AX04**| **CASPOFUNGINUM\*\*** | **Protocol: J010D** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J02AX04 CASPOFUNGINUM PULB. PT. CONC. PT. 50 mg

SOL. PERF.

CANCIDAS 50 mg 50 mg MERCK SHARP & DOHME LTD

J02AX04 CASPOFUNGINUM PULB. PT. CONC. PT. 70 mg

SOL. PERF.

CANCIDAS 70 mg 70 mg MERCK SHARP & DOHME LTD

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| **664** |**J04AB04**| **RIFABUTINUM** | |

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Prescriere limitată: **Tratamentul contra infecţiilor complexe cu**

**Mycobacterium avium la pacienţii HIV-pozitivi.**

**Profilaxia contra infecţiilor complexe cu Mycobacterium**

**avium la pacienţii HIV-pozitivi cu celule CD4 mai puţin**

**de 75 pe milimetru cub.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J04AB04 RIFABUTINUM CAPS. 150 mg

MYCOBUTIN 150 mg 150 mg PFIZER EUROPE MA EEIG

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| **665** |**J04AC01**| **ISONIAZIDUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J04AC01 ISONIAZIDUM COMPR. 100 mg

ISONIAZIDA 100 mg 100 mg ANTIBIOTICE SA

J04AC01 ISONIAZIDUM COMPR. 300 mg

ISONIAZIDA 300 mg ANTIBIOTICE SA

J04AC01 ISONIAZIDUM SOL. INJ. 500 mg/10 ml

IZONIAZIDA 500 mg 500 mg/10 ml TERAPIA SA

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| **666** |**J04AK01**| **PYRAZINAMIDUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J04AK01 PYRAZINAMIDUM COMPR. 500 mg

PIRAZINAMIDA ANTIBIOTICE 500 mg ANTIBIOTICE S.A.

500 mg

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| **667** |**J04AK02**| **ETHAMBUTOLUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J04AK02 ETHAMBUTOLUM COMPR. FILM. 250 mg

ETAMBUTOL 250 mg 250 mg ANTIBIOTICE SA

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| **668** |**J04AM02**| **COMBINATII (RIFAMPICINUM + IZONIAZIDUM)** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J04AM02 COMBINATII CAPS. 300 mg + 150 mg

(RIFAMPICINUM +

IZONIAZIDUM)

SINERDOL ISO 300 mg + 150 mg ANTIBIOTICE SA

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| **669** |**J05AB01**| **ACICLOVIRUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J05AB01 ACICLOVIRUM CAPS. 200 mg

ACICLOVIR 200 mg 200 mg ARENA GROUP SA

EUVIROX 200 mg 200 mg EUROPHARM SA

J05AB01 ACICLOVIRUM COMPR. 200 mg

ACICLOVIR 200 mg 200 mg TERAPIA SA

CLOVIRAL 200 mg 200 mg ANTIBIOTICE SA

ZOVIRAX 200 mg GLAXO WELLCOME FOUNDATION

LTD.

J05AB01 ACICLOVIRUM COMPR. DISP. 200 mg

ACICLOVIR 200 mg 200 mg OZONE LABORATORIES LTD.

LOVIR 200 mg 200 mg RANBAXY UK LIMITED

J05AB01 ACICLOVIRUM PULB. PT. SOL. 250 mg

INJ./PERF.

VIROLEX 250 mg KRKA D.D. NOVO MESTO

J05AB01 ACICLOVIRUM CAPS. 400 mg

ACICLOVIR 400 mg 400 mg ARENA GROUP S.A.

J05AB01 ACICLOVIRUM COMPR. 400 mg

ACICLOVIR 400 mg 400 mg EGIS PHARMACEUTICALS

P.L.C.

J05AB01 ACICLOVIRUM COMPR. FILM. 400 mg

ACIKLOVIR 400 mg A & G MED TRADING S.R.L.

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| **670** |**J05AB04**| **RIBAVIRINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J05AB04 RIBAVIRINUM CAPS. 200 mg

REBETOL 200 mg 200 mg SP EUROPE

J05AB04 RIBAVIRINUM COMPR. FILM. 200 mg

COPEGUS(R) 200 mg ROCHE ROMANIA SRL

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| **671** |**J05AB06**| **GANCICLOVIRUM** | |

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Prescriere limitată: **Infecţii severe cu citomegalovirus (CMV) la pacienţi imunocompromişi inclusiv cu localizare oculară.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J05AB06 GANCICLOVIRUM LIOF. PT. SOL. INJ. 500 mg

CYMEVENE 500 mg ROCHE ROMANIA S.R.L.

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| **672** |**J05AB11**| **VALACYCLOVIRUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J05AB11 VALACYCLOVIRUM COMPR. FILM. 500 mg

VALTREX 500 mg 500 mg THE WELLCOME FOUNDATION

LTD.

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| **673** |**J05AB14**| **VALGANCICLOVIRUM\*\*** | |

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Prescriere limitată: **Tratamentul de iniţiere şi menţinere pentru retinita cu citomegalovirus (CMV) la pacienţi imunocompromişi.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J05AB14 VALGANCICLOVIRUM COMPR. FILM. 450 mg

VALCYTE(R) 450 mg 450 mg ROCHE ROMANIA SRL

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| **674** |**J05ABN1**| **BRIVUDINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J05ABN1 BRIVUDINUM COMPR. 125 mg

BRIVAL(R) 125 mg BERLIN CHEME AG MENARINI

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| **676** |**J06BB16**| **PALIVIZUMABUM\*\*** | |

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Prescriere limitată: **Prevenirea bolilor severe ale tractului respirator inferior care necesită spitalizare, provocate de virusul sinciţial respirator (VSR) la copii născuţi la 35 săptămâni de gestaţie sau mai puţin şi cu vârsta mai mică de 6 luni la începutul sezonului de îmbolnăviri cu VSR sau la copii cu vârsta mai mică de 2 ani care au necesitat tratament pentru displazie bronhopulmonară în ultimele 6 luni.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J06BB16 PALIVIZUMABUM PULB. + SOLV. PT. SOL. 100 mg

INJ.

SYNAGIS 100 mg 100 mg ABBOTT LABORATORIES LTD.

J06BB16 PALIVIZUMABUM PULB. + SOLV. PT. SOL. 50 mg

INJ.

SYNAGIS 50 mg 50 mg ABBOTT LABORATORIES LTD.

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| **681** |**L03AA02**| **FILGRASTIMUM (G-CSF)\*\*** | |

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Prescriere limitată: **Tratamentul neutropeniei persistente (ANC mai mic sau egal cu 1,0 x 109/L) la pacienţii cu infecţie HIV aflaţi în stadii avansate, în scopul scăderii riscului de infecţii bacteriene în situaţiile în care alte opţiuni în tratamentul neutropeniei sunt inadecvate.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L03AA02 FILGRASTIMUM (G-CSF) SOL. INJ. 30 MU/0.5 ml

NEUPOGEN(R) 30 MU/0.5 ml AMGEN EUROPE B.V.

L03AA02 FILGRASTIMUM (G-CSF) SOL. INJ. 48 MU/0.5 ml

NEUPOGEN(R) 48 MU/0.5 ml AMGEN EUROPE B.V.

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| **682** |**S01AA23**| **NETILMICINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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S01AA23 NETILMICINUM PICATURI OFT. - SOL. 0.3%

NETTACIN(R) 0.3% S.I.F.I. SPA

S01AA23 NETILMICINUM UNG. OFT. 3 mg/g

NETTAVISC 3 mg/g 3 mg/g S.I.F.I. SPA

S01AA23 NETILMICINUM PIC. OFT., SOL 0.3%

NETTACIN(R) 0.3% S.I.F.I. SPA

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| **683** |**S01AX17**| **LOMEFLOXACINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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S01AX17 LOMEFLOXACINUM PICATURI OFT. - SOL. 3 mg/ml

OKACIN 3 mg/ml NOVARTIS PHARMA GMBH

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| **684** |**S03AAN2**| **NORFLOXACINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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S03AAN2 NORFLOXACINUM PICATURI OFT./ 0.3%

AURIC. - SOL

NORFLOX 0.3% CIPLA (UK) LIMITED

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| **685** |**S01BA01**| **DEXAMETHASONUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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S01BA01 DEXAMETHASONUM PICATURI OFT. - SUSP. 0.1%

MAXIDEX(R) 0.1% ALCON COUVREUR NV

S01BA01 DEXAMETHASONUM PIC. OFT. SUSP. 1 mg/ml

DEXAMETAZONA RPH 1 mg/ml ROMPHARM COMPANY SRL

1 mg/ml

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| **1207** |**J02AA01**| **AMPHOTERICINUM B LIPOSOMAL (4)** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J02AA01 AMPHOTERICINUM B

LIPOSOMAL

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| **1208** |**P01AX06**| **ATOVAQUONA (4)** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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P01AX06 ATOVAQUONA

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| **1209** |**J02AX01**| **FLUCYTOSINUM (4)** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J02AX01 FLUCYTOSINUM

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| **1210** |**P01BC02**| **MEFLOQUINE (4)** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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P01BC02 MEFLOQUINE

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| **1211** |**R01AX06**| **MUPIROCINUM (4)** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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R01AX06 MUPIROCINUM

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| **1212** |**A07AA06**| **PAROMOMYCINUM (4)** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A07AA06 PAROMOMYCINUM

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| **1213** |**P01CX01**| **PENTAMIDINUM (4)** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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P01CX01 PENTAMIDINUM

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| **1214** |**P01BA03**| **PRIMAQUINUM (4)** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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P01BA03 PRIMAQUINUM

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| **1215** |**P01BD01**| **PYRIMETHAMINUM (4)** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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P01BD01 PYRIMETHAMINUM

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| **1216** |**P01BD51**| **PYRIMETHAMINUM + SULFADIAZINUM (4)** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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P01BD51 PYRIMETHAMINUM +

SULFADIAZINUM

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| **1217** |**J01EA01**| **TRIMETHOPRIM (4)** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01EA01 TRIMETHOPRIM

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**SUBLISTA C2 - P1: PROGRAMUL NAŢIONAL DE BOLI TRANSMISIBILE. B) SUBPROGRAMUL DE TRATAMENT AL BOLNAVILOR CU TUBERCULOZA**

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| **686** |**A11HA02**| **PYRIDOXINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A11HA02 PYRIDOXINUM COMPR. 250 mg

VITAMINA B6 250 mg 250 mg ARENA GROUP SA

A11HA02 PYRIDOXINUM COMPR. 250 mg

SICOVIT B6 250 mg 250 mg ZENTIVA SA

A11HA02 PYRIDOXINUM SOL. INJ. 250 mg/5 ml

SICOVIT B6 250 mg/5 ml 250 mg/5 ml ZENTIVA SA

A11HA02 PYRIDOXINUM SOL. INJ. 50 mg/2 ml

SICOVIT B6 50 mg/2 ml 50 mg/2 ml ZENTIVA SA

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| **687** |**H02AB07**| **PREDNISONUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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H02AB07 PREDNISONUM COMPR. 5 mg

N - PREDNISON 5 mg MEDUMAN SA

PREDNISON 5 mg 5 mg SINTOFARM SA

PREDNISON ARENA 5 mg 5 mg ARENA GROUP SA

PREDNISON GEDEON RICHTER 5 mg 5 mg GEDEON RICHTER ROMANIA SA

PREDNISON MAGISTRA 5 mg 5 mg MAGISTRA C & C

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| **688** |**J01FA09**| **CLARITHROMYCINUM** | | |\_\_\_\_\_\_\_|\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_|

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01FA09 CLARITHROMYCINUM GRAN. PT. SUSP. ORALA 125 mg/5 ml

FROMILID(R) 125 mg/5 ml 125 mg/5 ml KRKA D.D.

KLABAX 125 mg/5 ml 125 mg/5 ml TERAPIA S.A.

KLACID(R) 125 mg/5 ml ABBOTT SPA

LEKOKLAR 125 mg/5 ml 125 mg/5 ml SANDOZ S.R.L

J01FA09 CLARITHROMYCINUM COMPR. FILM. 250 mg

CLAR 250 250 mg MEDICAROM GROUP S.R.L.

CLARITROMICINA 250 mg 250 mg OZONE LABORATORIES LTD.

FROMILID 250 250 mg KRKA D.D. NOVO MESTO

KLABAX 250 mg 250 mg TERAPIA S.A.

KLACID(R) 250 mg ABBOTT SPA

KLERIMED(R) 250 250 mg MEDOCHEMIE LTD.

LEKOKLAR(R) 250 mg 250 mg LEK PHARMACEUTICALS D.D.

J01FA09 CLARITHROMYCINUM GRAN. PT. SUSP. ORALA 250 mg/5 ml

KLABAX 250 mg/5 ml 250 mg/5 ml TERAPIA S.A.

LEKOKLAR 250 mg/5 ml 250 mg/5 ml SANDOZ SRL

J01FA09 CLARITHROMYCINUM COMPR. FILM. 500 mg

CLAR 500 500 mg MEDICAROM GROUP S.R.L.

CLARITROMICINA 500 mg 500 mg OZONE LABORATORIES LTD.

FROMILID 500 500 mg KRKA D.D. NOVO MESTO

KLABAX 500 mg 500 mg TERAPIA S.A.

KLERIMED(R) 500 500 mg MEDOCHEMIE LTD.

LEKOKLAR(R) 500 mg 500 mg LEK PHARMACEUTICALS D.D.

J01FA09 CLARITHROMYCINUM COMPR. FILM. ELIB. 500 mg

MODIF.

KLABAX MR 500 mg 500 mg TERAPIA S.A.

LEKOKLAR XL 500 mg 500 mg LEK PHARMACEUTICALS D.D.

J01FA09 CLARITHROMYCINUM COMPR. FILM. ELIB. PREL 500 mg

FROMILID(R) UNO 500 mg KRKA D.D.

KLACID SR 500 mg ABBOTT LABORATORIES LTD.

J01FA09 CLARITHROMYCINUM LIOF. PT. SOL. PERF. 500 mg

KLACID I.V. 500 mg ABBOTT LABORATORIES LTD.

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| **691** |**J01GB06**| **AMIKACINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01GB06 AMIKACINUM SOL. INJ. 100 mg/2 ml

AMIKOZIT(R) 100 mg/2 ml 100 mg/2 ml ECZACIBASI PHARMACEUTICALS

S.R.L.

J01GB06 AMIKACINUM SOL. INJ. 250 mg/ml

AMIKIN 250 mg/ml BRISTOL MYERS SQUIBB KFT

J01GB06 AMIKACINUM SOL. INJ. 500 mg/2 ml

AMIKOZIT(R) 500 mg/2 ml 500 mg/2 ml ECZACIBASI PHARMACEUTICALS

S.R.L.

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| **692** |**J01MA01**| **OFLOXACINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01MA01 OFLOXACINUM COMPR. FILM. 200 mg

OFLOXACIN 200 mg 200 mg ANTIBIOTICE SA

OFLOXIN 200 200 mg ZENTIVA AS

ZANOCIN 200 mg RANBAXY UK LIMITED

J01MA01 OFLOXACINUM COMPR. FILM. 400 mg

ELIB. PREL.

ZANOCIN(R) OD 400 400 mg RANBAXY U.K. LIMITED

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| **693** |**J01MA02**| **CIPROFLOXACINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01MA02 CIPROFLOXACINUM CONC. PT. SOL. PERF. 100 mg/10 ml

CIPRINOL(R) 100 mg/10 ml KRKA D.D.

CIPROFLOXACINA 100 mg/10 ml 100 mg/10 ml SICOMED SA

J01MA02 CIPROFLOXACINUM SOL. PERF. 100 mg/50 ml

CIPRINOL 100 mg/50 ml KRKA D.D. NOVO MESTO

J01MA02 CIPROFLOXACINUM SOL. PERF. 200 mg/100 ml

CIPRINOL 200 mg/100 ml KRKA D.D. NOVO MESTO

CIPROBAY(R) 200 200 mg/100 ml BAYER HEALTHCARE AG

J01MA02 CIPROFLOXACINUM CAPS. 250 mg

EUCIPRIN 250 mg EUROPHARM SA

J01MA02 CIPROFLOXACINUM COMPR. FILM. 250 mg

CIFRAN 250 mg RANBAXY UK LIMITED

CIPHIN 250 250 mg ZENTIVA A.S.

CIPRINOL 250 mg 250 mg KRKA D.D. NOVO MESTO

CIPROCIN 250 mg 250 mg E.I.P.I.CO. MED S.R.L.

CIPROFLOXACIN 250 mg 250 mg LAROPHARM SRL

CIPROFLOXACINA ALKALOID 250 mg ALKALOID D.O.O.

250 mg

CIPROLEN(R) 250 mg 250 mg AC HELCOR SRL

CIPROLET 250 mg 250 mg DR. REDDY'S LABORATORIES

CIPROZONE 250 mg 250 mg OZONE LABORATORIES LTD.

CUMINOL 250 mg 250 mg GEDEON RICHTER ROMANIA

J01MA02 CIPROFLOXACINUM SOL. PERF. 2 mg/ml

CIPROBAY(R) 400 2 mg/ml BAYER HEALTHCARE AG

UFEXIL 2 mg/ml DEMO SA

J01MA02 CIPROFLOXACINUM SOL. PERF. 400 mg/200 ml

CIPRINOL(R) 400 mg/200 ml KRKA D.D.

J01MA02 CIPROFLOXACINUM COMPR. FILM. 500 mg

CIFRAN 500 mg RANBAXY UK LIMITED

CIPHIN 500 500 mg ZENTIVA A.S.

CIPRINOL 500 mg 500 mg KRKA D.D. NOVO MESTO

CIPRO QUIN(R) 500 mg ANTIBIOTICE SA

CIPROBAY(R) 500 500 mg BAYER HEALTHCARE AG

CIPROCIN 500 mg 500 mg E.I.P.I.CO. MED S.R.L

CIPRODAR 500 mg DAR AL DAWA PHARMA S.R.L

CIPROFLOXACINA ALKALOID 500 mg ALKALOID D.O.O.

500 mg

CIPROLEN(R) 500 mg 500 mg AC HELCOR SRL

CIPROLET 500 mg 500 mg DR. REDDY'S LABORATORIES

CIPROZONE FORTE 500 mg 500 mg OZONE LABORATORIES LTD.

CUMINOL 500 mg 500 mg GEDEON RICHTER ROMANIA

SIFLOKS(R) 500 mg ECZACIBASI ILAC SANAYI VE

TICARET AS

J01MA02 CIPROFLOXACINUM COMPR. FILM. 750 mg

CIPRINOL 750 mg 750 mg KRKA D.D. NOVO MESTO

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| **694** |**J01MA14**| **MOXIFLOXACINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01MA14 MOXIFLOXACINUM COMPR. FILM. 400 mg

AVELOX(R) 400 mg 400 mg BAYER HEALTHCARE AG

J01MA14 MOXIFLOXACINUM SOL. PERF. 400 mg/250 ml

AVELOX(R) 400 mg/250 ml 400 mg/250 ml BAYER HEALTHCARE AG

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| **696** |**J04AB01**| **CICLOSERINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J04AB01 CICLOSERINUM CAPS. 250 mg

CICLOSERINA ANTIBIOTICE 250 mg ANTIBIOTICE S.A.

250 mg

HELPOCERIN 250 mg HELP PHARMACEUTICALS LTD.

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| **697** |**J04AB02**| **RIFAMPICINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J04AB02 RIFAMPICINUM CAPS. 150 mg

SINERDOL 150 mg 150 mg ANTIBIOTICE SA

J04AB02 RIFAMPICINUM CAPS. 300 mg

SINERDOL 300 mg 300 mg ANTIBIOTICE SA

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| **698** |**J04AB04**| **RIFABUTINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J04AB04 RIFABUTINUM CAPS. 150 mg

MYCOBUTIN 150 mg 150 mg PFIZER EUROPE MA EEIG

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| **699** |**J04AB30**| **CAPREOMYCINUM (4)** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J04AB30 CAPREOMYCINUM

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| **700** |**J04AC01**| **ISONIAZIDUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J04AC01 ISONIAZIDUM COMPR. 100 mg

ISONIAZIDA 100 mg 100 mg ANTIBIOTICE SA

J04AC01 ISONIAZIDUM COMPR. 300 mg

ISONIAZIDA 300 mg ANTIBIOTICE SA

J04AC01 ISONIAZIDUM SOL. INJ. 500 mg/10 ml

IZONIAZIDA 500 mg 500 mg/10 ml TERAPIA SA

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| **701** |**J04AD01**| **PROTIONAMIDUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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J04AD01 PROTIONAMIDUM COMPR. FILM. 250 mg

PROTIONAMIDA 250 mg 250 mg ANTIBIOTICE SA

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| **702** |**J04AK01**| **PYRAZINAMIDUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J04AK01 PYRAZINAMIDUM COMPR. 500 mg

PIRAZINAMIDA ANTIBIOTICE 500 mg ANTIBIOTICE S.A.

500 mg

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| **703** |**J04AK02**| **ETHAMBUTOLUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J04AK02 ETHAMBUTOLUM COMPR. FILM. 250 mg

ETAMBUTOL 250 mg 250 mg ANTIBIOTICE SA

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| **704** |**J04AM02**| **COMBINATII (RIFAMPICINUM + IZONIAZIDUM)** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J04AM02 COMBINATII CAPS. 300 mg + 150 mg

(RIFAMPICINUM +

IZONIAZIDUM)

SINERDOLISO 300 mg + 150 mg ANTIBIOTICE SA

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**SUBLISTA C2 - P3: PROGRAMUL NAŢIONAL DE ONCOLOGIE.**

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| **705** |**G03HA01**| **CYPROTERONUM** | **Protocol: L025C** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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G03HA01 CYPROTERONUM COMPR. 50 mg

ANDROCUR 50 mg SCHERING AG

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| **706** |**L01AA01**| **CYCLOPHOSPHAMIDUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L01AA01 CYCLOPHOSPHAMIDUM PULB. PT. SOL. 1 g

INJ./PERF.

ENDOXAN(R) 1 g 1 g BAXTER ONCOLOGY GMBH

L01AA01 CYCLOPHOSPHAMIDUM PULB. PT. SOL. 200 mg

PERF./INJ. I.V.

ENDOXAN 200 mg 200 mg ACTAVIS S.R.L.

L01AA01 CYCLOPHOSPHAMIDUM PULB. PT. SOL. 500 mg

INJ./PERF.

ENDOXAN(R) 500 mg 500 mg BAXTER ONCOLOGY GMBH

L01AA01 CYCLOPHOSPHAMIDUM DRAJ. 50 mg

ENDOXAN(R) 50 mg 50 mg BAXTER ONCOLOGY GMBH

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| **707** |**L01AA02**| **CHLORAMBUCILUM** | |

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NOTĂ:

**Indicat în schemele de tratament al limfomului Hodgkin.**

**Indicat în schemele de tratament ale anumitor forme de limfoame non-Hodgkin.**

**Indicat în schemele de tratament al leucemiei limfocitare cronice.**

**Indicat în schemele de tratament a macroglobulinemiei Waldenstrom.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L01AA02 CHLORAMBUCILUM COMPR. FILM. 2 mg

LEUKERAN 2 mg THE WELLCOME FOUNDATION

LTD.

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| **708** |**L01AA03**| **MELPHALANUM** | |

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NOTĂ:

**Indicat în schemele de tratament al mielomului multiplu.**

**Indicat în schemele de tratament ale adenocarcinomului ovarian avansat.**

**Indicat în schemele de tratament al cancerului de sân avansat.**

**Indicat în schemele de tratament a policitemia vera.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L01AA03 MELPHALANUM COMPR. FILM. 2 mg

ALKERAN 2 mg 2 mg THE WELLCOME FOUNDATION

LTD.

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| **709** |**L01AA06**| **IFOSFAMIDUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L01AA06 IFOSFAMIDUM PULB. PT. SOL. PERF. 1 g

HOLOXAN 1 g 1 g BAXTER ONCOLOGY GMBH

L01AA06 IFOSFAMIDUM PULB. PT. SOL. PERF. 2 g

HOLOXAN 2 g 2 g BAXTER ONCOLOGY GMBH

L01AA06 IFOSFAMIDUM PULB. PT. SOL. PERF. 500 mg

HOLOXAN 500 mg 500 mg BAXTER ONCOLOGY GMBH

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| **710** |**L01AB01**| **BUSULFANUM** | |

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NOTĂ:

**Indicat în schemele de tratament paliativ al fazei cronice în Leucemia Granulocitară Cronică.**

**Indicat în schemele de tratament a policitemiei vera.**

**Indicat în schemele de tratament a mielofibrozei şi trombocitemiei esenţiale.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L01AB01 BUSULFANUM COMPR. FILM. 2 mg

MYLERAN 2 mg THE WELLCOME FOUNDATION

LTD.

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| **712** |**L01AX03**| **TEMOZOLOMIDUM\*\*** | **Protocol: L046C** |

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NOTĂ:

**Tratamentul glioblastomului multiform nou diagnosticat, în asociere cu radioterapia şi apoi ca monoterapie.**

**Tratamentul glioamelor maligne, (glioblastomul multiform sau astrocitomul anaplazic), care au prezentat recurenţă sau progresie după terapia standard.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L01AX03 TEMOZOLOMIDUM CAPS. 100 mg

TEMODAL 100 mg 100 mg SP EUROPE

L01AX03 TEMOZOLOMIDUM CAPS. 20 mg

TEMODAL 20 mg 20 mg SP EUROPE

L01AX03 TEMOZOLOMIDUM CAPS. 250 mg

TEMODAL 250 mg 250 mg SP EUROPE

L01AX03 TEMOZOLOMIDUM CAPS. 5 mg

TEMODAL 5 mg 5 mg SP EUROPE

L01AX03 TEMOZOLOMIDUM

TEMODAL 100 mg 100 mg SP EUROPE

L01AX03 TEMOZOLOMIDUM

TEMODAL 20 mg 20 mg SP EUROPE

L01AX03 TEMOZOLOMIDUM

TEMODAL 5 mg 5 mg SP EUROPE

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| **713** |**L01AX04**| **DACARBAZINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L01AX04 DACARBAZINUM LIOF. PT. SOL. PERF. 200 mg

DALTRIZEN(R) 200 mg 200 mg ACTAVIS S.R.L.

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| **714** |**L01BA01**| **METHOTREXATUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L01BA01 METHOTREXATUM CONC. PT. SOL. 100 mg/ml

INJ./PERF.

METHOTREXAT "EBEWE" 1000 mg 100 mg/ml EBEWE PHARMA GMBH NFG. KG

METHOTREXAT "EBEWE" 500 mg 100 mg/ml EBEWE PHARMA GMBH NFG. KG

METHOTREXAT "EBEWE" 5000 mg 100 mg/ml EBEWE PHARMA GMBH NFG. KG

L01BA01 METHOTREXATUM SOL. INJ./PERF. 10 mg/ml

METHOTREXAT "EBEWE" 50 mg 10 mg/ml EBEWE PHARMA GMBH NFG. KG

L01BA01 METHOTREXATUM PULB. PT. SOL. 50 mg

INJ./PERF.

ANTIFOLAN(R) 50 mg 50 mg SINDAN SRL

L01BA01 METHOTREXATUM SOL. INJ. 5 mg/ml

METHOTREXAT "EBEWE" 5 mg 5 mg/ml EBEWE PHARMA GMBH NFG. KG

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| **715** |**L01BA04**| **PEMETREXEDUM\*\*\*\*** | **Protocol: L047C** |

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NOTĂ:

**Tratamentul în asociere cu cisplatină al pacienţilor cu mezoteliom pleural malign nerezecabil fără chimioterapie anterioară.**

**Tratamentul ca monoterapie al pacienţilor cu cancer pulmonar cu alt tip de celulă decât cu celulă mică, avansat local sau metastazat, după chimioterapie anterioară.**

**Doze mai mari de 500 mg pe metru pătrat de suprafaţă corporală nu se vor aproba pentru compensare. Suprafaţa corporală a pacientului va trebui declarată în dosarul de aprobare.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L01BA04 PEMETREXEDUM PULB. PT. CONC. PT. 500 mg

SOL. PERF.

ALIMTA 500 mg 500 mg ELI LILLY NEDERLAND BV

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| **716** |**L01BB02**| **MERCAPTOPURINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L01BB02 MERCAPTOPURINUM COMPR. 50 mg

PURI - NETHOL 50 mg THE WELLCOME FOUNDATION

LTD.

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| **717** |**L01BB03**| **TIOGUANINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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L01BB03 TIOGUANINUM COMPR. 40 mg

LANVIS 40 mg THE WELLCOME FOUNDATION

LTD.

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| **718** |**L01BB04**| **CLADRIBINUM** | |

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Prescriere limitată: **Leucemia cu celule păroase.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L01BB04 CLADRIBINUM SOL. INJ. 2 mg/ml

LITAK 2 mg/ml 2 mg/ml LIPOMED GMBH

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| **719** |**L01BB05**| **FLUDARABINUM\*\*\*\*** | **Protocol: L048C** |

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NOTĂ:

**Tratamentul pacienţilor cu leucemie limfocitară cronică cu celule B (LLC), cu rezervă medulară suficientă, care nu au răspuns la tratament sau a căror boală a avansat în timpul tratamentului cu o schemă conţinând cel puţin un agent alchilant standard sau ulterior acestuia.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L01BB05 FLUDARABINUM COMPR. FILM. 10 mg

FLUDARA(R) 0RAL 10 mg SCHERING AG

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| **720** |**L01BC01**| **CYTARABINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L01BC01 CYTARABINUM PULB. + SOLV. PT. SOL. 100 mg

INJ.

CYTOSAR(TM) 100 mg 100 mg PFIZER EUROPE MA EEIG

L01BC01 CYTARABINUM SOL. INJ. 20 mg/ml

ALEXAN 20 mg/ml 20 mg/ml EBEWE PHARMA GMBH NFG. KG

L01BC01 CYTARABINUM SUSP. INJ. 50 mg

DEPOCYTE 50 mg 50 mg SKYEPHARMKA PLC

L01BC01 CYTARABINUM SOL. INJ. 50 mg/ml

ALEXAN 50 mg/ml 50 mg/ml EBEWE PHARMA GMBH NFG. KG

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| **721** |**L01BC02**| **FLUOROURACILUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L01BC02 FLUOROURACILUM SOL. PERF./INJ. 250 mg/5 ml

FLUOROSINDAN 250 mg/5 ml 250 mg/5 ml ACTAVIS S.R.L.

L01BC02 FLUOROURACILUM UNGUENT 50 mg/g

EFUDIX 50 mg/g ICN HUNGARY CO. LTD.

L01BC02 FLUOROURACILUM CONC. PT. SOL. 50 mg/ml

INJ./PERF.

5 - FLUOROURACIL 50 mg/ml EBEWE PHARMA GMBH NFG. KG

EBEWE 50 mg/ml

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| **722** |**L01BC05**| **GEMCITABINUM\*\*** | |

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Prescriere limitată: **Terapia asociată a cancerului mamar avansat cu**

**paclitaxelum după eşecul terapiei anterioare cu un**

**derivat de antraciclină.**

**Terapia asociată a cancerului ovarian epitelial avansat**

**cu carboplatinum la pacientele cu recădere la mai mult**

**de 6 luni după chimioterapia cu derivaţi de platinum.**

**Tratamentul de prima intenţie al cancerului pulmonar cu**

**alt tip de celule decât cu celule mici, stadiile IHA**

**sau IIIB sau IV în asociere cu cisplatin.**

**Tratamentul paliativ al cancerului pulmonar cu alt tip**

**de celule decât cu celule mici avansat local sau**

**metastatic.**

**Adenocarcinom pancreatic avansat local sau metastatic.**

**Tratamentul asociat al cancerului vezical avansat local**

**sau metastatic în combinaţie cu cisplatin.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L01BC05 GEMCITABINUM PULB. PT. SOL. PERF. 1 g

GEMCITABINA SINDAN 1 g 1 g ACTAVIS S.R.L.

L01BC05 GEMCITABINUM PULB. PT. SOL. PERF. 200 mg

GEMCITABINA SINDAN 200 mg 200 mg ACTAVIS S.R.L.

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| **723** |**L01BC06**| **CAPECITABINUM** | |

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Prescriere limitată: **Cancer mamar avansat local sau metastazat după eşecul**

**terapiei anterioare cu un taxan şi un derivat de**

**antraciclină.**

**Cancer mamar avansat local sau metastazat în care**

**terapia cu un derivat de antraciclină nu mai este**

**indicată.**

**Terapia asociată a cancerului mamar avansat local sau**

**metastazat cu docetaxelum după eşecul terapiei**

**anterioare cu un derivat de antraciclină.**

**Tratamentul de primă linie al cancerului colorectal**

**metastatic avansat.**

**Tratamentul adjuvant al cancerului de colon stadiul III**

**(Dukes C), după rezecţia completă a tumorii primare.**

NOTĂ:

**Durata recomandată a tratamentului adjuvant este de 24 de săptămâni; nu se compensează tratamentul cu Capecitabinum pentru cancerul de colon stadiul II (Dukes B) şi tratamentul adjuvant al pacienţilor cu cancer rectal.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L01BC06 CAPECITABINUM COMPR. FILM. 150 mg

XELODA 150 mg 150 mg ROCHE REGISTRATION LTD.

L01BC06 CAPECITABINUM COMPR. FILM. 500 mg

XELODA 500 mg 500 mg ROCHE REGISTRATION LTD.

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| **724** |**L01BC53**| **COMBINATII (TEGAFUR + URACIL)** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L01BC53 COMBINATII CAPS. 100 mg + 224 mg

(TEGAFUR + URACIL)

UFT 100 mg + 224 mg MERCK KGAA

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| **726** |**L01CA02**| **VINCRISTINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L01CA02 VINCRISTINUM LIOF. PT. SOL. 1 mg

INJ./PERF. I.V.

SINDOVIN 1 mg 1 mg ACTAVIS S.R.L.

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| **727** |**L01CA04**| **VINORELBINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L01CA04 VINORELBINUM CONC. PT. SOL. 10 mg/ml

INJ./PERF.

VINORELBIN EBEWE 10 mg/ml 10 mg/ml EBEWE PHARMA GES.M.B.H.

NFG KG

L01CA04 VINORELBINUM CONC. PT. SOL. PERF. 10 mg/ml

VINORELBIN ACTAVIS 10 mg/ml 10 mg/ml ACTAVIS S.R.L.

VINORELBIN TEVA 10 mg/ml 10 mg/ml TEVA PHARMACEUTICALS SRL

L01CA04 VINORELBINUM SOL. INJ. 10 mg/ml

NAVELBINE(R) 10 mg/ml LAB. PIERRE FABRE

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Prescriere limitată: **Tratamentul cancerului mamar avansat după eşecul terapiei anterioare cu un derivat de antraciclină.**

Prescriere limitată: **Tratamentul de primă intenţie singular sau asociat al cancerului pulmonar cu alte celule decât celule mici avansat local sau metastatic.**

L01CA04 VINORELBINUM CAPS. MOI 20 mg

NAVELBINE 20 mg 20 mg PIERRE FABRE MEDICAMENT

Prescriere limitată: **Tratamentul cancerului mamar avansat după eşecul terapiei anterioare cu un derivat de antraciclină.**

Prescriere limitată: **Tratamentul de primă intenţie singular sau asociat al cancerului pulmonar cu alte celule decât celule mici avansat local sau metastatic.**

L01CA04 VINORELBINUM CAPS. MOI 30 mg

NAVELBINE 30 mg 30 mg PIERRE FABRE MEDICAMENT

Prescriere limitată: **Tratamentul cancerului mamar avansat după eşecul terapiei anterioare cu un derivat de antraciclină.**

Prescriere limitată: **Tratamentul de primă intenţie singular sau asociat al cancerului pulmonar cu alte celule decât celule mici avansat local sau metastatic.**

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| **728** |**L01CB01**| **ETOPOSIDUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L01CB01 ETOPOSIDUM CAPS. MOI 100 mg

VEPESID 100 mg BRISTOL MYERS SQUIBB KFT

L01CB01 ETOPOSIDUM CONC. PT. SOL. PERF. 100 mg/5 ml

ETOPOSID "EBEWE" 100 mg/5 ml 100 mg/5 ml EBEWE PHARMA GMBH NFG. KG

SINTOPOZID 100 mg/5 ml 100 mg/5 ml ACTAVIS S.R.L.

L01CB01 ETOPOSIDUM CONC. PT. SOL. PERF. 20 mg/ml

ETOPOSIDE - TEVA 20 mg/ml TEVA PHARMACEUTICALS

S.R.L.

L01CB01 ETOPOSIDUM CAPS. MOI 50 mg

VEPESID 50 mg BRISTOL MYERS SQUIBB KFT

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| **729** |**L01CD01**| **PACLITAXELUM\*\*** | |

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Prescriere limitată: **Tratamentul adjuvant al cancerului mamar cu ganglioni**

**pozitivi administrat secvenţial cu un derivat de**

**antraciclină şi ciclofosfamidă.**

**Cancer mamar avansat după eşecul terapiei anterioare**

**sau intoleranţă la un derivat de antraciclină.**

**Terapia de linia a doua cancerului ovarian avansat la**

**pacientele cu eşec anterior la chimioterapia cu**

**derivaţi de platinum.**

**Cancer pulmonar cu celule altele decât celule mici**

**avansat local sau metastatic.**

**Terapia asociată a cancerului de sân în stadiu precoce**

**(HER2 pozitiv) cu trastuzumab şi care nu sunt eligibili**

**pentru tratament cu un derivat de antraciclină.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L01CD01 PACLITAXELUM CONC. PT. SOL. PERF. 6 mg/ml

ONXOL 6 mg/ml 6 mg/ml IVAX - PHARMACEUTICALS

S.R.O.

PACLITAXEL 6 mg/ml 6 mg/ml PHARMEXPRESS S.R.L.

PACLITAXEL EBEWE 6 mg/ml 6 mg/ml EBEWE PHARMA GES.M.B.H.

NFG KG

SINDAXEL 6 mg/ml ACTAVIS S.R.L.

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| **730** |**L01CD02**| **DOCETAXELUM\*\*** | **Protocol: L049C** |

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NOTĂ:

**Tratamentul adjuvant în asociere cu doxorubicină şi ciclofosfamidă, adjuvant al pacientelor cu cancer mamar operabil, cu ganglioni pozitivi.**

**Tratamentul în asociere cu doxorubicină, al pacientelor cancer mamar avansat loco-regional sau metastazat, care nu au primit anterior tratament citotoxic pentru această afecţiune.**

**Tratamentul în monoterapie al pacientelor cu cancer mamar avansat loco-regional sau metastazat, după eşecul tratamentului citotoxic. Chimioterapia anterioară trebuie să fi inclus o antraciclină sau un agent alchilant.**

**Tratamentul în asociere cu trastuzumab, al pacientelor cu cancer mamar metastazat ale căror tumori exprimă în exces HER2 şi care nu au primit anterior chimioterapie pentru boala metastatică.**

**Tratamentul în asociere cu capecitabină, al pacientelor cu cancer mamar avansat loco-regional sau metastazat, după eşecul chimioterapiei citotoxice. Tratamentul anterior trebuie să fi inclus o antraciclină.**

**Tratamentul pacienţilor cu cancer bronhopulmonar, altul decât cel cu celule mici, avansat loco-regional sau metastazat, după eşecul chimioterapiei sau înainte de aceasta.**

**Tratamentul în asociere cu cisplatină, al pacienţilor cu cancer bronhopulmonar, altul decât cel cu celule mici, nerezecabil, avansat loco-regional sau metastazat, la pacienţii care nu au primit anterior chimioterapie pentru această afecţiune.**

**Tratamentul în asociere cu prednison sau prednisolon, al pacienţilor cu cancer de prostată metastazat, hormono-rezistent.**

**Tratamentul în asociere cu cisplatină şi 5-fluorouracil, al pacienţilor cu adenocarcinom gastric metastazat, inclusiv adenocarcinom al joncţiunii gastroesofagiene, care nu au primit anterior chimioterapie pentru boala metastatică.**

**Tratamentul în asociere cu cisplatină şi 5-fluorouracil de inducţie la pacienţi cu carcinom cu celule scuamoase, al capului şi gâtului, avansat local.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L01CD02 DOCETAXELUM CONC. + SOLV. PT. SOL. 20 mg

PERF.

TAXOTERE 20 mg 20 mg AVENTIS PHARMA SA

L01CD02 DOCETAXELUM CONC. + SOLV. PT. SOL. 80 mg

PERF.

TAXOTERE 80 mg 80 mg AVENTIS PHARMA SA

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| **732** |**L01DB01**| **DOXORUBICINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L01DB01 DOXORUBICINUM LIOF. PT. SOL. INJ. 10 mg

ADRIBLASTINA RD 10 mg 10 mg ACTAVIS S.R.L.

L01DB01 DOXORUBICINUM CONC. PT. SOL. PERF. 2 mg/ml

CAELYX 2 mg/ml 2 mg/ml SP EUROPE

Prescriere limitată: **Tratamentul ca monoterapie al cancerului mamar metastatic, la paciente cu risc cardiac crescut.**

Prescriere limitată: **Tratamentul cancerului ovarian în stadiu avansat, la paciente care nu au răspuns la regimul chimioterapie de primă linie, cu compuşi de platină.**

**Prescriere limitată: Tratamentul sarcomului Kaposi (SK) corelat cu SIDA (SK-SIDA), la pacienţii cu număr mic de limfocite CD4 (< 200 limfocite CD4/mm3) şi cu afectare mucocutanată sau viscerală extinsă. Poate fi utilizat în chimioterapia sistemică de primă linie sau în chimioterapia de linia a doua la pacienţii cu SK-SIDA la care boala a avansat sau la pacienţii cu intoleranţă la tratament, la care s-a administrat anterior chimioterapie sistemică combinată, cuprinzând cel puţin două dintre următoarele chimioterapice: alcaloid de vinca, bleomicină şi doxorubicină standard (sau altă antraciclină).**

L01DB01 DOXORUBICINUM CONC. PT. SOL. PERF. 2 mg/ml

DOXORUBICIN "EBEWE" 2 mg/ml 2 mg/ml EBEWE PHARMA GMBH NFG. KG

L01DB01 DOXORUBICINUM PULB. PT. SOL. PERF. 2 mg/ml

SINDROXOCIN 2 mg/ml 2 mg/ml ACTAVIS S.R.L.

L01DB01 DOXORUBICINUM SOL. INJ. 2 mg/ml

DOXORUBICIN TEVA 2 mg/ml 2 mg/ml TEVA PHARMACEUTICALS

S.R.L.

L01DB01 DOXORUBICINUM LIOF. PT. SOL. INJ. 50 mg

ADRIBLASTINA RD 50 mg 50 mg ACTAVIS S.R.L.

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| **733** |**L01DB03**| **EPIRUBICINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L01DB03 EPIRUBICINUM LIOF. PT. SOL. INJ. 10 mg

EPISINDAN 10 mg 10 mg ACTAVIS S.R.L.

FARMORUBICIN RD 10 mg 10 mg ACTAVIS S.R.L.

L01DB03 EPIRUBICINUM CONC. PT. SOL. INJ. 2 mg/ml

EPIRUBICIN "EBEWE" 2 mg/ml 2 mg/ml EBEWE PHARMA GMBH NFG. KG

L01DB03 EPIRUBICINUM LIOF. PT. SOL. INJ. 50 mg

EPISINDAN 50 mg 50 mg ACTAVIS S.R.L.

FARMORUBICIN(R) RD 50 mg 50 mg ACTAVIS S.R.L.

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| **734** |**L01DB06**| **IDARUBICINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L01DB06 IDARUBICINUM CAPS. 10 mg

ZAVEDOS 10 mg PFIZER EUROPE MA EEIG

L01DB06 IDARUBICINUM LIOF. PT. SOL. INJ. 5 mg

ZAVEDOS 5 mg 5 mg PFIZER EUROPE MA EEIG

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| **735** |**L01DB07**| **MITOXANTRONUM\*\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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L01DB07 MITOXANTRONUM CONC. PT. SOL. PERF. 2 mg/ml

MITOXANTRONE TEVA 2 mg/ml 2 mg/ml TEVA PHARMACEUTICALS SRL

L01DB07 MITOXANTRONUM SOL. PERF. 20 mg/10 ml

NOVANTRONE 20 mg/10 ml WYETH LEDERLE PHARMA GMBH

L01DB07 MITOXANTRONUM CONC. PT. SOL. INJ. 2 mg/ml

ONKOTRONE 2 mg/ml BAXTER ONCOLOGY GMBH

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| **736** |**L01DC01**| **BLEOMYCINUM SULFAS** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L01DC01 BLEOMYCINUM SULFAS LIOF. PT. SOL. INJ. 15 mg

BLEOCIN 15 mg EURO NIPPON KAYAKU GMBH

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| **738** |**L01XA01**| **CISPLATINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L01XA01 CISPLATINUM LIOF. PT. SOL. PERF. 10 mg

SINPLATIN 10 mg 10 mg ACTAVIS S.R.L.

L01XA01 CISPLATINUM CONC. PT. SOL. PERF. 10 mg/20 ml

CISPLATIN "EBEWE" 10 mg/20 ml 10 mg/20 ml EBEWE PHARMA GMBH NFG. KG

CISPLATIN TEVA 10 mg/20 ml 10 mg/20 ml TEVA PHARMACEUTICALS

S.R.L.

L01XA01 CISPLATINUM CONC. PT. SOL. PERF. 1 mg/1 ml

SINPLATIN 1 mg/1 ml 1 mg/1 ml ACTAVIS S.R.L.

L01XA01 CISPLATINUM CONC. PT. SOL. PERF. 25 mg/50 ml

CISPLATIN "EBEWE" 25 mg/50 ml 25 mg/50 ml EBEWE PHARMA GMBH NFG. KG

L01XA01 CISPLATINUM LIOF. PT. SOL. PERF. 50 mg

SINPLATIN 50 mg 50 mg ACTAVIS S.R.L.

L01XA01 CISPLATINUM CONC. PT. SOL. PERF. 50 mg/100 ml

CISPLATIN "EBEWE" 50 mg/100 ml EBEWE PHARMA GMBH NFG. KG

50 mg/100 ml

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| **739** |**L01XA02**| **CARBOPLATINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L01XA02 CARBOPLATINUM CONC. PT. SOL. PERF. 10 mg/ml

CARBOPLATIN "EBEWE" 10 mg/ml 10 mg/ml EBEWE PHARMA GES.M.B.H.

NFG KG

CARBOPLATIN ACTAVIS 10 mg/ml 10 mg/ml ACTAVIS S.R.L.

CARBOPLATIN TEVA 10 mg/ml 10 mg/ml TEVA PHARMACEUTICALS

S.R.L.

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| **740** |**L01XA03**| **OXALIPLATINUM** | |

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Prescriere limitată: **Cancer colorectal metastazat în combinaţie cu 5-FU şi**

**acid folic.**

**Tratament adjuvant al cancerului de colon stadiul III**

**(Dukes C) în combinaţie cu 5-FU şi acid folic după**

**rezecţia completă a tumorii primare.**

NOTĂ:

**Nu se compensează tratamentul cu Oxaliplatinum pentru cancerul de colon stadiul II (Dukes B) şi tratamentul adjuvant al pacienţilor cu cancer rectal.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L01XA03 OXALIPLATINUM LIOF. PT. SOL. PERF. 5 mg/ml

ELOXATIN 5 mg/ml 5 mg/ml SANOFI-AVENTIS FRANCE

OXALIPLATIN ACTAVIS 5 mg/ml 5 mg/ml ACTAVIS S.R.L.

NOTĂ:

**Nu se compensează tratamentul cu Oxaliplatinum pentru cancerul de colon stadiul II (Dukes B) şi tratamentul adjuvant al pacienţilor cu cancer rectal.**

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| **742** |**L01XC04**| **ALEMTUZUMABUM\*\*\*\*** | **Protocol: L024C** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L01XC04 ALEMTUZUMABUM CONC. PT. SOL. PERF. 10 mg/ml

MABCAMPATH 10 mg/ml 10 mg/ml GENZYME EUROPE BV

L01XC04 ALEMTUZUMABUM CONC. PT. SOL. PERF. 30 mg/ml

MABCAMPATH 30 mg/ml 30 mg/ml GENZYME EUROPE BV

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| **743** |**L01XC02**| **RITUXIMABUM\*\*\*\*** | **Protocol: L014C** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L01XC02 RITUXIMABUM CONC. PT. SOL. PERF. 10 mg/ml

MABTHERA 100 mg 10 mg/ml ROCHE REGISTRATION LTD.

MABTHERA 500 mg 10 mg/ml ROCHE REGISTRATION LTD.

L01XC02 RITUXIMABUM CONC. PT. SOL. PERF. 10 mg/ml

MABTHERA 100 mg 10 mg/ml ROCHE REGISTRATION LTD.

MABTHERA 500 mg 10 mg/ml ROCHE REGISTRATION LTD.

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| **744** |**L01XC03**| **TRASTUZUMABUM\*\*\*\*** | **Protocol: L026C** |

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NOTĂ:

**Tratamentul pacienţilor cu neoplasm de sân metastatic cu HER2 amplificat:**

**a) ca monoterapie în cazul pacienţilor trataţi cu cel puţin două regimuri chimioterapice pentru boala lor metastatică. Chimioterapia anterioară trebuie să fi inclus cel puţin o antraciclină şi un taxan, cu excepţia cazurilor în care aceste chimioterapice nu erau indicate. Pacienţii pozitivi la receptorii hormonali trebuie de asemenea să fi prezentat un eşec la tratamentul hormonal, cu excepţia cazurilor în care acest tip de tratament nu a fost indicat.**

**b) în asociere cu Paclitaxel pentru tratamentul pacienţilor care nu au primit chimioterapie pentru boala lor metastatică şi pentru care nu este indicat tratamentul cu antracicline. Herceptin trebuie folosit numai la pacienţii ale căror tumori prezintă HER2 amplificat la nivel 3+, determinat prin imunohistochimie.**

Trastuzumab nu trebuie utilizat la pacienţi cu o fracţie de ejecţie ventriculară a ventriculului stâng mai mică de 45% şi/sau cu insuficienţă cardiacă simptomatică. Funcţia cardiacă trebuie testată.

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L01XC03 TRASTUZUMABUM PULB. PT. CONC. PT. 150 mg

SOL. PERF.

HERCEPTIN 150 mg 150 mg ROCHE REGISTRATION LTD.

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| **745** |**L01XC06**| **CETUXIMABUM\*\*\*\*** | **Protocol: L037C** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L01XC06 CETUXIMABUM SOL. PERF. 2 mg/ml

ERBITUX 2 mg/ml 2 mg/ml MERCK KGAA

L01XC06 CETUXIMABUM SOL. PERF. 5 mg/ml

ERBITUX 5 mg/ml 5 mg/ml MERCK KGAA

L01XC06 CETUXIMABUM SOL. PERF. 5 mg/ml

ERBITUX 5 mg/ml 5 mg/ml MERCK KGAA

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| **746** |**L01XC07**| **BEVACIZUMABUM\*\*\*\*** | **Protocol: L004C** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L01XC07 BEVACIZUMABUM CONC. PT. SOL. PERF. 25 mg/ml

AVASTIN 25 mg/ml 25 mg/ml ROCHE REGISTRATION LTD.

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| **747** |**L01XE01**| **IMATINIBUM\*\*\*\*** | **Protocol: L008C** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L01XE01 IMATINIBUM CAPS. 100 mg

GLIVEC 100 mg 100 mg NOVARTIS EUROPHARM LTD.

L01XE01 IMATINIBUM CAPS. 100 mg

GLIVEC 100 mg 100 mg NOVARTIS EUROPHARM LTD.

L01XE01 IMATINIBUM CAPS. 100 mg

GLIVEC 100 mg 100 mg NOVARTIS EUROPHARM LTD.

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| **748** |**L01XE03**| **ERLOTINIBUM\*\*\*\*** | **Protocol: L031C** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L01XE03 ERLOTINIBUM COMPR. FILM. 100 mg

TARCEVA 100 mg 100 mg ROCHE REGISTRATION LTD.

L01XE03 ERLOTINIBUM COMPR. FILM. 150 mg

TARCEVA 150 mg 150 mg ROCHE REGISTRATION LTD.

L01XE03 ERLOTINIBUM COMPR. FILM. 25 mg

TARCEVA 25 mg 25 mg ROCHE REGISTRATION LTD.

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| **749** |**L01XE04**| **SUNITINIBUM\*\*\*\*** | **Protocol: L042C** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L01XE04 SUNITINIBUM CAPS. 12,5 mg

SUTENT 12,5 mg 12,5 mg PFIZER LIMITED

L01XE04 SUNITINIBUM CAPS. 25 mg

SUTENT 25 mg 25 mg PFIZER LIMITED

L01XE04 SUNITINIBUM CAPS. 50 mg

SUTENT 50 mg 50 mg PFIZER LIMITED

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| **750** |**L01XE05**| **SORAFENIBUM\*\*\*\*** | **Protocol: L038C** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L01XE05 SORAFENIBUM COMPR. FILM. 200 mg

NEXAVAR 200 mg 200 mg BAYER HEALTHCARE AG

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| **751** |**L01XE06**| **DASATINIBUM\*\*\*\*** | **Protocol: L035C** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L01XE06 DASATINIBUM COMPR. FILM. 20 mg

SPRYCEL 20 mg 20 mg BRISTOL-MYERS SQUIBB

PHARMA EEIG

L01XE06 DASATINIBUM COMPR. FILM. 50 mg

SPRYCEL 50 mg 50 mg BRISTOL-MYERS SQUIBB

PHARMA EEIG

L01XE06 DASATINIBUM COMPR. FILM. 70 mg

SPRYCEL 70 mg 70 mg BRISTOL-MYERS SQUIBB

PHARMA EEIG

L01XE06 DASATINIBUM COMPR. FILM. 20 mg

SPRYCEL 20 mg 20 mg BRISTOL-MYERS SQUIBB

PHARMA EEIG

L01XE06 DASATINIBUM COMPR. FILM. 50 mg

SPRYCEL 50 mg 50 mg BRISTOL-MYERS SQUIBB

PHARMA EEIG

L01XE06 DASATINIBUM COMPR. FILM. 70 mg

SPRYCEL 70 mg 70 mg BRISTOL-MYERS SQUIBB

PHARMA EEIG

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| **753** |**L01XX02**| **ASPARAGINAZUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L01XX02 ASPARAGINAZUM LIOF. PT. SOL. 10000 ui

INJ./PERF.

ASPARAGINASE 10000 MEDAC 10000 ui MEDAC GESELLSCAFT FUR

KUNISCHE SPEZIALPRĂPARATE

L01XX02 ASPARAGINAZUM LIOF. PT. SOL. 5000 ui

INJ./PERF.

ASPARAGINASE 5000 MEDAC 5000 ui MEDAC GESELLSCAFT FUR

KUNISCHE SPEZIALPRĂPARATE

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| **754** |**L01XX05**| **HYDROXYCARBAMIDUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L01XX05 HYDROXYCARBAMIDUM CAPS. 500 mg

HYDREA 500 mg BRISTOL MYERS SQUIBB KFT

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| **755** |**L01XX11**| **ESTRAMUSTINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L01XX11 ESTRAMUSTINUM CAPS. 140 mg

ESTRACYT 140 mg PFIZER EUROPE MA EEIG

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| **757** |**L01XX17**| **TOPOTECAMUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L01XX17 TOPOTECAMUM PULB. CONC. SOL. PERF. 4 mg

HYCAMTIN 4 mg 4 mg SMITHKLINE BEECHAM PLC

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| **758** |**L01XX19**| **IRINOTECANUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L01XX19 IRINOTECANUM CONC. PT. SOL. PERF. 20 mg/ml

CAMPTO 100 mg/5 ml 20 mg/ml PFIZER EUROPE MA EEIG

IRINOTESIN 20 mg/ml 20 mg/ml ACTAVIS S.R.L.

L01XX19 IRINOTECANUM CONC. PT. SOL. PERF. 20 mg/ml

CAMPTO 100 mg/5 ml 20 mg/ml PFIZER EUROPE MA EEIG

IRINOTESIN 20 mg/ml 20 mg/ml ACTAVIS S.R.L.

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| **759** |**L01XX32**| **BORTEZOMIBUM\*\*\*\*** | **Protocol: L012C** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L01XX32 BORTEZOMIBUM PULB. PT. SOL. INJ. 3.5 mg

VELCADE 3,5 mg 3.5 mg JANSSEN-CILAG

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| **760** |**L02AB01**| **MEGESTROLUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L02AB01 MEGESTROLUM COMPR. 160 mg

MEGESIN 160 mg 160 mg ACTAVIS S.R.L.

L02AB01 MEGESTROLUM SUSP. ORALA 40 mg/ml

MEGACE 40 mg/ml BRISTOL MYERS SQUIBB KFT

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| **761** |**L02AE02**| **LEUPRORELINUM\*\*** | |

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Prescriere limitată: **Cancer de prostată hormonodependent avansat local (echivalent stadiului C) sau metastatic (echivalent stadiului D).**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L02AE02 LEUPRORELINUM LIOF. + SOLV. PT. SUSP. 11.25 mg

INJ. ELIB. PREL

LUCRIN DEPOT 11.25 mg 11.25 mg ABBOTT LABORATORIES S.A.

L02AE02 LEUPRORELINUM LIOF. + SOLV. PT. SUSP. 11.25 mg

INJ. ELIB. PREL.

ELIGARD 22.5 mg 22.5 mg ASTELLAS PHARMA EUROPE

B.V.

L02AE02 LEUPRORELINUM LIOF. + SOLV. PT. SUSP. 11.25 mg

INJ. ELIB. PREL.

ELIGARD 22.5 mg 22.5 mg ASTELLAS PHARMA EUROPE

B.V.

L02AE02 LEUPRORELINUM LIOF. + SOLV. PT. SUSP. 11.25 mg

INJ. ELIB. PREL.

ELIGARD 7.5 mg 7.5 mg ASTELLAS PHARMA EUROPE

B.V.

L02AE02 LEUPRORELINUM LIOF. + SOLV. PT. SUSP.

INJ. ELIB. PREL.

LUCRIN DEPOT 3,75 mg 3.75 mg ABBOTT LABORATORIES

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| **762** |**L02AE03**| **GOSERELINUM\*\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L02AE03 GOSERELINUM IMPLANT 3.6 mg

ZOLADEX(R) 3.6 mg ASTRAZENECA UK LTD.

Prescriere limitată: **Cancer de prostată hormonodependent avansat local (echivalent stadiului T3 - T4) sau metastatic (echivalent stadiului M1).**

Prescriere limitată: **Cancer de sân hormonodependent avansat local (echivalent cu stadiul III) sau metastatic (echivalent cu stadiul IV) la femei în premenopauză.**

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| **763** |**L02AE04**| **TRIPTORELINUM\*\*** | |

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Prescriere limitată: **Cancer de prostata hormonodependent avansat local (echivalent stadiului T3 - T4) sau metastatic (echivalent stadiului M1).**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L02AE04 TRIPTORELINUM LIOF. + SOLV. PT. SOL. 0.1 mg

INJ.

DIPHERELINE 0,1 mg 0.1 mg BEAUFOUR IPSEN PHARMA

L02AE04 TRIPTORELINUM LIOF. + SOLV. PT. SUSP. 11.25 mg

INJ. I.M. ELIB. PREL.

DIPHERELINE(R) 11,25 mg 11.25 mg BEAUFOUR IPSEN PHARMA

L02AE04 TRIPTORELINUM LIOF. + SOLV. PT. SUSP. 3.75 mg

INJ. I.M. ELIB. PREL.

DIPHERELINE(R) 3,75 mg 3.75 mg BEAUFOUR IPSEN PHARMA

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| **764** |**L02BA01**| **TAMOXIFENUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L02BA01 TAMOXIFENUM COMPR. 10 mg

TAMONEPRIN(R) 10 mg 10 mg ACTAVIS S.R.L.

TAMOXIFEN 10 TEVA 10 mg PHARMACHEMIE BV

L02BA01 TAMOXIFENUM COMPR. FILM. 10 mg

TAMOXIFEN(R) 10 HEXAL 10 mg HEXAL AG

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| **765** |**L02BA03**| **FULVESTRANTUM\*\*** | **Protocol: L003C** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L02BA03 FULVESTRANTUM SOL. INJ. 250 mg/5 ml

FASLODEX 250 mg/5 ml 250 mg/5 ml ASTRAZENECA UK LTD.

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| **766** |**L02BB01**| **FLUTAMIDUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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L02BB01 FLUTAMIDUM COMPR. 250 mg

FLUTAN 250 mg MEDOCHEMIE LTD.

FLUTASIN(R) 250 mg 250 mg ACTAVIS S.R.L.

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| **767** |**L02BB03**| **BICALUTAMIDUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L02BB03 BICALUTAMIDUM COMPR. FILM. 150 mg

CASODEX 150 mg 150 mg ASTRAZENECA UK LTD.

L02BB03 BICALUTAMIDUM COMPR. FILM. 50 mg

CALUMID 50 mg GEDEON RICHTER PLC.

CASODEX 50 mg 50 mg ASTRAZENECA UK LTD.

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| **768** |**L02BG01**| **AMINOGLUTETHIMIDUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L02BG01 AMINOGLUTETHIMIDUM COMPR. 250 mg

ROGLUTEN(R) 250 mg 250 mg ACTAVIS S.R.L.

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| **769** |**L02BG03**| **ANASTROZOLUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L02BG03 ANASTROZOLUM COMPR. FILM. 1 mg

ARIMIDEX 1 mg ACTAVIS S.R.L.

ARIMIDEX 1 mg 1 mg ASTRAZENECA UK LTD.

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| **770** |**L02BG04**| **LETROZOLUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L02BG04 LETROZOLUM COMPR. FILM. 2.5 mg

FEMARA 2,5 mg 2.5 mg NOVARTIS PHARMA GMBH

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| **771** |**L02BG06**| **EXEMESTANUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L02BG06 EXEMESTANUM DRAJ. 25 mg

AROMASIN 25 mg 25 mg PFIZER EUROPE MA EEIG

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| **772** |**L03AA02**| **FILGRASTIMUM (G-CSF)\*\*** | |

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Prescriere limitată: **Reducerea duratei neutropeniei şi a incidenţei neutropeniei febrile la pacienţii trataţi cu chimioterapie citotoxică standard pentru bolile maligne (cu excepţia leucemiei mieloide cronice şi a sindroamelor mielodisplazice), precum şi pentru reducerea duratei neutropeniei la pacienţii care primesc terapie mieloablativă urmată de transplant de măduvă osoasă.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L03AA02 FILGRASTIMUM (G-CSF) SOL. INJ. 30 MU/0.5 ml

NEUPOGEN(R) 30 MU/0.5 ml AMGEN EUROPE B.V.

L03AA02 FILGRASTIMUM (G-CSF) SOL. INJ. 48 MU/0.5 ml

NEUPOGEN(R) 48 MU/0.5 ml AMGEN EUROPE B.V.

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| **773** |**L03AA13**| **PEGFILGRASTIMUM\*\*\*** | |

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Prescriere limitată: **Reducerea duratei neutropeniei şi a incidenţei neutropeniei febrile la pacienţii trataţi cu chimioterapie citotoxică standard pentru bolile maligne (cu excepţia leucemiei mieloide cronice şi a sindroamelor mielodisplazice).**

NOTĂ:

**Pentru indicaţia mai sus menţionată, o doză de 6 mg (o singură seringă preumplută) de Pegfilgrastimum este recomandată pentru fiecare ciclu de chimioterapie, administrată ca injecţie subcutanată la aproximativ 24 de ore după chimioterapia citotoxică.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L03AA13 PEGFILGRASTIMUM SOL. INJ. 6 mg

NEULASTA 6 mg 6 mg AMGEN EUROPE B.V.

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| **774** |**L03AB04**| **INTERFERONUM ALFA 2a\*\*\*** | **Protocol: L050C** |

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Tratamentul cu interferon alfa a fost asociat cu depresie şi suicid la unii pacienţi. Pacienţii cu istoric de ideaţie suicidară sau boală depresivă trebuie avertizaţi de riscuri. Trebuie monitorizat statusul psihiatric în timpul tratamentului.

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L03AB04 INTERFERONUM ALFA 2a SOL. INJ. 18 Mui/0.6 ml

ROFERON A 18 Mui/0.6 ml ROCHE ROMANIA S.R.L.

L03AB04 INTERFERONUM ALFA 2a SOL. INJ. 3 Mui/0.5 ml

ROFERON A 3 Mui/0.5 ml ROCHE ROMANIA S.R.L.

L03AB04 INTERFERONUM ALFA 2a SOL. INJ. 4.5 Mui/0.5 ml

ROFERON A 4.5 Mui/0.5 ml ROCHE ROMANIA S.R.L.

L03AB04 INTERFERONUM ALFA 2a SOL. INJ. 9 Mui/0.5 ml

ROFERON A 9 Mui/0.5 ml ROCHE ROMANIA S.R.L.

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| **775** |**L03AB05**| **INTERFERONUM ALFA 2b\*\*\*** | **Protocol: L016C** |

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Tratamentul cu interferon alfa a fost asociat cu depresie şi suicid la unii pacienţi. Pacienţii cu istoric de ideaţie suicidară sau boală depresivă trebuie avertizaţi de riscuri. Trebuie monitorizat statusul psihiatric în timpul tratamentului.

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L03AB05 INTERFERONUM ALFA 2b SOL. INJ. PEN MULTIDOZA 18 milioane U.I.

INTRON A 18 milioane U.I. 18 milioane U.I. SP EUROPE

L03AB05 INTERFERONUM ALFA 2b SOL. INJ. PEN MULTIDOZA 30 milioane U.I.

INTRON A 30 milioane U.I. 30 milioane U.I. SP EUROPE

INTRON A 60 milioane U.I. 60 milioane U.I. SP EUROPE

L03AB05 INTERFERONUM ALFA 2b SOL. INJ. PEN MULTIDOZA 60 milioane U.I.

INTRON A 30 milioane U.I. 30 milioane U.I. SP EUROPE

INTRON A 60 milioane U.I. 60 milioane U.I. SP EUROPE

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| **777** |**M05BA02**| **ACIDUM CLODRONICUM\*\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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M05BA02 ACIDUM CLODRONICUM CAPS. 400 mg

BONEFOS(R) 400 mg 400 mg SCHERING OY (SCHERING AG)

SINDRONAT(R) 400 mg 400 mg ACTAVIS S.R.L.

Prescriere limitată: **Metastaze osoase consecutive cancerului de sân.**

Prescriere limitată: **Tratament de întreţinere în hipercalcemia din cancerele refractare la terapia antineoplazică**

Prescriere limitată: **Mielomul multiplu**

M05BA02 ACIDUM CLODRONICUM CONC. PT. SOL. PERF. 60 mg/ml

BONEFOS(R) 60 mg/ml 60 mg/ml SCHERING OY

Prescriere limitată: **Tratamentul hipercalcemiei asociată cancerului**

M05BA02 ACIDUM CLODRONICUM COMPR. FILM. 800 mg

BONEFOS(R) 800 mg 800 mg SCHERING OY

Prescriere limitată: **Metastaze osoase consecutive cancerului de sân.**

Prescriere limitată: **Tratament de întreţinere în hipercalcemia din cancerele refractare la terapia antineoplazică**

Prescriere limitată: **Mielomul multiplu**

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| **778** |**M05BA03**| **ACIDUM PAMIDRONICUM\*\*** | |

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Prescriere limitată: **Metastaze osoase consecutive cancerului de sân.**

**Tratament de întreţinere în hipercalcemia din cancerele**

**refractare la terapia antineoplazică.**

**Mielomul multiplu.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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M05BA03 ACIDUM PAMIDRONICUM LIOF. + SOLV. PT. SOL. 15 mg

PERF.

AREDIA(R) 15 mg 15 mg NOVARTIS PHARMA GMBH

M05BA03 ACIDUM PAMIDRONICUM CONC. PT. SOL. PERF. 15 mg/ml

PAMIDRONAT TORREX 15 mg/ml TORREX CHIESI PHARMA GMBH

M05BA03 ACIDUM PAMIDRONICUM LIOF. PT. SOL. PERF. 30 mg

I.V.

PAMIRED 30 30 mg DR. REDDY'S LABORATORIES

M05BA03 ACIDUM PAMIDRONICUM LIOF. PT. SOL. PERF. 60 mg

I.V.

PAMIRED 60 60 mg DR. REDDY'S LABORATORIES

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| **779** |**M05BA06**| **ACIDUM IBANDRONICUM\*\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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M05BA06 ACIDUM IBANDRONICUM COMPR. FILM. 50 mg

BONDRONAT 50 mg 50 mg ROCHE REGISTRATION LTD.

Prescriere limitată: **Prevenţia afectării osoase (fracturi patologice, complicaţii osoase care necesită radioterapie sau intervenţii chirurgicale) la pacienţii cu cancer de sân şi metastaze osoase.**

M05BA06 ACIDUM IBANDRONICUM CONC. PT. SOL. PERF. 6 mg/6 ml

BONDRONAT 6 mg/6 ml 6 mg/6 ml ROCHE REGISTRATION LTD.

Prescriere limitată: **Prevenţia afectării osoase (fracturi patologice, complicaţii osoase care necesită radioterapie sau intervenţii chirurgicale) la pacienţii cu cancer de sân şi metastaze osoase.**

Prescriere limitată: **Tratamentul hipercalcemiei induse de tumoră cu sau fără metastaze osoase.**

M05BA06 ACIDUM IBANDRONICUM SOL. INJ. IN SERINGA 3 mg/3 ml

PREUMPLUTA

BONVIVA 3 mg/3 ml 3 mg/3 ml ROCHE REGISTRATION LTD

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| **780** |**M05BA08**| **ACIDUM ZOLEDRONICUM\*\*** | |

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Prescriere limitată: **Prevenirea manifestărilor osoase (fracturi patologice,**

**compresie spinală, iradiere sau chirurgie osoasă sau**

**hipercalcemie indusă de tumori) la pacienţi cu tumori**

**maligne avansate, cu implicare osoasă.**

**Tratamentul hipercalcemiei induse de tumori.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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M05BA08 ACIDUM ZOLEDRONICUM PULB. + SOLV. SOL. 4 mg

PERF.

ZOMETA 4 mg 4 mg NOVARTIS EUROPHARM LTD.

M05BA08 ACIDUM ZOLEDRONICUM SOL. PERF. 5 mg/100 ml

ACLASTA 5 mg/100 ml 5 mg/100 ml NOVARTIS EUROPHARM LTD.

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| **781** |**V03AF01**| **MESNUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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V03AF01 MESNUM SOL. INJ. 400 mg/4 ml

UROMITEXAN(R) 400 mg 400 mg/4 ml BAXTER ONCOLOGY GMBH

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| **782** |**V03AF03**| **CALCII FOLINAS** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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V03AF03 CALCII FOLINAS SOL. INJ. 10 mg/ml

FOLCASIN 10 mg/ml 10 mg/ml ACTAVIS S.R.L.

FOLCASIN(R) 100 mg/10 ml 10 mg/ml ACTAVIS S.R.L.

LEUCOVORIN-TEVA 100 mg/10 ml 10 mg/ml TEVA PHARM. IND. LTD.

LEUCOVORIN-TEVA 50 mg/5 ml 10 mg/ml TEVA PHARMACEUTICALS

S.R.L.

V03AF03 CALCII FOLINAS SOL. INJ. 10 mg/ml

FOLCASIN 10 mg/ml 10 mg/ml ACTAVIS S.R.L.

FOLCASIN(R) 100 mg/10 ml 10 mg/ml ACTAVIS S.R.L.

LEUCOVORIN-TEVA 100 mg/10 ml 10 mg/ml TEVA PHARM. IND. LTD.

LEUCOVORIN-TEVA 50 mg/5 ml 10 mg/ml TEVA PHARMACEUTICALS

S.R.L.

V03AF03 CALCII FOLINAS SOL. INJ./PERF. 10 mg/ml

CALCIUMFOLINAT 10 mg/ml EBEWE PHARMA GMBH NFG. KG

"EBEWE" 10 mg/ml

V03AF03 CALCII FOLINAS CAPS. 15 mg

CALCIUM FOLINAT 15 mg EBEWE PHARMA GES.M.B.H.

"EBEWE" 15 mg NFG KG

V03AF03 CALCII FOLINAS SOL. INJ. 3 mg/ml

FOLCASIN(R) 30 mg/10 ml 3 mg/ml ACTAVIS S.R.L.

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| **783** |**V03AF05**| **AMIFOSTINUM\*\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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V03AF05 AMIFOSTINUM LIOF. PT. SOL. PERF. 375 mg

ETHYOL 375 mg SCHERING PLOUGH EUROPE

V03AF05 AMIFOSTINUM LIOF. PT. SOL. PERF. 500 mg

ETHYOL(R) 500 mg SCHERING PLOUGH EUROPE

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**SUBLISTA C2 - P4: PROGRAMUL NAŢIONAL DE BOLI NEUROLOGICE. SUBPROGRAMUL DE TRATAMENT AL SCLEROZEI MULTIPLE**

**Protocol: L002G**

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| **784** |**L03AB07**| **INTERFERONUM BETA 1a\*\*\*\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L03AB07 INTERFERONUM BETA 1a SOL. INJ. 22 µg/0,5 ml

REBIF 22 µg 22 µg/0,5 ml SERONO EUROPE LTD.

L03AB07 INTERFERONUM BETA 1a PULB. + SOLV. PT. SOL. 30 µg (6 mil. UI)

INJ.

AVONEX 30 µg BIO-SET 30 µg (6 mil. UI) BIOGEN IDEC LIMITED

L03AB07 INTERFERONUM BETA 1a SOL. INJ. 44 µg

REBIF 44 µg 44 µg SERONO EUROPE LTD.

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| **785** |**L03AB08**| **INTERFERONUM BETA 1B\*\*\*\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L03AB08 INTERFERONUM BETA 1B PULB. + SOLV. PT. SOL. 250 µg/ml

INJ.

BETAFERON 250 µg/ml 250 µg/ml BAYER SCHERING AG

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| **786** |**L03AX13**| **GLATIRAMER ACETAT\*\*\*\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L03AX13 GLATIRAMER ACETAT SOL. INJ. 20 mg/ml

COPAXONE 20 mg/ml TEVA PHARMACEUTICALS

S.R.L.

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| **787** |**L04AA23**| **NATALIZUMABUM\*\*\*\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L04AA23 NATALIZUMABUM CONC. PT. SOL. PERF. 20 mg/ml

TYSABRI 300 mg 20 mg/ml ELAN PHARMA INTERNATIONAL

LTD

A fost raportat la acest medicament leucoencefalopatie multifocală progresivă.

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| **788** |**L04AX01**| **AZATHIOPRINUM\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L04AX01 AZATHIOPRINUM COMPR. FILM. 50 mg

IMURAN(R) 50 mg THE WELLCOME FOUNDATION

LTD.

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**SUBLISTA C2 - P5: PROGRAMUL NAŢIONAL DE DIABET ZAHARAT.**

**Protocol: AE01E**

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| **789** |**A10AB01**| **INSULINE UMANE** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A10AB01 INSULINE UMANE SOL. INJ. 100 UI/ml

HUMULIN R 100 UI/ml LILLY FRANCE SAS

A10AB01 INSULINE UMANE SOL. INJ. 100 UI/ml

HUMULIN R 100 UI/ml LILLY FRANCE SAS

A10AB01 INSULINE UMANE SOL. INJ. ÎN CARTUŞ 100 UI/ml

ACTRAPID PENFILL 100 UI/ml 100 UI/ml NOVO NORDISK A/S

INSUMAN RAPID 100 UI/ml 100 UI/ml SANOFI - AVENTIS

DEUTSCHLAND GMBH

A10AB01 INSULINE UMANE SOL. INJ. ÎN FLACON 100 UI/ml

ACTRAPID 100 UI/ml 100 UI/ml NOVO NORDISK A/S

INSUMAN RAPID 100 UI/ml 100 UI/ml SANOFI - AVENTIS

DEUTSCHLAND GMBH

A10AB01 INSULINE UMANE SOL. INJ. ÎN FLACON 100 UI/ml

ACTRAPID 100 UI/ml 100 UI/ml NOVO NORDISK A/S

INSUMAN RAPID 100 UI/ml 100 UI/ml SANOFI - AVENTIS

DEUTSCHLAND GMBH

A10AB01 INSULINE UMANE SOL. INJ. ÎN STILOU 100 UI/ml

INJECTOR PREUMPLUT

ACTRAPID NOVOLET 100 UI/ml 100 UI/ml NOVO NORDISK A/S

INSUMAN RAPID 100 UI/ml SANOFI - AVENTIS

100 UI/ml OPTISET DEUTSCHLAND GMBH

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| **790** |**A10AB04**| **INSULINUM LISPRO\*\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A10AB04 INSULINUM LISPRO SOL. INJ. 100 U/ml

HUMALOG 100 U/ml 100 U/ml ELI LILLY NEDERLAND BV

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| **791** |**A10AB05**| **INSULINUM ASPART\*\*** | **Protocol: A016E** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A10AB05 INSULINUM ASPART SOL. INJ. ÎN CARTUŞ 100 Uml

NOVORAPID PENFILL 100 U/ml 100 Uml NOVO NORDISK A/S

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| **792** |**A10AB06**| **INSULINUM GLULIZINA\*\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A10AB06 INSULINUM GLULIZINA SOL. INJ. ÎN CARTUŞ 100 U/ml

APIDRA 100 U/ml 100 U/ml SANOFI - AVENTIS

DEUTSCHLAND GMBH

A10AB06 INSULINUM GLULIZINA SOL. INJ. ÎN FLACON 100 U/ml

APIDRA 100 U/ml 100 U/ml SANOFI - AVENTIS

DEUTSCHLAND GMBH

A10AB06 INSULINUM GLULIZINA SOL. INJ. ÎN STILOU 100 U/ml

INJECTOR PREUMPLUT

APIDRA 100 U/ml 100 U/ml SANOFI - AVENTIS

DEUTSCHLAND GMBH

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| **793** |**A10AC01**| **INSULINE UMANE** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A10AC01 INSULINE UMANE SUSP. INJ. 100 UI/ml

HUMULIN N 100 UI/ml LILLY FRANCE SAS

A10AC01 INSULINE UMANE SUSP. INJ. ÎN STILOU 100 UI/ml

INJECTOR PREUMPLUT

INSULATARD NOVOLET 100 UI/ml 100 UI/ml NOVO NORDISK A/S

INSUMAN BASAL 100 UI/ml SANOFI - AVENTIS

100 UI/ml OPTISET DEUTSCHLAND GMBH

A10AC01 INSULINE UMANE SUSP. INJ. ÎN CARTUŞ 100 UI/ml

INSULATARD PENFILL 100 UI/ml 100 UI/ml NOVO NORDISK A/S

INSUMAN BASAL 100 UI/ml 100 UI/ml SANOFI - AVENTIS

DEUTSCHLAND GMBH

A10AC01 INSULINE UMANE SUSP. INJ. ÎN FLACON 100 UI/ml

INSULATARD 100 UI/ml 100 UI/ml NOVO NORDISK A/S

INSUMAN BASAL 100 UI/ml 100 UI/ml SANOFI - AVENTIS

DEUTSCHLAND GMBH

A10AC01 INSULINE UMANE SUSP. INJ. ÎN FLACON 100 UI/ml

INSULATARD 100 UI/ml 100 UI/ml NOVO NORDISK A/S

INSUMAN BASAL 100 UI/ml 100 UI/ml SANOFI - AVENTIS

DEUTSCHLAND GMBH

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| **794** |**A10AC04**| **INSULINUM LISPRO\*\*** | **Protocol: A029E** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A10AC04 INSULINUM LISPRO SOL. INJ. 100 U/ml

HUMALOG NPL 100 U/ml 100 U/ml ELI LILLY NEDERLAND BV

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| **795** |**A10AD01**| **INSULINE UMANE** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A10AD01 INSULINE UMANE SUSP. INJ.

HUMULIN M3 100 ui/ml LILLY FRANCE S.A.S.

A10AD01 INSULINE UMANE SUSP. INJ. ÎN STILOU 100 UI/ml

INJECTOR PREUMPLUT

INSUMAN COMB 25 100 UI/ml SANOFI - AVENTIS

100 UI/ml OPTISET DEUTSCHLAND GMBH

INSUMAN COMB 50 100 UI/ml SANOFI - AVENTIS

100 UI/ml OPTISET DEUTSCHLAND GMBH

MIXTARD 30 NOVOLET 100 Ul/ml 100 UI/ml NOVO NORDISK A/S

A10AD01 INSULINE UMANE SUSP. INJ. ÎN CARTUŞ 100 UI/ml

INSUMAN COMB 25 100 UI/ml 100 UI/ml SANOFI - AVENTIS

DEUTSCHLAND GMBH

INSUMAN COMB 50 100 UI/ml 100 UI/ml SANOFI - AVENTIS

DEUTSCHLAND GMBH

MIXTARD 20 PENFILL 100 UI/ml 100 UI/ml NOVO NORDISK A/S

MIXTARD 30 PENFILL 100 UI/ml 100 UI/ml NOVO NORDISK A/S

MIXTARD 40 PENFILL 100 UI/ml 100 UI/ml NOVO NORDISK A/S

A10AD01 INSULINE UMANE SUSP. INJ. ÎN FLACON 100 UI/ml

INSUMAN COMB 25 100 UI/ml 100 UI/ml SANOFI - AVENTIS

DEUTSCHLAND GMBH

INSUMAN COMB 50 100 UI/ml 100 UI/ml SANOFI - AVENTIS

DEUTSCHLAND GMBH

MIXTARD 30 100 UI/ml 100 UI/ml NOVO NORDISK A/S

A10AD01 INSULINE UMANE SUSP. INJ. ÎN FLACON 100 UI/ml

INSUMAN COMB 25 100 UI/ml 100 UI/ml SANOFI - AVENTIS

DEUTSCHLAND GMBH

INSUMAN COMB 50 100 UI/ml 100 UI/ml SANOFI - AVENTIS

DEUTSCHLAND GMBH

MIXTARD 30 100 UI/ml 100 UI/ml NOVO NORDISK A/S

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| **796** |**A10AD04**| **INSULINUM LISPRO\*\*** | **Protocol: A015E** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A10AD04 INSULINUM LISPRO SUSP. INJ. 100 U/ml

HUMALOG MIX25 100 U/ml ELI LILLY NEDERLAND BV

HUMALOG MIX50 100 U/ml ELI LILLY NEDERLAND BV

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| **797** |**A10AD05**| **INSULINUM ASPART\*\*** | **Protocol: A018E** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A10AD05 INSULINUM ASPART SUSP. INJ. ÎN STILOU 100 UIml

INJECTOR PREUMPLUT

NOVOMIX 30 FLEXPEN 100 UIml NOVO NORDISK A/S

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| **798** |**A10AE04**| **INSULINUM GLARGINE\*\*** | **Protocol: A024E** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A10AE04 INSULINUM GLARGINE SOL. INJ. ÎN CARTUŞ 100 UI/ml

LANTUS 100 UI/ml 100 UI/ml SANOFI - AVENTIS

DEUTSCHLAND GMBH

A10AE04 INSULINUM GLARGINE SOL. INJ. ÎN FLACON 100 UI/ml

LANTUS 100 UI/ml 10O UI/ml SANOFI - AVENTIS

DEUTSCHLAND GMBH

A10AE04 INSULINUM GLARGINE SOL. INJ. ÎN STILOU 100 UI/ml

INJECTOR PREUMPLUT

LANTUS OptiSet 10O UI/ml SANOFI - AVENTIS

DEUTSCHLAND GMBH

LANTUS SoloStar 10O UI/ml SANOFI - AVENTIS

DEUTSCHLAND GMBH

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| **799** |**A10AE05**| **INSULINUM DETEMIR\*\*** | **Protocol: A023E** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A10AE05 INSULINUM DETEMIR SOL. INJ. ÎN CARTUŞ 100 U/ml

LEVEMIR PENFILL 100 U/ml 100 U/ml NOVO NORDISK A/S

A10AE05 INSULINUM DETEMIR SOL. INJ. ÎN STILOU 100 U/ml

INJECTOR PREUMPLUT

LEVEMIR FLEXPEN 100 U/ml 100 U/ml NOVO NORDISK A/S

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| **800** |**A10BA02**| **METFORMINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A10BA02 METFORMINUM COMPR. 1000 mg

METFORMIN 1000 mg 1000 mg ARENA GROUP SA

A10BA02 METFORMINUM COMPR. FILM. 1000 mg

GLUCOPHAGE 1000 mg 10OO mg MERCK SANTE

METFOGAMMA 1000 mg 1000 mg WORWAG PHARMA

GMBH & CO. KG

SIOFOR 1000 1000 mg BERLIN CHEME AG MENARINI

GROUP

A10BA02 METFORMINUM COMPR. PT. SOL. ORALA 1000 mg

FORMIRAN 1000 mg 1000 mg TERAPIA SA

A10BA02 METFORMINUM COMPR. 500 mg

DIGUAN(R) 500 mg 500 mg ZENTIVA SA

METFORMIN 500 mg 500 mg ARENA GROUP SA

A10BA02 METFORMINUM COMPR. ELIB. PREL 500 mg

GLUCOPHAGE XR 500 mg MERCK SANTE S.A.S.

A10BA02 METFORMINUM COMPR. FILM. 500 mg

DIPIMET 500 mg 500 mg ANTIBIOTICE SA

GLUCOPHAGE 500 500 mg MERCK SANTE

MEGUAN(R) 500 mg 500 mg GEDEON RICHTER ROMANIA SA

METFOGAMMA(R) 500 500 mg WORWAG PHARMA

GMBH & CO. KG

METFORMIN AL 500 500 mg ALIUD PHARMA GMBH & CO. KG

METFORMIN LPH(R) 500 mg 500 mg LABORMED PHARMA SA

METFORMIN-TEVA 500 mg 500 mg TEVA PHARMACEUTICAL S.R.L.

A10BA02 METFORMINUM COMPR. PT. SOL. ORALA 500 mg

FORMIRAN 500 mg 500 mg TERAPIA S.A.

A10BA02 METFORMINUM COMPR. 850 mg

DIAFORMIN(R) 850 mg 850 mg TERAPIA SA

METFORMIN 850 mg 850 mg ARENA GROUP SA

A10BA02 METFORMINUM COMPR. FILM. 850 mg

GLUCOPHAGE 850 mg 850 mg MERCK SANTE

MEDIFOR 850 850 mg STD CHEMICALS LTD.

MEGUAN(R) 850 mg 850 mg GEDEON RICHTER ROMANIA SA

METFOGAMMA 850 850 mg WORWAG PHARMA

GMBH & CO. KG

METFORMIN AL 850 850 mg ALIUD PHARMA GMBH & CO. KG

METFORMIN LPH(R) 850 mg 850 mg LABORMED PHARMA SA

METFORMIN-TEVA 850 mg 850 mg TEVA PHARMACEUTICAL S.R.L.

SIOFOR(R) 850 850 mg BERLIN CHEME AG MENARINI

GROUP

A10BA02 METFORMINUM COMPR. PT. SOL. ORALA 850 mg

FORMIRAN 850 mg 850 mg TERAPIA S.A.

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| **801** |**A10BA03**| **BUFORMINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A10BA03 BUFORMINUM DRAJ. RET. 100 mg

SILUBIN RETARD 100 mg DITA IMPORT EXPORT SRL

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| **802** |**A10BB01**| **GLIBENCLAMIDUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A10BB01 GLIBENCLAMIDUM COMPR. 1,75 mg

GLIBENCLAMID 1,75 mg ANTIBIOTICE S.A.

ANTIBIOTICE 1,75 mg

A10BB01 GLIBENCLAMIDUM COMPR. 1.75 mg

GLIBENCIAMID LPH 1,75 mg 1.75 mg LABORMED PHARMA SA

GLIBENCLAMID ARENA 1,75 mg 1.75 mg ARENA GROUP SA

MANINIL 1,75 mg 1.75 mg BERLIN CHEME AG MENARINI

GROUP

A10BB01 GLIBENCLAMIDUM COMPR. 3,5 mg

GLIBENCIAMID 3,5 mg ANTIBIOTICE SA

ANTIBIOTICE 3,5 mg

A10BB01 GLIBENCLAMIDUM COMPR. 3.5 mg

GLIBENCIAMID ARENA 3,5 mg 3.5 mg ARENA GROUP SA

GLIBENCIAMID LPH 3,5 mg 3.5 mg LABORMED PHARMA SA

MANINIL 3,5 mg 3.5 mg BERLIN CHEME AG MENARINI

GROUP

A10BB01 GLIBENCLAMIDUM COMPR. 5 mg

GLIBENCIAMID 5 mg 5 mg ARENA GROUP SA

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| **803** |**A10BB03**| **TOLBUTAMIDUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A10BB03 TOLBUTAMIDUM COMPR. 500 mg

TOLBUTAMID 500 mg SINTOFARM SA

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| **804** |**A10BB07**| **GLIPIZIDUM** | |

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Sulfonilurea poate cauza hipoglicemie, în mod particular la vârstnici.

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A10BB07 GLIPIZIDUM COMPR. FILM. ELIB. 10 mg

MODIF.

GLUCOTROL XL 10 mg 10 mg PFIZER EUROPE MA EEIG

A10BB07 GLIPIZIDUM COMPR. 5 mg

GLIPIZID LPH 5 mg 5 mg LABORMED PHARMA SA

A10BB07 GLIPIZIDUM COMPR. FILM. ELIB. 5 mg

MODIF.

GLUCOTROL XL 5 mg 5 mg PFIZER EUROPE MA EEIG

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| **805** |**A10BB08**| **GLIQUIDONUM** | |

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Sulfonilurea poate cauza hipoglicemie, în mod particular la vârstnici.

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A10BB08 GLIQUIDONUM COMPR. 30 mg

GLURENORM 30 mg BOEHRINGER INGELHEIM INT.

GMBH

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| **806** |**A10BB09**| **GLICLAZIDUM** | |

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Sulfonilurea poate cauza hipoglicemie, în mod particular la vârstnici

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A10BB09 GLICLAZIDUM COMPR. ELIB. MODIF. 30 mg

DIAPREL MR 30 mg LES LABORATOIRES SERVER

A10BB09 GLICLAZIDUM COMPR. ELIB. PREL 30 mg

GLICLAZID MR LPH 30 mg 30 mg LABORMED PHARMA SA

A10BB09 GLICLAZIDUM COMPR. 80 mg

DIABREZIDE 80 mg L. MOLTENI

ESQUEL(R) 80 mg 80 mg GEDEON RICHTER ROMANIA SA

GLICLAZID LPH 80 mg LABORMED PHARMA SA

GLIDIET 80 mg MEDICAROM GROUP S.R.L.

A10BB09 GLICLAZIDUM COMPR. DIVIZ. 80 mg

DIAPREL 80 mg LES LABORATOIRES SERVER

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| **807** |**A10BB12**| **GLIMEPIRIDUM** | |

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Sulfonilurea poate cauza hipoglicemie, în mod particular la vârstnici

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A10BB12 GLIMEPIRIDUM COMPR. 1 mg

AMYX 1 1 mg ZENTIVA A.S.

A10BB12 GLIMEPIRIDUM COMPR. 1 mg

AMARYL 1 mg 1 mg AVENTIS PHARMA DEUTSCHLAND

GLEMPID 1 mg 1 mg EGIS PHARMACEUTICALS

P.L.C.

GLIME TAD 1 mg 1 mg TAD PHARMA GMBH

GLIMEPIRID LPH 1 mg 1 mg LABORMED PHARMA SA

GLIMERAN 1 mg 1 mg RANBAXY UK LIMITED

GLIPREX 1 mg 1 mg MEDICO UNO PHARMACEUTICAL

SRL

MEGLIMID 1 mg 1 mg KRKA D.D.

OLTAR 1 mg 1 mg BERLIN CHEME AG (MENARINI

GROUP)

TINERIL 1 mg 1 mg GEDEON RICHTER ROMANIA

S.A.

A10BB12 GLIMEPIRIDUM COMPR. 2 mg

AMARYL 2 mg 2 mg AVENTIS PHARMA DEUTSCHLAND

AMYX 2 2 mg ZENTIVA A.S.

DIBIGLIM 2 mg 2 mg SANDOZ SRL

GLEMPID 2 mg 2 mg EGIS PHARMACEUTICALS

P.L.C.

GLIME TAD 2 mg 2 mg TAD PHARMA GMBH

GLIMEPIRID LPH 2 mg 2 mg LABORMED PHARMA SA

GLIMEPIRIDE 2 mg 2 mg ACTAVIS GROUP HF.

GLIMERAN 2 mg 2 mg RANBAXY UK LIMITED

GLIPREX 2 mg 2 mg MEDICO UNO PHARMACEUTICAL

SRL

MEGLIMID 2 mg 2 mg KRKA D.D.

TINERIL 2 mg 2 mg GEDEON RICHTER ROMANIA

S.A.

A10BB12 GLIMEPIRIDUM COMPR. 3 mg

AMARYL 3 mg 3 mg AVENTIS PHARMA DEUTSCHLAND

AMYX 3 3 mg ZENTIVA A.S.

DIBIGLIM 3 mg 3 mg SANDOZ SRL

GLEMPID 3 mg 3 mg EGIS PHARMACEUTICALS

P.L.C.

GLIME TAD 3 mg 3 mg TAD PHARMA GMBH

GLIMEPIRID LPH 3 mg 3 mg LABORMED PHARMA SA

GLIMEPIRIDE 3 mg 3 mg ACTAVIS GROUP HF.

GLIMERAN 3 mg 3 mg RANBAXY UK LIMITED

GLIPREX 3 mg 3 mg MEDICO UNO PHARMACEUTICAL

SRL

MEGLIMID 3 mg 3 mg KRKA D.D.

OLTAR 3 mg 3 mg BERLIN CHEME AG (MENARINI

GROUP)

TINERIL 3 mg 3 mg GEDEON RICHTER ROMANIA

S.A.

A10BB12 GLIMEPIRIDUM COMPR. 4 mg

AMYX 4 4 mg ZENTIVA A.S.

GLEMPID 4 mg 4 mg EGIS PHARMACEUTICALS

P.L.C.

GLIMERAN 4 mg 4 mg RANBAXY UK LIMITED

GLIPREX 4 mg 4 mg MEDICO UNO PHARMACEUTICAL

SRL

MEGLIMID 4 mg 4 mg KRKA D.D.

A10BB12 GLIMEPIRIDUM COMPR. 6 mg

MEGLIMID 6 mg 6 mg KRKA D.D.

A10BB12 GLIMEPIRIDUM COMPR. 4 mg

TINERIL 4 mg 4 mg GEDEON RICHTER ROMANIA

S.A.

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| **808** |**A10BD02**| **COMBINATII (GLIBENCLAMIDUM + METFORMINUM)** | **Protocol: A027E** |

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Sulfonilurea poate cauza hipoglicemie, în mod particular la vârstnici

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A10BD02 COMBINATII COMPR. FILM. 2,5 mg/400 mg

(GLIBENCLAMIDUM +

METFORMINUM)

GLIBOMET(R) 2,5 mg/400 mg LAB. GUIDOTTI SPA

A10BD02 COMBINATII COMPR. FILM. 400 mg + 2.5 mg

(GLIBENCLAMIDUM +

METFORMINUM)

GLIFORMIN 400 mg + 2.5 mg LABORMED PHARMA SA

A10BD02 COMBINATII CAPS. 400 mg + 2.5 mg

(GLIBENCLAMIDUM +

METFORMINUM)

BIDIAB 400 mg + 2.5 mg ARENA GROUP SA

A10BD02 COMBINATII COMPR. FILM. 500 mg/2.5 mg

(GLIBENCLAMIDUM +

METFORMINUM)

GLUCOVANCE(R) 500 mg/2.5 mg 500 mg/2.5 mg MERCK SANTE

A10BD02 COMBINATII COMPR. FILM. 500 mg/5 mg

(GLIBENCLAMIDUM +

METFORMINUM)

GLUCOVANCE(R) 500 mg/5 mg 500 mg/5 mg MERCK SANTE

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| **809** |**A10BD03**| **COMBINATII (ROSIGLITAZONUM +** | **Protocol: A026E** |

| | | **METFORMINUM)\*\*\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A10BD03 COMBINATII COMPR. FILM. 1 mg/500 mg

(ROSIGLITAZONUM +

METFORMINUM)

AVANDAMET 1 mg/500 mg 1 mg/500 mg SMITHKLINE BEECHAM PLC

A10BD03 COMBINATII COMPR. FILM. 2 mg/1000 mg

(ROSIGLITAZONUM +

METFORMINUM)

AVANDAMET 2 mg/1000 mg 2 mg/1000 mg SMITHKLINE BEECHAM PLC

A10BD03 COMBINATII COMPR. FILM. 2 mg/500 mg

(ROSIGLITAZONUM +

METFORMINUM)

AVANDAMET 2 mg/500 mg 2 mg/500 mg SMITHKLINE BEECHAM PLC

A10BD03 COMBINATII COMPR. FILM. 4 mg/1000 mg

(ROSIGLITAZONUM +

METFORMINUM)

AVANDAMET 4 mg/1000 mg 4 mg/1000 mg SMITHKLINE BEECHAM PLC

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| **810** |**A10BD04**| **COMBINATII (ROSIGLITAZONUM +** | **Protocol: A027E** |

| | | **GLIMEPIRIDUM)\*\*\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A10BD04 COMBINATII COMPR. FILM. 4 mg/4 mg

(ROSIGLITAZONUM +

GLIMEPIRIDUM)

AVAGLIM 4 mg/4 mg 4 mg/4 mg SMITHKLINE BEECHAM PLC

A10BD04 COMBINATII COMPR. FILM. 8 mg/4 mg

(ROSIGLITAZONUM +

GLIMEPIRIDUM)

AVAGLIM 8 mg/4 mg 8 mg/4 mg SMITHKLINE BEECHAM PLC

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| **811** |**A10BD05**| **COMBINATII (PIOGLITAZONUM + METFORMINUM)\*\*\***| **Protocol: A025E** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A10BD05 COMBINATII COMPR. FILM. 15 mg/850 mg

(PIOGLITAZONUM +

METFORMINUM)

COMPETACT 15 mg/850 mg TAKEDA GLOBAL RESEARCH AND

DEVELOPMENT CENTRE LTD

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| **812** |**A10BF01**| **ACARBOSUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A10BF01 ACARBOSUM COMPR. 100 mg

GLUCOBAY(R) 100 100 mg BAYER HEALTHCARE AG

A10BF01 ACARBOSUM COMPR. 50 mg

GLUCOBAY(R) 50 50 mg BAYER HEALTHCARE AG

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| **813** |**A10BG02**| **ROSIGLITAZONUM\*\*\*** | **Protocol: A020E** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A10BG02 ROSIGLITAZONUM COMPR. FILM. 4 mg

AVANDIA 4 mg 4 mg SMITHKLINE BEECHAM PLC

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| **814** |**A10BG03**| **PIOGLITAZONUM\*\*\*** | **Protocol: A020E** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A10BG03 PIOGLITAZONUM COMPR. 15 mg

ACTOS 15 mg 15 mg TAKEDA GLOBAL RESEARCH AND

DEVELOPMENT CENTRE LTD

A10BG03 PIOGLITAZONUM COMPR. 30 mg

ACTOS 30 mg 30 mg TAKEDA GLOBAL RESEARCH AND

DEVELOPMENT CENTRE LTD

A10BG03 PIOGLITAZONUM COMPR. 45 mg

ACTOS 45 mg 45 mg TAKEDA GLOBAL RESEARCH AND

DEVELOPMENT CENTRE LTD

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| **815** |**A10BH01**| **SITAGLIPTINUM\*\*\*** | **Protocol: A022E** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A10BH01 SITAGLIPTINUM COMPR. FILM. 100 mg

JANUVIA 100 mg 100 mg MERCK SHARP & DOHME LTD.

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| **816** |**A10BX02**| **REPAGLINIDUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A10BX02 REPAGLINIDUM COMPR. 0.5 mg

NOVONORM 0.5 mg 0.5 mg NOVO NORDISK A/S

A10BX02 REPAGLINIDUM COMPR. 1 mg

NOVONORM 1 mg 1 mg NOVO NORDISK A/S

A10BX02 REPAGLINIDUM COMPR. 2 mg

NOVONORM 2 mg 2 mg NOVO NORDISK A/S

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| **817** |**A10BX04**| **EXENATIDUM\*\*\*** | **Protocol: A028E** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A10BX04 EXENATIDUM SOL. INJ. IN STILOU 10 µg/doza

INJECTOR PREUMPLUT

BYETTA 10 µg/doza 10 µg/doza ELI LILLY NEDERLAND BV

A10BX04 EXENATIDUM SOL. INJ. IN STILOU 5 µg/doza

INJECTOR PREUMPLUT

BYETTA 5 µg/doza 5 µg/doza ELI LILLY NEDERLAND BV

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| **818** |**A11DA03**| **BENFOTIAMINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A11DA03 BENFOTIAMINUM DRAJ. 50 mg

BENFOGAMMA 50 mg WORWAG PHARMA GMBH & CO.

KG

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| **819** |**A11DBN1**| **COMBINATII\*\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A11DBN1 COMBINATII CAPS. MOI

MILGAMMA(R) N WORWAG PHARMA GMBH & CO.

KG

A11DBN1 COMBINATII SOL. INJ.

MILGAMMA(R) N WORWAG PHARMA GMBH & CO.

KG

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| **820** |**H04AA01**| **GLUCAGONUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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H04AA01 GLUCAGONUM PULB. + SOLV. PT. SOL. 1 mg

INJ.

GLUCAGEN HYPOKIT 1 mg 1 mg NOVO NORDISK A/S

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**SUBLISTA C2 - P6: PROGRAMUL NAŢIONAL DE HEMOFILIE, TALASEMIE ŞI ALTE BOLI RARE. P6.1: HEMOFILIE ŞI TALASEMIE**

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| **827** |**V03AC01**| **DEFEROXAMINUM\*\*(3)** | **Protocol: V001D** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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V03AC01 DEFEROXAMINUM LIOF. PT. SOL. 500 mg

INJ./PERF.

DESFERAL 500 mg NOVARTIS PHARMA GMBH

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| **828** |**V03AC03**| **DEFERASIROXUM\*\*\*\*** | **Protocol: V002D** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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V03AC03 DEFERASIROXUM COMPR. DISP. 125 mg

EXJADE 125 mg 125 mg NOVARTIS EUROPHARM LTD.

V03AC03 DEFERASIROXUM COMPR. DISP. 250 mg

EXJADE 250 mg 250 mg NOVARTIS EUROPHARM LTD.

V03AC03 DEFERASIROXUM COMPR. DISP. 500 mg

EXJADE 500 mg 500 mg NOVARTIS EUROPHARM LTD.

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**SUBLISTA C2 - P6: PROGRAMUL NAŢIONAL DE HEMOFILIE, TALASEMIE ŞI ALTE BOLI RARE. P6.2: EPIDERMOLIZA BULOASĂ**

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| **830** |**D06AA04**| **TETRACYCLINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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D06AA04 TETRACYCLINUM UNGUENT 3,00%

TETRACICLINA CLORHIDRAT 3% ANTIBIOTICE SA

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| **831** |**D06AX01**| **ACIDUM FUSIDICUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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D06AX01 ACIDUM FUSIDICUM CREMA 2,00%

FUCIDIN(R) 2% LEO PHARMACEUTICAL

PRODUCTS

D06AX01 ACIDUM FUSIDICUM UNGUENT 2,00%

FUCIDIN(R) 2% LEO PHARMACEUTICAL

PRODUCTS

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| **832** |**D06BA01**| **SULFADIAZINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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D06BA01 SULFADIAZINUM CREMA 1,00%

DERMAZIN(R) 1% 1% LEK PHARMACEUTICALS D.D.

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| **833** |**D07CA01**| **COMBINATII (ACIDUM FUSIDICUM +** | **Protocol: D001L** |

| | | **HYDROCORTISONUM)** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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D07CA01 COMBINATII (ACIDUM CREMA

FUSIDICUM +

HYDROCORTISONUM)

FUCIDIN(R) H LEO PHARMACEUTICAL

PRODUCTS

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| **834** |**D07CC01**| **COMBINATII** | **Protocol: D001L** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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D07CC01 COMBINATII CREMA

BELOGENT A & G MED TRADING S.R.L.

DIPROGENTA(R) SCHERING PLOUGH EUROPE

TRIDERM(R) SCHERING PLOUGH EUROPE

D07CC01 COMBINATII UNGUENT

BELOGENT A & G MED TRADING S.R.L.

DIPROGENTA(R) SCHERING PLOUGH EUROPE

TRIDERM SCHERING PLOUGH EUROPE

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| **836** |**J01AA07**| **TETRACYCLINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01AA07 TETRACYCLINUM CAPS. 250 mg

TETRACICLINA 250 mg 250 mg EUROPHARM SA

TETRACICLINA SANDOZ 250 mg 250 mg SANDOZ SRL

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| **838** |**N03AB02**| **PHENYTOINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N03AB02 PHENYTOINUM COMPR. 100 mg

FENITOIN 100 mg 100 mg GEDEON RICHTER ROMANIA SA

N03AB02 PHENYTOINUM SOL. INJ. 50 mg/ml

PHENHYDAN(R) SOLUTIE 50 mg/ml DESITIN

INJECTABILA

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**SUBLISTA C2 - P6: PROGRAMUL NAŢIONAL DE HEMOFILIE, TALASEMIE ŞI ALTE BOLI RARE. P6.3: HIPERTENSIUNEA PULMONARĂ**

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| **839** |**C02KX01**| **BOSENTANUM\*\*** | **Protocol: CI01I** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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C02KX01 BOSENTANUM COMPR. FILM. 125 mg

TRACLEER 125 mg 125 mg ACTELION REGISTRATION LTD.

Bosentanum este un medicament care nu trebuie administrat la gravide. Sarcina trebuie evitată timp de trei luni după întreruperea tratamentului.

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| **840** |**G04BE03**| **SILDENAFILUM\*\*** | **Protocol: CI01I** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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G04BE03 SILDENAFILUM COMPR. FILM. 20 mg

REVATIO 20 mg 20 mg PFIZER LTD.

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**SUBLISTA C2 - P6: PROGRAMUL NAŢIONAL DE HEMOFILIE, TALASEMIE ŞI ALTE BOLI RARE. P6.4: MUCOVISCIDOZA**

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| **841** |**J01FA09**| **CLARITHROMYCINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01FA09 CLARITHROMYCINUM GRAN. PT. SUSP. ORALA 125 mg/5 ml

FROMILID(R) 125 mg/5 ml 125 mg/5 ml KRKA D.D.

KLABAX 125 mg/5 ml 125 mg/5 ml TERAPIA S.A.

KLACID(R) 125 mg/5 ml ABBOTT SPA

LEKOKLAR 125 mg/5 ml 125 mg/5 ml SANDOZ S.R.L.

J01FA09 CLARITHROMYCINUM COMPR. FILM. 250 mg

CLAR 250 250 mg MEDICAROM GROUP S.R.L.

CLARITROMICINA 250 mg 250 mg OZONE LABORATORIES LTD.

FROMILID 250 250 mg KRKA D.D. NOVO MESTO

KLABAX 250 mg 250 mg TERAPIA S.A.

KLACID(R) 250 mg ABBOTT SPA

KLERIMED(R) 250 250 mg MEDOCHEMIE LTD.

LEKOKLAR(R) 250 mg 250 mg LEK PHARMACEUTICALS D.D.

J01FA09 CLARITHROMYCINUM GRAN. PT. SUSP. ORALA 250 mg/5 ml

KLABAX 250 mg/5 ml 250 mg/5 ml TERAPIA S.A.

LEKOKLAR 250 mg/5 ml 250 mg/5 ml SANDOZ SRL

J01FA09 CLARITHROMYCINUM COMPR. FILM. 500 mg

CLAR 500 500 mg MEDICAROM GROUP S.R.L.

CLARITROMICINA 500 mg 500 mg OZONE LABORATORIES LTD.

FROMILID 500 500 mg KRKA D.D. NOVO MESTO

KLABAX 500 mg 500 mg TERAPIA S.A.

KLERIMED(R) 500 500 mg MEDOCHEMIE LTD.

LEKOKLAR(R) 500 mg 500 mg LEK PHARMACEUTICALS D.D.

J01FA09 CLARITHROMYCINUM COMPR. FILM. ELIB. 500 mg

MODIF.

KLABAX MR 500 mg 500 mg TERAPIA S.A.

LEKOKLAR XL 500 mg 500 mg LEK PHARMACEUTICALS D.D.

J01FA09 CLARITHROMYCINUM COMPR. FILM. ELIB. PREL 500 mg

FROMILID(R) UNO 500 mg KRKA D.D.

KLACID SR 500 mg ABBOTT LABORATORIES LTD.

J01FA09 CLARITHROMYCINUM LIOF. PT. SOL. PERF. 500 mg

KLACID I.V. 500 mg ABBOTT LABORATORIES LTD.

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| **842** |**J01GB01**| **TOBRAMYCINUM\*\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01GB01 TOBRAMYCINUM SOL. INHAL. 300 mg/5 ml

TOBI(R) 300 mg/5 ml NOVARTIS PHARMA GMBH

Prescriere limitată: **Infecţii cu agent patogen sensibil confirmat pentru acest tip de antibiotic.**

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| **843** |**R05CB13**| **DORNAZA ALFA\*\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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R05CB13 DORNAZA ALFA SOL. INHAL. 1 mg/ml

PULMOZYME 1 mg/ml ROCHE ROMANIA S.R.L.

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**SUBLISTA C2 - P6: PROGRAMUL NAŢIONAL DE HEMOFILIE, TALASEMIE ŞI ALTE BOLI RARE. P6.5: BOLI NEUROLOGICE DEGENERATIVE/INFLAMATORII (POLIRADICULONEVRITA PRIMITIVĂ, POLINEUROPATIE INFLAMATORIE CRONICĂ DEMIELINIZANTĂ, SCLEROZA LATERALĂ AMIOTROFICĂ) ŞI MIASTENIA GRAVIS**

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| **844** |**N07XX02**| **RILUZOLUM\*\*** | **Protocol: N024G** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N07XX02 RILUZOLUM COMPR. FILM. 50 mg

RILUTEK 50 mg 50 mg AVENTIS PHARMA SA

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**SUBLISTA C2 - P6: PROGRAMUL NAŢIONAL DE HEMOFILIE, TALASEMIE ŞI ALTE BOLI RARE. P6.6: OSTEOGENEZA IMPERFECTA**

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| **846** |**M05BA03**| **ACIDUM PAMIDRONICUM** | **Protocol: M002Q** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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M05BA03 ACIDUM PAMIDRONICUM LIOF. + SOLV. PT. SOL. 15 mg

PERF.

AREDIA(R) 15 mg 15 mg NOVARTIS PHARMA GMBH

M05BA03 ACIDUM PAMIDRONICUM CONC. PT. SOL. PERF. 15 mg/ml

PAMIDRONAT TORREX 15 mg/ml TORREX CHIESI PHARMA GMBH

M05BA03 ACIDUM PAMIDRONICUM LIOF. PT. SOL. PERF. 30 mg

I.V.

PAMIRED 30 30 mg DR. REDDY'S LABORATORIES

M05BA03 ACIDUM PAMIDRONICUM LIOF. PT. SOL. PERF. 60 mg

I.V.

PAMIRED 60 60 mg DR. REDDY'S LABORATORIES

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**SUBLISTA C2 - P6: PROGRAMUL NAŢIONAL DE HEMOFILIE, TALASEMIE ŞI ALTE BOLI RARE. P6.7: SINDROM PRADER WILLI**

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| **847** |**H01AC01**| **SOMATROPINUM\*\*** | **Protocol: H011Q** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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H01AC01 SOMATROPINUM SOL. INJ. 10 mg/1.5 ml

NORDITROPIN 10 mg/1.5 ml NOVO NORDISK A/S

SIMPLEX x 10 mg/1,5 ml

H01AC01 SOMATROPINUM SOL. INJ. 10 mg/2 ml

NUTROPINAq 10 mg/2 ml 10 mg/2 ml IPSEN LIMITED

H01AC01 SOMATROPINUM SOL. INJ. 3,3 mg/ml

OMNITROPE 3,3 mg/ml 3,3 mg/ml SANDOZ GMBH

H01AC01 SOMATROPINUM LIOF. + SOLV. PT. SOL. 4 mg (12 ui)

INJ.

ZOMACTON 4 mg (12 ui) FERING GMBH

H01AC01 SOMATROPINUM PULB. + SOLV. PT. SOL. 5.3 mg/ml (16 ui)

INJ.

GENOTROPIN(R) 16 ui (5.3 mg) 5.3 mg/ml (16 ui) PFIZER EUROPE MA EEIG

H01AC01 SOMATROPINUM SOL. INJ. 5 mg/1.5 ml

NORDITROPIN 5 mg/1.5 ml NOVO NORDISK A/S

SIMPLEX x 5 mg/1.5 ml

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**SUBLISTA C2 - P6: PROGRAMUL NAŢIONAL DE HEMOFILIE, TALASEMIE ŞI ALTE BOLI RARE. P6.8: BOALA FABRY**

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| **848** |**A16AB04**| **AGALSIDASUM BETA\*\*** | **Protocol: A014E** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A16AB04 AGALSIDASUM BETA PULB. PT. CONC. PT. 35 mg

SOL. PERF.

FABRAZYME 35 mg 35 mg GENZYME EUROPE BV

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**SUBLISTA C2 - P6: PROGRAMUL NAŢIONAL DE HEMOFILIE, TALASEMIE ŞI ALTE BOLI RARE. P6.9: BOALA POMPE**

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| **849** |**A16AB07**| **ALGLUCOSIDASUM ALPHA\*\*** | **Protocol: A030Q** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A16AB07 ALGLUCOSIDASUM ALPHA PULB. PT. CONC. PT. 50 mg

SOL. PERF.

MYOZYME 50 mg 50 mg GENZYME EUROPE B.V.

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**SUBLISTA C2 - P7: PROGRAMUL NAŢIONAL DE BOLI ENDOCRINE. TRATAMENTUL MEDICAMENTOS AL BOLNAVILOR CU OSTEOPOROZĂ, GUŞĂ DATORATĂ CARENŢEI DE IOD ŞI PROLIFERĂRII MALIGNE**

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| **850** |**A11CC02**| **DIHYDROTACHYSTEROLUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A11CC02 DIHYDROTACHYSTEROLUM PICATURI ORALE-SOL 0.1 mg/ml

TACHYSTIN 0.1 mg/ml CHAUVIN ANKERPHARM GMBH

A11CC02 DIHYDROTACHYSTEROLUM PICATURI ORALE-SOL. 1 mg/ml

A.T. 10(R) 1 mg/ml MERCK KGAA

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| **851** |**A11CC03**| **ALFACALCIDOLUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A11CC03 ALFACALCIDOLUM CAPS. MOI 0.25 µg

ALPHA D3 0,25 µg 0.25 µg TEVA PHARMACEUTICALS SRL

A11CC03 ALFACALCIDOLUM CAPS. MOI 0.50 µg

ALPHA D3 0.50 µg 0.50 µg TEVA PHARMACEUTICALS

S.R.L.

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| **852** |**A11CC04**| **CALCITRIOLUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A11CC04 CALCITRIOLUM CAPS. MOI 0.25 µg

ROCALTROL 0.25 µg ROCHE ROMANIA S.R.L.

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| **853** |**G03CA03**| **ESTRADIOLUM** | |

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Prescriere limitată: **Utilizat în simptomele caracteristice post-menopauzei,**

**în cazul în care terapia estrogenică în doze reduse a**

**demonstrat intoleranţă la administrarea orală cu**

**estrogeni.**

**Această limitare este valabilă doar pentru formele**

**farmaceutice Sistem terapeutic transdermic şi plasture**

**transdermic.**

NOTĂ:

**Estradiol trebuie folosit împreună cu un progestativ oral la femeile nehisterectomizate.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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G03CA03 ESTRADIOLUM GEL 0.06%

OESTROGEL(R) 0.06% LAB. BESINS INTERNATIONAL

G03CA03 ESTRADIOLUM GEL 0.1%

ESTREVA(R) 0.1% LAB. THERAMEX

G03CA03 ESTRADIOLUM COMPR. FILM. 1 mg

ESTROFEM 1 mg 1 mg NOVO NORDISK A/S

G03CA03 ESTRADIOLUM COMPR. VAG. 25 µg

VAGIFEM 25 µg NOVO NORDISK A/S

G03CA03 ESTRADIOLUM IMPLANT 25 mg

RISELLE 25 mg 25 mg ORGANON NV

G03CA03 ESTRADIOLUM PLASTURE TRANSDERM. 50 µg/24 ore

CLIMARA 50 µg/24 ore SCHERING AG

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| **854** |**G03DC05**| **TIBOLONUM** | **Protocol: G007N** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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G03DC05 TIBOLONUM COMPR. 2,5 mg

LADYBON 2,5 mg ZENTIVA A.S.

G03DC05 TIBOLONUM COMPR. 2.5 mg

LIVIAL(R) 2.5 mg 2.5 mg ORGANON NV

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| **855** |**G03FA15**| **ESTRADIOLUMVALERAT + DIENOGEST** | **Protocol: G002N** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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G03FA15 ESTRADIOLUMVALERAT + DRAJ.

DIENOGEST

KLIMODIEN SCHERING AG

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| **856** |**G03XC01**| **RALOXIFENUM** | |

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**Cod restricţie 2647: Monoterapie cu medicamente antiresorbtive pentru tratamentul osteoporozei sexoidoprive la femeile până la vârsta de 60 ani, cu scor T </= -2,5, măsurat DEXA (coloana vertebrală sau sold).**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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G03XC01 RALOXIFENUM COMPR. FILM. 60 mg

EVISTA 60 mg 60 mg ELI LILLY NEDERLAND BV

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| **857** |**H01AB01**| **TIREOTROPINUM ALFA** | |

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Prescriere limitată: **Anterior administrării iodului radioactiv pentru tratamentul carcinomului tiroidian diferenţiat posttiroidectomie totală.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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H01AB01 TIREOTROPINUM ALFA PULB. PT. SOL. INJ. 0.9 mg

THYROGEN 0.9 mg 0.9 mg GENZYME EUROPE BV

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| **858** |**H02AB04**| **METHYLPREDNISOLONUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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H02AB04 METHYLPREDNISOLONUM LIOF. PT. SOL. INJ. 125 mg

LEMOD SOLU 125 mg 125 mg HEMOFARM S.R.L.

H02AB04 METHYLPREDNISOLONUM LIOF. SI SOLV. PT. SOL. 125 mg/2 ml

INJ.

SOLU-MEDROL ACT-O-VIAL 125 mg/2 ml PFIZER EUROPE MA EEIG

H02AB04 METHYLPREDNISOLONUM COMPR. 16 mg

MEDROL A 16 16 mg PFIZER EUROPE MA EEIG

H02AB04 METHYLPREDNISOLONUM LIOF. PT. SOL. INJ. 20 mg

LEMOD SOLU 20 mg 20 mg HEMOFARM S.R.L.

H02AB04 METHYLPREDNISOLONUM LIOF. ŞI SOLV. PT. SOL. 250 mg/4 ml

INJ.

SOLU-MEDROL ACT-O-VIAL 250 mg/4 ml PFIZER EUROPE MA EEIG

H02AB04 METHYLPREDNISOLONUM COMPR. 32 mg

MEDROL 32 32 mg PFIZER EUROPE MA EEIG

H02AB04 METHYLPREDNISOLONUM LIOF. PT. SOL. INJ. 40 mg

LEMOD SOLU 40 mg 40 mg HEMOFARM S.R.L.

H02AB04 METHYLPREDNISOLONUM LIOF. SI SOLV. PT. SOL. 40 mg/1 ml

INJ.

SOLU-MEDROL ACT-O-VIAL 40 mg/1 ml PFIZER EUROPE MA EEIG

H02AB04 METHYLPREDNISOLONUM COMPR. 4 mg

MEDROL 4 mg 4 mg PFIZER EUROPE MA EEIG

H02AB04 METHYLPREDNISOLONUM LIOF. PT. SOL. INJ. 500 mg

LEMOD SOLU 500 mg 500 mg HEMOFARM S.R.L.

H02AB04 METHYLPREDNISOLONUM LIOF. + SOLV. PT. SOL. 500 mg/7.8 ml

INJ.

SOLU-MEDROL 500 mg/7,8 ml 500 mg/7.8 ml PFIZER EUROPE MA EEIG

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| **859** |**H03AA01**| **LEVOTHYROXINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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H03AA01 LEVOTHYROXINUM COMPR. 100 µg

EUTHYROX(R) 100 100 µg MERCK KGAA

L-THYROXIN 100 100 µg BERLIN CHEME AG

BERLIN-CHEME MENARINI GROUP

H03AA01 LEVOTHYROXINUM COMPR. 200 µg

EUTHYROX(R) 200 200 µg MERCK KGAA

H03AA01 LEVOTHYROXINUM COMPR. 25 µg

EUTHYROX(R) 25 25 µg MERCK KGAA

H03AA01 LEVOTHYROXINUM COMPR. 50 µg

EUTHYROX(R) 50 50 µg MERCK KGAA

L-THYROXIN 50 50 µg BERLIN CHEME AG MENARINI

GROUP

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| **860** |**H03AAN1**| **LEVOTHYROXINUM + KALII IODIDUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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H03AAN1 LEVOTHYROXINUM + COMPR.

KALII IODIDUM

JODTHYROX(R) 100/130,8 MERCK KGAA

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| **861** |**H03BB02**| **THIAMAZOLUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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H03BB02 THIAMAZOLUM COMPR. FILM. 10 mg

THYROZOL(R) 10 mg 10 mg MERCK KGAA

H03BB02 THIAMAZOLUM COMPR. FILM. 20 mg

THYROZOL(R) 20 mg 20 mg MERCK KGAA

H03BB02 THIAMAZOLUM COMPR. FILM. 5 mg

THYROZOL(R) 5 mg 5 mg MERCK KGAA

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| **862** |**H03CA01**| **KALII IODIDUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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H03CA01 KALII IODIDUM COMPR. 100 µg

JODID 100 100 µg MERCK KGAA

H03CA01 KALII IODIDUM COMPR. 200 µg

JODID 200 200 µg MERCK KGAA

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| **863** |**H05AA02**| **TERIPARATIDUM\*\*** | **Protocol: M003M** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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H05AA02 TERIPARATIDUM SOL. INJ. 20 µg/80 µg

FORSTEO 20 µg/80 µg 20 µg/80 µg ELI LILLY NEDERLAND BV

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| **864** |**H05BA01**| **CALCITONINUM (SOMON)** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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H05BA01 CALCITONINUM (SOMON) SOL. INJ. 100 UI

TONOCALCIN 100 UI 100 UI ALFA WASSERMANN SPA

H05BA01 CALCITONINUM (SOMON) SPRAY NAZ., SOL. 100 ui/doza

NYLEX 100 UI/doza 100 UI/doza PHARMACEUTICAL IND. PROEL

EPAM. G. CORONIS SA

H05BA01 CALCITONINUM (SOMON) SOL. INJ. 100 UI/ml

NYLEX(R) 10O UI/ml PROEL E.P. CORONIS SA

H05BA01 CALCITONINUM (SOMON) SPRAY NAZAL - SOL. 200 UI/doza

MIACALCIC(R) NASAL 200 200 ui/doza NOVARTIS PHARMA GMBH

NYLEX(R) 200 UI/doza PROEL E.P. CORONIS SA

H05BA01 CALCITONINUM (SOMON) SOL. INJ. 50 ui/ml

MIACALCIC(R) 50 ui/ml NOVARTIS PHARMA GMBH

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| **865** |**M05BA04**| **ACIDUM ALENDRONICUM\*\*** | **Protocol: M003M** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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M05BA04 ACIDUM ALENDRONICUM COMPR. 10 mg

FOSAMAX 10 mg 10 mg MERCK SHARP & DOHME S.R.L.

M05BA04 ACIDUM ALENDRONICUM COMPR. 70 mg

TEVA NAT 70 mg TEVA PHARMACEUTICALS SRL

M05BA04 ACIDUM ALENDRONICUM COMPR. 70 mg

FOSAMAX 70 mg 70 mg MERCK SHARP & DOHME S.R.L.

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| **866** |**M05BA06**| **ACIDUM IBANDRONICUM\*\*** | **Protocol: M003M** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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M05BA06 ACIDUM IBANDRONICUM SOL. INJ. IN SERINGA 3 mg/3 ml

PREUMPLUTA

BONVIVA 3 mg/3 ml 3 mg/3 ml ROCHE REGISTRATION LTD

M05BA06 ACIDUM IBANDRONICUM CONC. PT. SOL. PERF.

BONDRONAT 6 mg/6 ml 6 mg/6 ml ROCHE REGISTRATION L

M05BA06 ACIDUM IBANDRONICUM COMPR. FILM.

BONDRONAT 50 mg 50 mg ROCHE REGISTRATION L

M05BA06 ACIDUM IBANDRONICUM COMPR. FILM.

BONDRONAT 50 mg 50 mg ROCHE REGISTRATION L

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| **867** |**M05BA07**| **ACIDUM RISEDRONICUM\*\*** | **Protocol: M003M** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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M05BA07 ACIDUM RISEDRONICUM COMPR. FILM. 35 mg

ACTONEL(R) SAPTAMANAL 35 mg AVENTIS PHARMA AB

RISENDROS 35 mg 35 mg ZENTIVA A.S.

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| **868** |**M05BB03**| **COMBINATII (ACIDUM ALENDRONICUM +** | **Protocol: M003M** |

| | | **COLECALCIFEROLUM)\*\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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M05BB03 COMBINATII (ACIDUM COMPR. 70 mg/2800 UI

ALENDRONICUM +

COLECALCIFEROLUM)

FOSAVANCE 70 mg/2800 UI 70 mg/2800 UI MERCK SHARP & DOHME LTD.

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| **869** |**M05BX03**| **STRONTIUM RANELATUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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M05BX03 STRONTIUM RANELATUM GRAN. PT. SUSP. ORALA 2 g

OSSEOR 2 g 2 g LES LAB. SERVIER

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| **872** |**M05BA08**| **ACIDUM ZOLEDRONICUM\*\*** | **Protocol: M001M** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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M05BA08 ACIDUM ZOLEDRONICUM SOL. PERF. 5 mg/100 ml

ACLASTA 5 mg/100 ml 5 mg/100 ml NOVARTIS EUROPHARM LTD.

M05BA08 ACIDUM ZOLEDRONICUM PULB. + SOLV. SOL.

PERF.

ZOMETA 4 mg 4 mg NOVARTIS EUROPHARM L

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| **1218** |**H03BB01**| **CARBIMAZOLUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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H03BB01 CARBIMAZOLUM COMPR. FILM. 5 mg

CARBIMAZOLE 5 5 mg REMEDICA LTD.

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**SUBLISTA C2 - P9: PROGRAM NAŢIONAL DE TRANSPLANT DE ORGANE, ŢESUTURI ŞI CELULE DE ORIGINE UMANĂ. P9.1: TRANSPLANT MEDULAR**

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| **873** |**A04AA01**| **ONDANSETRONUM\*\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A04AA01 ONDANSETRONUM SOL. INJ.

OSETRON 4 mg 2 mg/ml DR. REDDY'S LABORATO

OSETRON 8 mg 2 mg/ml DR. REDDY'S LABORATORIES

A04AA01 ONDANSETRONUM SOL. INJ./PERF. 2 mg/ml

EMESET 4 mg/2 ml 2 mg/ml CIPLA (UK) LIMITED

EMESET 8 mg/4 ml 2 mg/ml CIPLA (UK) LIMITED

A04AA01 ONDANSETRONUM COMPR. FILM. 4 mg

ONDANSETRON TEVA 4 mg 4 mg TEVA PHARMACEUTICALS SRL

ONDANTOR 4 mg 4 mg SANDOZ SRL

OSETRON 4 mg 4 mg DR. REDDY'S LABORATORIES

SETRONON 4 mg 4 mg PLIVA LJUBLJANA D.O.O.

ZOFRAN 4 mg 4 mg GLAXO WELLCOME UK LTD.

A04AA01 ONDANSETRONUM COMPR. ORODISPERSABILE 4 mg

ONDARAN MD 4 mg 4 mg RANBAXY UK LTD.

A04AA01 ONDANSETRONUM SOL. INJ. 4 mg/2 ml

ZOFRAN 4 mg/2 ml 4 mg/2 ml GLAXO WELLCOME UK LIMITED

A04AA01 ONDANSETRONUM SOL. INJ./PERF. 4 mg/2 ml

SETRONON 4 mg/2 ml 4 mg/2 ml PLIVA LJUBLJANA D.O.O.

A04AA01 ONDANSETRONUM COMPR. FILM. 8 mg

ONDANSETRON TEVA 8 mg 8 mg TEVA PHARMACEUTICALS SRL

ONDANTOR 8 mg 8 mg SANDOZ SRL

OSETRON 8 mg 8 mg DR. REDDY'S LABORATORIES

(UK) LTD

SETRONON 8 mg 8 mg PLIVA LJUBLJANA D.O.O.

ZOFRAN 8 mg 8 mg GLAXO WELLCOME UK LTD.

A04AA01 ONDANSETRONUM COMPR. ORODISPERSABILE 8 mg

ONDARAN MD 8 mg 8 mg RANBAXY UK LIMITED

A04AA01 ONDANSETRONUM SOL. INJ. 8 mg/4 ml

ZOFRAN 8 mg/4 ml 8 mg/4 ml GLAXO WELLCOME UK LIMITED

A04AA01 ONDANSETRONUM SOL. INJ./PERF. 8 mg/4 ml

SETRONON 8 mg/4 ml 8 mg/4 ml PLIVA LJUBLJANA D.O.O.

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| **874** |**A05AA02**| **ACIDUM URSODEOXYCHOLICUM** | |

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NOTĂ:

**Nu se va prescrie în regim compensat pentru tratamentul litiazei biliare.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A05AA02 ACIDUM CAPS. 250 mg

URSODEOXYCHOLICUM

URSOFALK(R) 250 mg DR. FALK PHARMA GMBH

URSOSAN 250 mg PRO. MED. CS PRAHA AS

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| **875** |**B01AB08**| **REVIPARINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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B01AB08 REVIPARINUM SOL. INJ. 1432 ui/0.25 ml

CLIVARIN(R) 1432 UI/0.25 ml 1432 ui/0.25 ml ABBOTT GMBH & CO. KG

B01AB08 REVIPARINUM SOL. INJ. 3436 ui/0.6 ml

CLIVARIN(R) 3436 UI/0.6 ml 3436 ui/0.6 ml ABBOTT GMBH & CO. KG

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*|* ***878*** *| \*\*\* Abrogată |*

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| **880** |**J01CR03**| **TICARCILLINUM + ACIDUM CLAVULANICUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01CR03 TICARCILLINUM + PULB. PT. SOL. 3.2 g

ACIDUM CLAVULANICUM INJ./PERF.

TIMENTIN 3,2 g 3.2 g BEECHAM GROUP PLC

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| **881** |**J01CR05**| **PIPERACILLINUM + TAZOBACTAMUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01CR05 PIPERACILLINUM + LIOF. PT. SOL. INJ.

TAZOBACTAMUM

TAZOCIN 2,25 WYETH LEDERLE PHARMA GMBH

TAZOCIN 4,5 WYETH LEDERLE PHARMA GMBH

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| **882** |**J01DH02**| **MEROPENEMUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01DH02 MEROPENEMUM PULB. PT. SOL. INJ. 1 g

I.V./PERF.

MERONEM IV 1 g 1 g ASTRAZENECA UK LTD.

J01DH02 MEROPENEMUM PULB. PT. SOL. INJ. 500 mg

I.V./PERF.

MERONEM IV 500 mg 500 mg ASTRAZENECA UK LTD.

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| **883** |**J01DH51**| **IMIPENEMUM + CILASTATINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01DH51 IMIPENEMUM + PULB. PT. SOL. PERF.

CILASTATINUM

TIENAM I.V. MERCK SHARP & DOHME

ROMANIA S.R.L.

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| **884** |**J01XA01**| **VANCOMYCINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01XA01 VANCOMYCINUM LIOF. PT. SOL. PERF. 1 g

VANCOMYCIN TEVA 1 g TEVA PHARM. WORKS PRIVATE

LTD. COMPANY

J01XA01 VANCOMYCINUM PULB. LIOF. PT. SOL. 1 g

PERF./INJ

EDICIN 1 g LEK PHARMACEUTICALS D.D.

J01XA01 VANCOMYCINUM LIOF. PT. SOL. PERF. 500 mg

VANCOMYCIN TEVA 500 mg TEVA PHARM. WORKS PRIVATE

LTD. COMPANY

J01XA01 VANCOMYCINUM LIOF. PT. SOL. 500 mg

PERF./INJ.

EDICIN 500 mg LEK PHARMACEUTICALS D.D.

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| **885** |**J01XA02**| **TEICOPLANINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01XA02 TEICOPLANINUM LIOF. + SOLV. PT. SOL. 400 mg

INJ.

TARGOCID(R) 400 mg 400 mg AVENTIS PHARMA LTD.

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| **887** |**J01XX08**| **LINEZOLIDUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01XX08 LINEZOLIDUM GRAN. PT. SUSP. ORALA 100 mg/5 ml

ZYVOXID(R) 100 mg/5 ml PFIZER EUROPE MA EEIG

J01XX08 LINEZOLIDUM SOL. PERF. 2 mg/ml

ZYVOXID(R) 2 mg/ml PFIZER EUROPE MA EEIG

J01XX08 LINEZOLIDUM COMPR. FILM. 600 mg

ZYVOXID(R) 600 mg PFIZER EUROPE MA EEIG

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| **888** |**J02AC01**| **FLUCONAZOLUM** | |

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Prescriere limitată: **Tratament de întreţinere la pacienţi cu meningită**

**criptococică şi imunosupresie.**

**Profilaxia secundară a candidozei orofaringiene la**

**pacienţi cu imunosupresie.**

**Tratamentul meningitei criptococice la pacienţii care**

**nu pot lua sau nu tolerează amfotericina.**

**Tratamentul candidozelor severe şi care pun în pericol**

**viaţa la pacienţi care nu tolerează amfotericina.**

**Tratamentul candidozei orofaringiene la pacienţi cu**

**imunosupresie.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J02AC01 FLUCONAZOLUM CAPS. 100 mg

DIFLAZON 100 mg 100 mg KRKA D.D.

FLUCONAZOLE TEVA 100 mg 100 mg TEVA PHARMACEUTICALS SRL

FLUCORIC 100 mg 100 mg TERAPIA S.A.

FLUCOVIM 100 100 mg VIM SPECTRUM SRL

FUNGOLON 100 mg 100 mg BALKANPHARMA RAZGRAD AD

J02AC01 FLUCONAZOLUM CAPS. 150 mg

DIFLAZON 150 mg 150 mg KRKA D.D.

DIFLUCAN 150 mg 150 mg PFIZER EUROPE MA EEIG

FLUCONAZOL 150 mg 150 mg OZONE LABORATORIES LTD.

FLUCONAZOL MEDICO UNO 150 mg 150 mg MEDICO UNO PHARMACEUTICAL

SRL

FLUCONAZOL MEDOCHEMIE 150 mg 150 mg MEDOCHEMIE ROMANIA SRL

FLUCONAZOL SANDOZ(R) 150 150 mg SANDOZ SRL

FLUCONAZOL TERAPIA 150 mg 150 mg TERAPIA SA

FLUCONAZOLE TEVA 150 mg 150 mg TEVA PHARMACEUTICALS SRL

FLUCORIC 150 mg 150 mg TERAPIA S.A.

FLUCOVIM 150 150 mg VIM SPECTRUM SRL

MYCOMAX 150 150 mg ZENTIVA AS

MYCOSYSTA(R) 150 mg 150 mg GEDEON RICHTER PLC.

J02AC01 FLUCONAZOLUM CAPS. 200 mg

DIFLAZON 200 mg 200 mg KRKA D.D.

FLUCONAZOLE TEVA 200 mg 200 mg TEVA PHARMACEUTICALS SRL

J02AC01 FLUCONAZOLUM SOL. PERF. 2 mg/ml

DIFLAZON(R) 2 mg/ml KRKA D.D.

DIFLUCAN(R) 2 mg/ml PFIZER EUROPE MA EEIG

MYCOMAX(R) INF 2 mg/ml ZENTIVA AS

J02AC01 FLUCONAZOLUM CAPS. 50 mg

DIFLAZON 50 mg 50 mg KRKA D.D.

DIFLUCAN 50 mg 50 mg PFIZER EUROPE MA EEIG

FLUCONAZOL 50 mg 50 mg ARENA GROUP SA

FLUCONAZOL MEDOCHEMIE 50 mg 50 mg MEDOCHEMIE ROMANIA SRL

FLUCONAZOL SANDOZ(R) 50 50 mg SANDOZ SRL

FLUCONAZOL TERAPIA 50 mg 50 mg TERAPIA S.A.

FLUCONAZOLE TEVA 50 mg 50 mg TEVA PHARMACEUTICALS SRL

FLUCORIC 50 mg 50 mg TERAPIA S.A.

FLUCOVIM 50 50 mg VIM SPECTRUM SRL

FUNGOLON 50 mg 50 mg BALKANPHARMA RAZGRAD AD

J02AC01 FLUCONAZOLUM PULB. PT. SUSP. ORALA 50 mg/5 ml

DIFLUCAN(R) 50 mg/5 ml 50 mg/5 ml PFIZER EUROPE MA EEIG

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| **889** |**J02AC03**| **VORICONAZOLUM\*\*** | **Protocol: J012B** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J02AC03 VORICONAZOLUM COMPR. FILM. 200 mg

VFEND 200 mg 200 mg PFIZER LTD.

J02AC03 VORICONAZOLUM PULB. PT. SOL. PERF. 200 mg

VFEND 200 mg 200 mg PFIZER LTD.

J02AC03 VORICONAZOLUM PULB. PT. SUSP. ORALA 40 mg/ml

VFEND 40 mg/ml 40 mg/ml PFIZER LTD.

J02AC03 VORICONAZOLUM COMPR. FILM. 50 mg

VFEND 50 mg 50 mg PFIZER LTD.

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| **890** |**J02AC04**| **POSACONAZOLUM\*\*** | |

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Prescriere limitată: **Profilaxia şi tratamentul infecţiilor fungice invazive**

**la pacienţii aflaţi sub chimioterapie de**

**inducţie-remisie pentru LAM sau pentru sindroame**

**mielodisplazice şi care prezintă risc înalt de a**

**dezvolta infecţii fungice masive.**

**Profilaxia şi tratamentul infecţiilor fungice invazive**

**la pacienţii în procedura de transplant medular şi**

**aflaţi sub terapie imunosupresoare cu doze mari, cu**

**risc mare de a dezvolta infecţii fungice masive.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J02AC04 POSACONAZOLUM SUSP. ORALA 40 mg/ml

NOXAFIL SP 40 mg/ml 40 mg/ml SP EUROPE

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| **891** |**J02AX04**| **CASPOFUNGINUM\*\*** | **Protocol: J010D** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J02AX04 CASPOFUNGINUM PULB. PT. CONC. PT. 50 mg

SOL. PERF.

CANCIDAS 50 mg 50 mg MERCK SHARP & DOHME LTD

J02AX04 CASPOFUNGINUM PULB. PT. CONC. PT. 70 mg

SOL. PERF.

CANCIDAS 70 mg 70 mg MERCK SHARP & DOHME LTD

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| **893** |**J05AB01**| **ACICLOVIRUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J05AB01 ACICLOVIRUM CAPS. 200 mg

ACICLOVIR 200 mg 200 mg ARENA GROUP SA

EUVIROX 200 mg 200 mg EUROPHARM SA

J05AB01 ACICLOVIRUM COMPR. 200 mg

ACICLOVIR 200 mg 200 mg TERAPIA SA

CLOVIRAL 200 mg 200 mg ANTIBIOTICE SA

ZOVIRAX 200 mg GLAXO WELLCOME FOUNDATION

LTD.

J05AB01 ACICLOVIRUM COMPR. DISP. 200 mg

ACICLOVIR 200 mg 200 mg OZONE LABORATORIES LTD.

LOVIR 200 mg 200 mg RANBAXY UK LIMITED

J05AB01 ACICLOVIRUM PULB. PT. SOL. 250 mg

INJ./PERF.

VIROLEX 250 mg KRKA D.D. NOVO MESTO

J05AB01 ACICLOVIRUM CAPS. 400 mg

ACICLOVIR 400 mg 400 mg ARENA GROUP S.A.

J05AB01 ACICLOVIRUM COMPR. 400 mg

ACICLOVIR 400 mg 400 mg EGIS PHARMACEUTICALS

P.L.C.

J05AB01 ACICLOVIRUM COMPR. FILM. 400 mg

ACIKLOVIR 400 mg A & G MED TRADING S.R.L.

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| **894** |**J05AB11**| **VALACYCLOVIRUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J05AB11 VALACYCLOVIRUM COMPR. FILM. 500 mg

VALTREX 500 mg 500 mg THE WELLCOME FOUNDATION

LTD.

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| **895** |**J05AB14**| **VALGANCICLOVIRUM\*\*** | |

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Prescriere limitată: **Tratamentul de iniţiere şi menţinere pentru retinita cu citomegalovirus (CMV) la pacienţi imunocompromişi.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J05AB14 VALGANCICLOVIRUM COMPR. FILM. 450 mg

VALCYTE(R) 450 mg 450 mg ROCHE ROMANIA SRL

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| **897** |**L01AA01**| **CYCLOPHOSPHAMIDUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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L01AA01 CYCLOPHOSPHAMIDUM PULB. PT. SOL. 1 g

INJ./PERF.

ENDOXAN(R) 1 g 1 g BAXTER ONCOLOGY GMBH

L01AA01 CYCLOPHOSPHAMIDUM PULB. PT. SOL. 200 mg

PERF./INJ. I.V.

ENDOXAN 200 mg 200 mg ACTAVIS S.R.L.

L01AA01 CYCLOPHOSPHAMIDUM PULB. PT. SOL. 500 mg

INJ./PERF.

ENDOXAN(R) 500 mg 500 mg BAXTER ONCOLOGY GMBH

L01AA01 CYCLOPHOSPHAMIDUM DRAJ. 50 mg

ENDOXAN(R) 50 mg 50 mg BAXTER ONCOLOGY GMBH

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| **898** |**L01AA03**| **MELPHALANUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L01AA03 MELPHALANUM COMPR. FILM. 2 mg

ALKERAN 2 mg 2 mg THE WELLCOME FOUNDATION

LTD.

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| **899** |**L01AA06**| **IFOSFAMIDUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L01AA06 IFOSFAMIDUM PULB. PT. SOL. PERF. 1 g

HOLOXAN 1 g 1 g BAXTER ONCOLOGY GMBH

L01AA06 IFOSFAMIDUM PULB. PT. SOL. PERF. 2 g

HOLOXAN 2 g 2 g BAXTER ONCOLOGY GMBH

L01AA06 IFOSFAMIDUM PULB. PT. SOL. PERF. 500 mg

HOLOXAN 500 mg 500 mg BAXTER ONCOLOGY GMBH

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| **900** |**L01AB01**| **BUSULFANUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L01AB01 BUSULFANUM COMPR. FILM. 2 mg

MYLERAN 2 mg THE WELLCOME FOUNDATION

LTD.

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| **901** |**L01BA01**| **METHOTREXATUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L01BA01 METHOTREXATUM CONC. PT. SOL. 100 mg/ml

INJ./PERF.

METHOTREXAT "EBEWE" 1000 mg 100 mg/ml EBEWE PHARMA GMBH NFG. KG

METHOTREXAT "EBEWE" 500 mg 100 mg/ml EBEWE PHARMA GMBH NFG. KG

METHOTREXAT "EBEWE" 5000 mg 100 mg/ml EBEWE PHARMA GMBH NFG. KG

L01BA01 METHOTREXATUM SOL. INJ./PERF. 10 mg/ml

METHOTREXAT "EBEWE" 50 mg 10 mg/ml EBEWE PHARMA GMBH NFG. KG

L01BA01 METHOTREXATUM PULB. PT. SOL. 50 mg

INJ./PERF.

ANTIFOLAN(R) 50 mg 50 mg SINDAN SRL

L01BA01 METHOTREXATUM SOL. INJ. 5 mg/ml

METHOTREXAT "EBEWE" 5 mg 5 mg/ml EBEWE PHARMA GMBH NFG. KG

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| **902** |**L01BB05**| **FLUDARABINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L01BB05 FLUDARABINUM COMPR. FILM. 10 mg

FLUDARA(R) ORAL 10 mg SCHERING AG

L01BB05 FLUDARABINUM LIOF. PT. SOL. 50 mg

INJ./PERF.

FLUDARA 50 mg SCHERING AG

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| **903** |**L01CB01**| **ETOPOSIDUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L01CB01 ETOPOSIDUM CAPS. MOI 100 mg

VEPESID 100 mg BRISTOL MYERS SQUIBB KFT

L01CB01 ETOPOSIDUM CONC. PT. SOL. PERF. 100 mg/5 ml

ETOPOSID "EBEWE" 100 mg/5 ml 100 mg/5 ml EBEWE PHARMA GMBH NFG. KG

SINTOPOZID 100 mg/5 ml 100 mg/5 ml ACTAVIS S.R.L

L01CB01 ETOPOSIDUM CONC. PT. SOL. PERF. 20 mg/ml

ETOPOSIDE - TEVA 20 mg/ml TEVA PHARMACEUTICALS

S.R.L.

L01CB01 ETOPOSIDUM CAPS. MOI 50 mg

VEPESID 50 mg BRISTOL MYERS SQUIBB KFT

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| **904** |**L01DB06**| **IDARUBICINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L01DB06 IDARUBICINUM CAPS. 10 mg

ZAVEDOS 10 mg PFIZER EUROPE MA EEIG

L01DB06 IDARUBICINUM LIOF. PT. SOL. INJ. 5 mg

ZAVEDOS 5 mg 5 mg PFIZER EUROPE MA EEIG

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| **905** |**L01DB07**| **MITOXANTRONUM\*\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L01DB07 MITOXANTRONUM CONC. PT. SOL. PERF. 2 mg/ml

MITOXANTRONE TEVA 2 mg/ml 2 mg/ml TEVA PHARMACEUTICALS SRL

L01DB07 MITOXANTRONUM SOL. PERF. 20 mg/10 ml

NOVANTRONE 20 mg/10 ml WYETH LEDERLE PHARMA GMBH

L01DB07 MITOXANTRONUM CONC. PT. SOL. INJ. 2 mg/ml

ONKOTRONE 2 mg/ml BAXTER ONCOLOGY GMBH

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| **906** |**L01XA01**| **CISPLATINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L01XA01 CISPLATINUM LIOF. PT. SOL. PERF. 10 mg

SINPLATIN 10 mg 10 mg ACTAVIS S.R.L.

L01XA01 CISPLATINUM CONC. PT. SOL. PERF. 10 mg/20 ml

CISPLATIN "EBEWE" 10 mg/20 ml 10 mg/20 ml EBEWE PHARMA GMBH NFG. KG

CISPLATIN TEVA 10 mg/20 ml 10 mg/20 ml TEVA PHARMACEUTICALS

S.R.L.

L01XA01 CISPLATINUM CONC. PT. SOL. PERF. 1 mg/1 ml

SINPLATIN 1 mg/1 ml 1 mg/1 ml ACTAVIS S.R.L.

L01XA01 CISPLATINUM CONC. PT. SOL. PERF. 25 mg/50 ml

CISPLATIN "EBEWE" 25 mg/50 ml 25 mg/50 ml EBEWE PHARMA GMBH NFG. KG

L01XA01 CISPLATINUM LIOF. PT. SOL. PERF. 50 mg

SINPLATIN 50 mg 50 mg ACTAVIS S.R.L.

L01XA01 CISPLATINUM CONC. PT. SOL. PERF. 50 mg/100 ml

CISPLATIN "EBEWE" 50 mg/100 ml EBEWE PHARMA GMBH NFG. KG

50 mg/100 ml

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| **907** |**L01XA02**| **CARBOPLATINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L01XA02 CARBOPLATINUM CONC. PT. SOL. PERF. 10 mg/ml

CARBOPLATIN "EBEWE" 10 mg/ml 10 mg/ml EBEWE PHARMA GES.M.B.H.

NFG KG

CARBOPLATIN ACTAVIS 10 mg/ml 10 mg/ml ACTAVIS S.R.L.

CARBOPLATIN TEVA 10 mg/ml 10 mg/ml TEVA PHARMACEUTICALS

S.R.L.

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| **908** |**L01XC04**| **ALEMTUZUMABUM\*\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L01XC04 ALEMTUZUMABUM CONC. PT. SOL. PERF. 10 mg/ml

MABCAMPATH 10 mg/ml 10 mg/ml GENZYME EUROPE BV

L01XC04 ALEMTUZUMABUM CONC. PT. SOL. PERF. 30 mg/ml

MABCAMPATH 30 mg/ml 30 mg/ml GENZYME EUROPE BV

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| **909** |**L01XC02**| **RITUXIMABUM\*\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L01XC02 RITUXIMABUM CONC. PT. SOL. PERF. 10 mg/ml

MABTHERA 100 mg 10 mg/ml ROCHE REGISTRATION LTD.

MABTHERA 500 mg 10 mg/ml ROCHE REGISTRATION LTD.

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| **910** |**L03AA02**| **FILGRASTIMUM (G-CSF)\*\*** | |

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Prescriere limitată: **Reducerea duratei neutropeniei şi a incidenţei neutropeniei febrile la pacienţii trataţi cu chimioterapie citotoxică standard pentru bolile maligne (cu excepţia leucemiei mieloide cronice şi a sindroamelor mielodisplazice), precum şi pentru reducerea duratei neutropeniei la pacienţii care primesc terapie mieloablativă urmată de transplant de măduvă osoasă.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L03AA02 FILGRASTIMUM SOL. INJ. 30 MU/0.5 ml

(G-CSF)

NEUPOGEN(R) 30 MU/0.5 ml AMGEN EUROPE B.V.

L03AA02 FILGRASTIMUM SOL. INJ. 48 MU/0.5 ml

(G-CSF)

NEUPOGEN(R) 48 MU/0.5 ml AMGEN EUROPE B.V.

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| **911** |**L04AA01**| **CICLOSPORINUM** | |

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Prescriere limitată: **Managementul rejectului de grefă la pacienţii supuşi**

**procedurii de transplant.**

Monitorizarea atentă a pacienţilor este obligatorie.

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L04AA01 CICLOSPORINUM CAPS. MOI 100 mg

EQUORAL(R) 100 mg 100 mg IVAX - PHARMACEUTICALS

S.R.O.

L04AA01 CICLOSPORINUM SOL. ORALA 100 mg/ml

EQUORAL(R) 100 mg/ml IVAX - PHARMACEUTICALS

S.R.O.

SANDIMMUN NEORAL(R) 100 mg/ml NOVARTIS PHARMA GMBH

L04AA01 CICLOSPORINUM CAPS. MOI 25 mg

CICLORAL(R) HEXAL(R) 25 mg 25 mg HEXAL AG

EQUORAL(R) 25 mg 25 mg IVAX - PHARMACEUTICALS

S.R.O.

SANDIMMUN NEORAL(R) 25 mg NOVARTIS PHARMA GMBH

L04AA01 CICLOSPORINUM CAPS. MOI 50 mg

CICLORAL(R) HEXAL 50 mg 50 mg HEXAL AG

EQUORAL(R) 50 mg 50 mg IVAX - PHARMACEUTICALS

S.R.O.

SANDIMMUN NEORAL(R) 50 mg NOVARTIS PHARMA GMBH

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| **913** |**L04AA05**| **TACROLIMUSUM\*\*** | |

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Prescriere limitată: **Tratamentul rejetului de alogrefă rezistent la alte terapii imunosupresoare, la pacienţii adulţi.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L04AA05 TACROLIMUSUM CAPS. ELIB. PREL 0,5 mg

ADVAGRAF 0,5 mg 0,5 mg ASTELLAS PHARMA GMBH

L04AA05 TACROLIMUSUM CAPS. 0.5 mg

PROGRAF(R) 0,5 mg 0.5 mg ASTELLAS PHARMA GMBH

L04AA05 TACROLIMUSUM CAPS. 1 mg

PROGRAF(R) 1 mg 1 mg ASTELLAS IRELAND CO. LTD.

L04AA05 TACROLIMUSUM CAPS. ELIB. PREL. 1 mg

ADVAGRAF 1 mg 1 mg ASTELLAS PHARMA GMBH

L04AA05 TACROLIMUSUM CAPS. 5 mg

PROGRAF(R) 5 mg 5 mg ASTELLAS PHARMA GMBH

L04AA05 TACROLIMUSUM CAPS. ELIB. PREL. 5 mg

ADVAGRAF 5 mg 5 mg ASTELLAS PHARMA GMBH

L04AA05 TACROLIMUSUM CONC. PT. SOL. PERF. 5 mg/ml

PROGRAF(R) 5 mg/ml 5 mg/ml ASTELLAS PHARMA GMBH

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| **914** |**L04AA06**| **MYCOPHENOLATUM\*\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L04AA06 MYCOPHENOLATUM COMPR. FILM. GASTROREZ. 180 mg

MYFORTIC 180 mg 180 mg NOVARTIS PHARMA GMBH

L04AA06 MYCOPHENOLATUM PULB. PT. SUSP. ORALA 1 g/5 ml

CELLCEPT 1 mg/5 ml 1 g/5 ml ROCHE REGISTRATION LTD.

L04AA06 MYCOPHENOLATUM CAPS. 250 mg

CELLCEPT 250 mg 250 mg ROCHE REGISTRATION LTD.

MYFENAX 250 mg 250 mg TEVA PHARMA BV

L04AA06 MYCOPHENOLATUM COMPR. FILM. GASTROREZ. 360 mg

MYFORTIC 360 mg 360 mg NOVARTIS PHARMA GMBH

L04AA06 MYCOPHENOLATUM CAPS. 500 mg

MYFENAX 500 mg 500 mg TEVA PHARMA BV

L04AA06 MYCOPHENOLATUM COMPR. FILM. 500 mg

CELLCEPT 500 mg 500 mg ROCHE REGISTRATION LTD.

L04AA06 MYCOPHENOLATUM PULB. PT. CONC. PT. 500 mg

SOL. PERF.

CELLCEPT 500 mg 500 mg ROCHE REGISTRATION LTD.

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| **915** |**L04AA08**| **DACLIZUMABUM\*\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L04AA08 DACLIZUMABUM CONC. PT. SOL. PERF. 5 mg/ml

ZENAPAX 5 mg/ml 5 mg/ml ROCHE REGISTRATION LTD.

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| **916** |**L04AA10**| **SIROLIMUS\*\*** | |

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Monitorizarea atentă a pacienţilor este obligatorie

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L04AA10 SIROLIMUS COMPR. FILM. 1 mg

RAPAMUNE 1 mg 1 mg WYETH EUROPA LTD.

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| **917** |**L04AA11**| **ETANERCEPTUM\*\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L04AA11 ETANERCEPTUM PULB. + SOLV. PT. 25 mg

SOL. INJ.

ENBREL 25 mg 25 mg WYETH EUROPA LIMITED

L04AA11 ETANERCEPTUM PULB + SOLV. PT. 50 mg

SOL INJ

ENBREL 50 mg 50 mg WYETH EUROPA LIMITED

L04AA11 ETANERCEPTUM SOL. INJ. IN SERINGA 25 mg

PREUMPLUTA

ENBREL 25 mg 25 mg WYETH EUROPA LIMITED

L04AA11 ETANERCEPTUM SOL. INJ. IN SERINGA 50 mg

PREUMPLUTA

ENBREL 50 mg 50 mg WYETH EUROPA LIMITED

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| **918** |**N02AX02**| **TRAMADOLUM** | |

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Prescriere limitată: **Durere severă, care nu răspunde la analgezice**

**non-opioide**

**Pentru durere acută la care tratamentul cu aspirină**

**şi/sau paracetamol este contraindicat sau nu a dat**

**rezultate.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N02AX02 TRAMADOLUM COMPR. ELIB. MODIF. 100 mg

TRAMADOLOR(R) 100 ID 100 mg HEXAL AG

N02AX02 TRAMADOLUM COMPR. ELIB. PREL. 100 mg

NOAX UNO 100 mg 100 mg LABOPHARM EUROPE LIMITED

TRALGIT SR 100 100 mg ZENTIVA AS

TRAMADOL(R) RETARD 100 mg KRKA D.D.

N02AX02 TRAMADOLUM COMPR. FILM. ELIB. 100 mg

PREL.

TRAMAL RETARD 100 mg 100 mg GRUNENTHAL GMBH

N02AX02 TRAMADOLUM SOL. INJ. 100 mg

MABRON 100 mg MEDOCHEMIE LTD.

TRADOLAN 100 mg LANNACHER HEILMITTEL GMBH

Prescriere limitată: **Tratamentul de scurtă durată al durerii acute**

N02AX02 TRAMADOLUM SUPOZ. 100 mg

TRADOLAN 100 mg LANNACHER HEILMITTEL GMBH

TRAMADOL 100 mg KRKA D.D.

TRAMAG 100 100 mg MAGISTRA C & C

TRAMAL(R) 100 mg GRUNENTHAL GMBH

N02AX02 TRAMADOLUM SOL. INJ. 100 mg/2 ml

TRALGIT 100 100 mg/2 ml ZENTIVA A.S.

Prescriere limitată: **Tratamentul de scurtă durată al durerii acute**

N02AX02 TRAMADOLUM PIC. ORALE, SOL. 100 mg/ml

TRALGIT 100 mg/ml ZENTIVA A.S.

N02AX02 TRAMADOLUM SOL. ORALA 100 mg/ml

TRADOLAN 100 mg/ml LANNACHER HEILMITTEL GMBH

N02AX02 TRAMADOLUM COMPR. ELIB. PREL 150 mg

TRALGIT SR 150 150 mg ZENTIVA AS

N02AX02 TRAMADOLUM COMPR. FILM. ELIB. 150 mg

PREL.

TRAMADOL RETARD 150 mg 150 mg KRKA D.D. NOVO MESTO

TRAMAL RETARD 150 mg 150 mg GRUNENTHAL GMBH

N02AX02 TRAMADOLUM COMPR. ELIB. PREL. 200 mg

NOAX UNO 200 mg 200 mg LABOPHARM EUROPE LIMITED

TRALGIT SR 200 200 mg ZENTIVA AS

N02AX02 TRAMADOLUM COMPR. FILM. ELIB. 200 mg

PREL.

TRAMADOL RETARD 200 mg 200 mg KRKA D.D. NOVO MESTO

TRAMAL RETARD 200 mg 200 mg GRUNENTHAL GMBH

N02AX02 TRAMADOLUM COMPR. ELIB. PREL. 300 mg

NOAX UNO 300 mg 300 mg LABOPHARM EUROPE LIMITED

N02AX02 TRAMADOLUM CAPS. 50 mg

K-ALMA(R) 50 mg ANTIBIOTICE SA

MABRON 50 mg 50 mg MEDOCHEMIE LTD.

TRALGIT 50 50 mg ZENTIVA A.S.

TRAMACALM 50 mg AC HELCOR SRL

TRAMADOL 50 mg KRKA D.D.

TRAMADOL LPH 50 mg 50 mg LABORMED PHARMA SA

TRAMADOL AL 50 50 mg ALIUD(R) PHARMA

GMBH & CO. KG

TRAMADOL ARENA 50 mg ARENA GROUP S.A.

TRAMAL(R) 50 mg GRUNENTHAL GMBH

URGENDOL 50 mg MEDICAROM GROUP SRL

N02AX02 TRAMADOLUM COMPR. 50 mg

TRAMADOL 50 mg 50 mg OZONE LABORATORIES LTD.

TRAMADOL EEL 50 mg BIO EEL SRL

TRAMAG 50 50 mg MAGISTRA C & C

N02AX02 TRAMADOLUM COMPR. FILM. 50 mg

TRADOLAN 50 mg 50 mg LANNACHER HEILMITTEL GMBH

N02AX02 TRAMADOLUM SOL. INJ. 50 mg

TRADOLAN 50 mg 50 mg LANNACHER HEILMITTEL GMBH

Prescriere limitată: **Tratamentul de scurtă durată al durerii acute**

N02AX02 TRAMADOLUM SOL. INJ. 50 mg/ml

TRALGIT 50 50 mg/ml ZENTIVA A.S.

TRAMADOL 50 mg/ml KRKA D.D.

TRAMADOL(R) AL 100 Fiole 50 mg/ml ALIUDR(R) PHARMA

GMBH & CO. KG

TRAMAL(R) 100 50 mg/ml GRUNENTHAL GMBH

TRAMAL(R) 50 50 mg/ml GRUNENTHAL GMBH

URGENDOL 50 mg/ml MEDICAROM GROUP SRL

Prescriere limitată: **Tratamentul de scurtă durată al durerii acute**

N02AX02 TRAMADOLUM PIC. ORALE, SOL.

TRAMADOL AL PICĂTURI ALIUD PHARMA GMBH & CO. KG

N02AX02 TRAMADOLUM PICATURI ORALE - SOL. 100 mg/ml

TRAMAL(R) 100 mg/ml GRUNENTHAL GMBH

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| **919** |**R05CB13**| **DORNAZA ALFA\*\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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R05CB13 DORNAZA ALFA SOL. INHAL 1 mg/ml

PULMOZYME 1 mg/ml ROCHE ROMANIA S.R.L.

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| **920** |**V03AC03**| **DEFERASIROXUM\*\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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V03AC03 DEFERASIROXUM COMPR. DISP. 125 mg

EXJADE 125 mg 125 mg NOVARTIS EUROPHARM LTD.

V03AC03 DEFERASIROXUM COMPR. DISP. 250 mg

EXJADE 250 mg 250 mg NOVARTIS EUROPHARM LTD.

V03AC03 DEFERASIROXUM COMPR. DISP. 500 mg

EXJADE 500 mg 500 mg NOVARTIS EUROPHARM LTD.

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| **921** |**V03AF01**| **MESNUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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V03AF01 MESNUM SOL. INJ. 400 mg/4 ml

UROMITEXAN(R) 400 mg 400 mg/4 ml BAXTER ONCOLOGY GMBH

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**SUBLISTA C2 - P9: PROGRAM NAŢIONAL DE TRANSPLANT DE ORGANE, ŢESUTURI ŞI CELULE DE ORIGINE UMANĂ. P9.2: TRANSPLANT DE CORD**

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| **922** |**B01AB08**| **REVIPARINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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B01AB08 REVIPARINUM SOL. INJ. 1432 ui/0.25 ml

CLIVARIN(R) 1432 UI/0.25 ml 1432 ui/0.25 ml ABBOTT GMBH & CO. KG

B01AB08 REVIPARINUM SOL. INJ. 3436 ui/0.6 ml

CLIVARIN(R) 3436 UI/0,6 ml 3436 ui/0.6 ml ABBOTT GMBH & CO. KG

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| **923** |**B05AA06**| **POLYGELINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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B05AA06 POLYGELINUM SOL. PERF. 3.5%

HAEMACCEL 3.5% THERASELECT GMBH

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| **924** |**C01CA24**| **EPINEPHRINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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C01CA24 EPINEPHRINUM SOL. INJ. 1 mg/ml

ADRENALINA 1 mg 1 mg/ml TERAPIA SA

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| **925** |**J01CR05**| **PIPERACILLINUM + TAZOBACTAMUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01CR05 PIPERACILLINUM + LIOF. PT. SOL. INJ.

TAZOBACTAMUM

TAZOCIN 2,25 WYETH LEDERLE PHARMA GMBH

TAZOCIN 4,5 WYETH LEDERLE PHARMA GMBH

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| **926** |**J01DD12**| **CEFOPERAZONUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01DD12 CEFOPERAZONUM PULB. PT. SOL. INJ. 1 g

LYZONE 1 g 1 g MEDICAROM GROUP S.R.L.

MEDOCEF 1 g 1 g MEDOCHEMIE LTD.

J01DD12 CEFOPERAZONUM PULB. PT. SOL. INJ. 2 g

LYZONE 2 g 2 g MEDICAROM GROUP S.R.L.

MEDOCEF 2 g 2 g MEDOCHEMIE LTD.

J01DD12 CEFOPERAZONUM PULB. PT. SOL. INJ. 500 mg

CEFOZON 500 mg 500 mg E.I.P.I.CO. MED S.R.L.

J01DD12 CEFOPERAZONUM PULB. PT. SOL. 1 g

INJ./PERF. I.M./I.V.

CEFOZON 1 g 1 g E.I.P.I.CO. MED S.R.L.

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| **927** |**J01DH51**| **IMIPENEMUM + CILASTATINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01DH51 IMIPENEMUM + PULB. PT. SOL. PERF.

CILASTATINUM

TIENAM I.V. MERCK SHARP & DOHME

ROMANIA S.R.L.

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| **928** |**J01XX08**| **LINEZOLIDUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01XX08 LINEZOLIDUM GRAN. PT. SUSP. ORALA 100 mg/5 ml

ZYVOXID(R) 100 mg/5 ml PFIZER EUROPE MA EEIG

J01XX08 LINEZOLIDUM SOL. PERF. 2 mg/ml

ZYVOXID(R) 2 mg/ml PFIZER EUROPE MA EEIG

J01XX08 LINEZOLIDUM COMPR. FILM. 600 mg

ZYVOXID(R) 600 mg PFIZER EUROPE MA EEIG

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| **929** |**J02AC01**| **FLUCONAZOLUM** | |

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Prescriere limitată: **Tratament de întreţinere la pacienţi cu meningită**

**criptococică şi imunosupresie.**

**Profilaxia secundară a candidozei orofaringiene la**

**pacienţi cu imunosupresie.**

**Tratamentul meningitei criptococice la pacienţii care**

**nu pot lua sau nu tolerează amfotericina.**

**Tratamentul candidozelor severe şi care pun în pericol**

**viaţa la pacienţi care nu tolerează amfotericina.**

**Tratamentul candidozei orofaringiene la pacienţi cu**

**imunosupresie.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J02AC01 FLUCONAZOLUM CAPS. 100 mg

DIFLAZON 100 mg 100 mg KRKA D.D.

FLUCONAZOLE TEVA 100 mg 100 mg TEVA PHARMACEUTICALS SRL

FLUCORIC 100 mg 100 mg TERAPIA S.A.

FLUCOVIM 100 100 mg VIM SPECTRUM SRL

FUNGOLON 100 mg 100 mg BALKANPHARMA RAZGRAD AD

J02AC01 FLUCONAZOLUM CAPS. 150 mg

DIFLAZON 150 mg 150 mg KRKA D.D.

DIFLUCAN 150 mg 150 mg PFIZER EUROPE MA EEIG

FLUCONAZOL 150 mg 150 mg OZONE LABORATORIES LTD.

FLUCONAZOL MEDICO UNO 150 mg 150 mg MEDICO UNO PHARMACEUTICAL

SRL

FLUCONAZOL MEDOCHEMIE 150 mg 150 mg MEDOCHEMIE ROMANIA SRL

FLUCONAZOL SANDOZ(R) 150 150 mg SANDOZ SRL

FLUCONAZOL TERAPIA 150 mg 150 mg TERAPIA SA

FLUCONAZOLE TEVA 150 mg 150 mg TEVA PHARMACEUTICALS SRL

FLUCORIC 150 mg 150 mg TERAPIA S.A.

FLUCOVIM 150 150 mg VIM SPECTRUM SRL

MYCOMAX 150 150 mg ZENTIVA AS

MYCOSYSTA(R) 150 mg 150 mg GEDEON RICHTER PLC.

J02AC01 FLUCONAZOLUM CAPS. 200 mg

DIFLAZON 200 mg 200 mg KRKA D.D.

FLUCONAZOLE TEVA 200 mg 200 mg TEVA PHARMACEUTICALS SRL

J02AC01 FLUCONAZOLUM SOL. PERF. 2 mg/ml

DIFLAZON(R) 2 mg/ml KRKA D.D.

DIFLUCAN(R) 2 mg/ml PFIZER EUROPE MA EEIG

MYCOMAX(R) INF 2 mg/ml ZENTIVA AS

J02AC01 FLUCONAZOLUM CAPS. 50 mg

DIFLAZON 50 mg 50 mg KRKA D.D.

DIFLUCAN 50 mg 50 mg PFIZER EUROPE MA EEIG

FLUCONAZOL 50 mg 50 mg ARENA GROUP SA

FLUCONAZOL MEDOCHEMIE 50 mg 50 mg MEDOCHEMIE ROMANIA SRL

FLUCONAZOL SANDOZ(R) 50 50 mg SANDOZ SRL

FLUCONAZOL TERAPIA 50 mg 50 mg TERAPIA S.A.

FLUCONAZOLE TEVA 50 mg 50 mg TEVA PHARMACEUTICALS SRL

FLUCORIC 50 mg 50 mg TERAPIA S.A.

FLUCOVIM 50 50 mg VIM SPECTRUM SRL

FUNGOLON 50 mg 50 mg BALKANPHARMA RAZGRAD AD

J02AC01 FLUCONAZOLUM PULB. PT. SUSP. ORALA 50 mg/5 ml

DIFLUCAN(R) 50 mg/5 ml 50 mg/5 ml PFIZER EUROPE MA EEIG

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| **930** |**J02AC03**| **VORICONAZOLUM\*\*** | **Protocol: J012B** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J02AC03 VORICONAZOLUM COMPR. FILM. 200 mg

VFEND 200 mg 200 mg PFIZER LTD.

J02AC03 VORICONAZOLUM PULB. PT. SOL. PERF. 200 mg

VFEND 200 mg 200 mg PFIZER LTD.

J02AC03 VORICONAZOLUM PULB. PT. SUSP. ORALA 40 mg/ml

VFEND 40 mg/ml 40 mg/ml PFIZER LTD.

J02AC03 VORICONAZOLUM COMPR. FILM. 50 mg

VFEND 50 mg 50 mg PFIZER LTD.

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| **932** |**J05AB14**| **VALGANCICLOVIRUM\*\*** | |

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Prescriere limitată: **Tratamentul de iniţiere şi menţinere pentru retinita cu citomegalovirus (CMV) la pacienţi imunocompromişi.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J05AB14 VALGANCICLOVIRUM COMPR. FILM. 450 mg

VALCYTE(R) 450 mg 450 mg ROCHE ROMANIA SRL

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| **933** |**L04AA01**| **CICLOSPORINUM** | |

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Prescriere limitată: **Managementul rejectului de grefa la pacienţii supuşi procedurii de transplant.**

Monitorizarea atentă a pacienţilor este obligatorie.

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L04AA01 CICLOSPORINUM CAPS. MOI 100 mg

EQUORAL(R) 100 mg 100 mg IVAX - PHARMACEUTICALS

S.R.O.

L04AA01 CICLOSPORINUM SOL. ORALA 100 mg/ml

EQUORAL(R) 100 mg/ml IVAX - PHARMACEUTICALS

S.R.O.

SANDIMMUN NEORAL(R) 100 mg/ml NOVARTIS PHARMA GMBH

L04AA01 CICLOSPORINUM CAPS. MOI 25 mg

CICLORAL(R) HEXAL(R) 25 mg 25 mg HEXAL AG

EQUORAL(R) 25 mg 25 mg IVAX - PHARMACEUTICALS

S.R.O.

SANDIMMUN NEORAL(R) 25 mg NOVARTIS PHARMA GMBH

L04AA01 CICLOSPORINUM CAPS. MOI 50 mg

CICLORAL(R) HEXAL 50 mg 50 mg HEXAL AG

EQUORAL(R) 50 mg 50 mg IVAX - PHARMACEUTICALS

S.R.O.

SANDIMMUN NEORAL(R) 50 mg NOVARTIS PHARMA GMBH

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| **935** |**L04AA05**| **TACROLIMUSUM\*\*** | |

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Prescriere limitată: **Tratamentul rejetului de alogrefă rezistent la alte terapii imunosupresoare, la pacienţii adulţi.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L04AA05 TACROLIMUSUM CAPS. ELIB. PREL 0,5 mg

ADVAGRAF 0,5 mg 0,5 mg ASTELLAS PHARMA GMBH

L04AA05 TACROLIMUSUM CAPS. 0.5 mg

PROGRAF(R) 0,5 mg 0.5 mg ASTELLAS PHARMA GMBH

Prescriere limitată: **Profilaxia rejetului de alogrefă la adulţii cu transplant cardiac**

L04AA05 TACROLIMUSUM CAPS. 1 mg

PROGRAF(R) 1 mg 1 mg ASTELLAS IRELAND CO. LTD.

Prescriere limitată: **Profilaxia rejetului de alogrefă la adulţii cu transplant cardiac**

L04AA05 TACROLIMUSUM CAPS. ELIB. PREL. 1 mg

ADVAGRAF 1 mg 1 mg ASTELLAS PHARMA GMBH

L04AA05 TACROLIMUSUM CAPS. 5 mg

PROGRAF(R) 5 mg 5 mg ASTELLAS PHARMA GMBH

Prescriere limitată: **Profilaxia rejetului de alogrefă la adulţii cu transplant cardiac**

L04AA05 TACROLIMUSUM CAPS. ELIB. PREL. 5 mg

ADVAGRAF 5 mg 5 mg ASTELLAS PHARMA GMBH

L04AA05 TACROLIMUSUM CONC. PT. SOL. PERF. 5 mg/ml

PROGRAF(R) 5 mg/ml 5 mg/ml ASTELLAS PHARMA GMBH

Prescriere limitată: **Profilaxia rejetului de alogrefă la adulţii cu transplant cardiac**

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| **936** |**L04AA06**| **MYCOPHENOLATUM\*\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L04AA06 MYCOPHENOLATUM COMPR. FILM. GASTROREZ. 180 mg

MYFORTIC 180 mg 180 mg NOVARTIS PHARMA GMBH

L04AA06 MYCOPHENOLATUM PULB. PT. SUSP. ORALA 1 g/5 ml

CELLCEPT 1 mg/5 ml 1 g/5 ml ROCHE REGISTRATION LTD.

Prescriere limitată: **Profilaxia rejetului acut de grefă la pacienţii care primesc transplant alogen cardiac.**

L04AA06 MYCOPHENOLATUM CAPS. 250 mg

CELLCEPT 250 mg 250 mg ROCHE REGISTRATION LTD.

MYFENAX 250 mg 250 mg TEVA PHARMA BV

Prescriere limitată: **Profilaxia rejetului acut de grefă la pacienţii care primesc transplant alogen cardiac.**

L04AA06 MYCOPHENOLATUM COMPR. FILM. GASTROREZ. 360 mg

MYFORTIC 360 mg 360 mg NOVARTIS PHARMA GMBH

L04AA06 MYCOPHENOLATUM CAPS. 500 mg

MYFENAX 500 mg 500 mg TEVA PHARMA BV

L04AA06 MYCOPHENOLATUM COMPR. FILM. 500 mg

CELLCEPT 500 mg 500 mg ROCHE REGISTRATION LTD.

Prescriere limitată: **Profilaxia rejetului acut de grefă la pacienţii care primesc transplant alogen cardiac.**

L04AA06 MYCOPHENOLATUM PULB. PT. CONC. PT. 500 mg

SOL. PERF.

CELLCEPT 500 mg 500 mg ROCHE REGISTRATION LTD.

Prescriere limitată: **Profilaxia rejetului acut de grefă la pacienţii care primesc transplant alogen cardiac.**

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**SUBLISTA C2 - P9: PROGRAM NAŢIONAL DE TRANSPLANT DE ORGANE, ŢESUTURI ŞI CELULE DE ORIGINE UMANĂ. P9.3 TRANSPLANT HEPATIC**

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| **937** |**A05AA02**| **ACIDUM URSODEOXYCHOLICUM** | |

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NOTĂ:

**Nu se va prescrie în regim compensat pentru tratamentul litiazei biliare.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A05AA02 ACIDUM CAPS. 250 mg

URSODEOXYCHOLICUM

URSOFALK(R) 250 mg DR. FALK PHARMA GMBH

URSOSAN 250 mg PRO. MED. CS PRAHA AS

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| **938** |**B01AB05**| **ENOXAPARINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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B01AB05 ENOXAPARINUM SOL. INJ. 2000 ui

anti-Xa/0.2 ml

CLEXANE 2000 ui 2000 ui anti-Xa/0.2 ml LAB. AVENTIS

anti-Xa/0.2 ml

B01AB05 ENOXAPARINUM SOL. INJ. 4000 ui

anti-Xa/0,4 ml

CLEXANE 4000 ui 4000 ui anti-Xa/0,4 ml LAB. AVENTIS

anti-Xa/0.4 ml

B01AB05 ENOXAPARINUM SOL. INJ. 6000 ui

anti-Xa/0.6 ml

CLEXANE 6000 ui 6000 ui anti-Xa/0.6 ml LAB. AVENTIS

anti-Xa/0.6 ml

B01AB05 ENOXAPARINUM SOL. INJ. 8000 ui

anti-Xa/0.8 ml

CLEXANE 8000 ui 8000 ui anti-Xa/0.8 ml LAB. AVENTIS

anti-Xa/0.8 ml

B01AB05 ENOXAPARINUM SOL. INJ. 2000 ui

anti-Xa/0.2 ml

CLEXANE 2000 ui 2000 ui anti-Xa/0.2 ml LAB. AVENTIS

anti-Xa/0.2 ml

B01AB05 ENOXAPARINUM SOL. INJ. 4000 ui

anti-Xa/0,4 ml

CLEXANE 4000 ui 4000 ui anti-Xa/0,4 ml LAB. AVENTIS

anti-Xa/0.4 ml

B01AB05 ENOXAPARINUM SOL. INJ. 6000 ui

anti-Xa/0.6 ml

CLEXANE 6000 ui 6000 ui anti-Xa/0.6 ml LAB. AVENTIS

anti-Xa/0.6 ml

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| **939** |**B01AB08**| **REVIPARINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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B01AB08 REVIPARINUM SOL. INJ. 1432 ui/0.25 ml

CLIVARIN(R) 1432 UI/0.25 ml 1432 ui/0.25 ml ABBOTT GMBH & CO. KG

B01AB08 REVIPARINUM SOL. INJ. 3436 ui/0.6 ml

CLIVARIN(R) 3436 UI/0,6 ml 3436 ui/0.6 ml ABBOTT GMBH & CO. KG

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| **940** |**B01AC11**| **ILOPROSTUM\*\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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B01AC11 ILOPROSTUM CONC. PT. SOL. PERF. 20 µg/ml

ILOMEDIN(R) 20 20 µg/ml SCHERING AG

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| **941** |**B01AD02**| **ALTEPLASUM\*\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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B01AD02 ALTEPLASUM LIOF. + SOLV. PT. SOL. 50 mg

INJ.

ACTILYSE 50 mg BOEHRINGER INGELHEIM INT.

GMBH

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| **944** |**C03EB01**| **COMBINAŢII (SPIRONOLACTONUM + FUROSEMIDUM)** | |

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Electroliţii serici trebuie să fie verificaţi periodic.

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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C03EB01 COMBINAŢII CAPS.

(SPIRONOLACTONUM +

FUROSEMIDUM)

DIUREX 50 TERAPIA SA

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| **945** |**H01BA02**| **DESMOPRESSINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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H01BA02 DESMOPRESSINUM

MINIRIN 0,2 mg 0.2 mg FERRING AB

H01BA02 DESMOPRESSINUM COMPR. 0.2 mg

MINIRIN 0,2 mg 0.2 mg FERRING AB

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| **946** |**J01CR05**| **PIPERACILLINUM + TAZOBACTAMUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01CR05 PIPERACILLINUM + LIOF. PT. SOL. INJ.

TAZOBACTAMUM

TAZOCIN 2,25 WYETH LEDERLE PHARMA GMBH

TAZOCIN 4,5 WYETH LEDERLE PHARMA GMBH

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| **947** |**J01XX08**| **LINEZOLIDUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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J01XX08 LINEZOLIDUM GRAN. PT. SUSP. ORALA 100 mg/5 ml

ZYVOXID(R) 100 mg/5 ml PFIZER EUROPE MA EEIG

J01XX08 LINEZOLIDUM SOL. PERF. 2 mg/ml

ZYVOXID(R) 2 mg/ml PFIZER EUROPE MA EEIG

J01XX08 LINEZOLIDUM COMPR. FILM. 600 mg

ZYVOXID(R) 600 mg PFIZER EUROPE MA EEIG

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| **948** |**J02AC03**| **VORICONAZOLUM\*\*** | **Protocol: J012B** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J02AC03 VORICONAZOLUM COMPR. FILM. 200 mg

VFEND 200 mg 200 mg PFIZER LTD.

J02AC03 VORICONAZOLUM PULB. PT. SOL. PERF. 200 mg

VFEND 200 mg 200 mg PFIZER LTD.

J02AC03 VORICONAZOLUM PULB. PT. SUSP. ORALA 40 mg/ml

VFEND 40 mg/ml 40 mg/ml PFIZER LTD.

J02AC03 VORICONAZOLUM COMPR. FILM. 50 mg

VFEND 50 mg 50 mg PFIZER LTD.

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| **949** |**J02AX04**| **CASPOFUNGINUM\*\*** | **Protocol: J010D** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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J02AX04 CASPOFUNGINUM PULB. PT. CONC. PT. 50 mg

SOL. PERF.

CANCIDAS 50 mg 50 mg MERCK SHARP & DOHME LTD

J02AX04 CASPOFUNGINUM PULB. PT. CONC. PT. 70 mg

SOL. PERF.

CANCIDAS 70 mg 70 mg MERCK SHARP & DOHME LTD

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| **951** |**J05AB14**| **VALGANCICLOVIRUM\*\*** | |

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Prescriere limitată: **Tratamentul de iniţiere şi menţinere pentru retinita cu citomegalovirus (CMV) la pacienţi imunocompromişi.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J05AB14 VALGANCICLOVIRUM COMPR. FILM. 450 mg

VALCYTE(R) 450 mg 450 mg ROCHE ROMANIA SRL

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| **953** |**L03AA02**| **FILGRASTIMUM (G-CSF)** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L03AA02 FILGRASTIMUM (G-CSF) SOL. INJ. 30 MU/0.5 ml

NEUPOGEN(R) 30 MU/0.5 ml AMGEN EUROPE B.V.

L03AA02 FILGRASTIMUM (G-CSF) SOL. INJ. 48 MU/0.5 ml

NEUPOGEN(R) 48 MU/0.5 ml AMGEN EUROPE B.V.

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| **954** |**L04AA01**| **CICLOSPORINUM** | |

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Prescriere limitată: **Managementul rejectului de grefă la pacienţii supuşi procedurii de transplant.**

Monitorizarea atentă a pacienţilor este obligatorie.

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L04AA01 CICLOSPORINUM CAPS. MOI 100 mg

EQUORAL(R) 100 mg 100 mg IVAX - PHARMACEUTICALS

S.R.O.

L04AA01 CICLOSPORINUM SOL. ORALA 100 mg/ml

EQUORAL(R) 100 mg/ml IVAX - PHARMACEUTICALS

S.R.O.

SANDIMMUN NEORAL(R) 100 mg/ml NOVARTIS PHARMA GMBH

L04AA01 CICLOSPORINUM CAPS. MOI 25 mg

CICLORAL(R) HEXAL(R) 25 mg 25 mg HEXAL AG

EQUORAL(R) 25 mg 25 mg IVAX - PHARMACEUTICALS

S.R.O.

SANDIMMUN NEORAL(R) 25 mg NOVARTIS PHARMA GMBH

L04AA01 CICLOSPORINUM CAPS. MOI 50 mg

CICLORAL(R) HEXAL 50 mg 50 mg HEXAL AG

EQUORAL(R) 50 mg 50 mg IVAX - PHARMACEUTICALS

S.R.O.

SANDIMMUN NEORAL(R) 50 mg NOVARTIS PHARMA GMBH

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| **955** |**L04AA05**| **TACROLIMUSUM\*\*** | |

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Prescriere limitată: **Tratamentul rejetului de alogrefă rezistent la alte**

**terapii imunosupresoare, la pacienţii adulţi.**

**Profilaxia rejetului de grefă la pacienţii care primesc**

**transplant hepatic alogen.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L04AA05 TACROLIMUSUM CAPS. ELIB. PREL 0,5 mg

ADVAGRAF 0,5 mg 0,5 mg ASTELLAS PHARMA GMBH

L04AA05 TACROLIMUSUM CAPS. 0.5 mg

PROGRAF(R) 0,5 mg 0.5 mg ASTELLAS PHARMA GMBH

L04AA05 TACROLIMUSUM CAPS. 1 mg

PROGRAF(R) 1 mg 1 mg ASTELLAS IRELAND CO. LTD.

L04AA05 TACROLIMUSUM CAPS. ELIB. PREL. 1 mg

ADVAGRAF 1 mg 1 mg ASTELLAS PHARMA GMBH

L04AA05 TACROLIMUSUM CAPS. 5 mg

PROGRAF(R) 5 mg 5 mg ASTELLAS PHARMA GMBH

L04AA05 TACROLIMUSUM CAPS. ELIB. PREL. 5 mg

ADVAGRAF 5 mg 5 mg ASTELLAS PHARMA GMBH

L04AA05 TACROLIMUSUM CONC. PT. SOL. PERF. 5 mg/ml

PROGRAF(R) 5 mg/ml 5 mg/ml ASTELLAS PHARMA GMBH

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| **956** |**L04AA06**| **MYCOPHENOLATUM\*\*** | |

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Prescriere limitată: **Profilaxia rejetului acut de grefă la pacienţii care primesc transplant alogen hepatic.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L04AA06 MYCOPHENOLATUM COMPR. FILM. GASTROREZ. 180 mg

MYFORTIC 180 mg 180 mg NOVARTIS PHARMA GMBH

L04AA06 MYCOPHENOLATUM PULB. PT. SUSP. ORALA 1 g/5 ml

CELLCEPT 1 mg/5 ml 1 g/5 ml ROCHE REGISTRATION LTD.

Prescriere limitată: **Profilaxia rejetului acut de grefă la pacienţii care primesc transplant alogen hepatic**

L04AA06 MYCOPHENOLATUM CAPS. 250 mg

CELLCEPT 250 mg 250 mg ROCHE REGISTRATION LTD.

MYFENAX 250 mg 250 mg TEVA PHARMA BV

Prescriere limitată: **Profilaxia rejetului acut de grefă la pacienţii care primesc transplant alogen hepatic**

L04AA06 MYCOPHENOLATUM COMPR. FILM. GASTROREZ. 360 mg

MYFORTIC 360 mg 360 mg NOVARTIS PHARMA GMBH

L04AA06 MYCOPHENOLATUM CAPS. 500 mg

MYFENAX 500 mg 500 mg TEVA PHARMA BV

Prescriere limitată: **Profilaxia rejetului acut de grefă la pacienţii care primesc transplant alogen hepatic**

L04AA06 MYCOPHENOLATUM COMPR. FILM. 500 mg

CELLCEPT 500 mg 500 mg ROCHE REGISTRATION LTD.

L04AA06 MYCOPHENOLATUM PULB. PT. CONC. PT. 500 mg

SOL. PERF.

CELLCEPT 500 mg 500 mg ROCHE REGISTRATION LTD.

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| **957** |**L04AA10**| **SIROLIMUS\*\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L04AA10 SIROLIMUS COMPR. FILM. 1 mg

RAPAMUNE 1 mg 1 mg WYETH EUROPA LTD.

Monitorizarea atentă a pacienţilor este obligatorie

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**SUBLISTA C2 - P9: PROGRAM NAŢIONAL DE TRANSPLANT DE ORGANE, ŢESUTURI ŞI CELULE DE ORIGINE UMANĂ. P9.4 TRANSPLANT RENAL, TRANSPLANT COMBINAT RINICHI ŞI PANCREAS**

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| **958** |**A05AA02**| **ACIDUM URSODEOXYCHOLICUM** | |

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NOTĂ:

**Nu se va prescrie în regim compensat pentru tratamentul litiazei biliare**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A05AA02 ACIDUM CAPS. 250 mg

URSODEOXYCHOLICUM

URSOFALK(R) 250 mg DR. FALK PHARMA GMBH

URSOSAN 250 mg PRO. MED. CS PRAHA AS

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| **959** |**A11CC03**| **ALFACALCIDOLUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A11CC03 ALFACALCIDOLUM CAPS. MOI 0.25 µg

ALPHA D3 0,25 µg 0.25 µg TEVA PHARMACEUTICALS SRL

A11CC03 ALFACALCIDOLUM CAPS. MOI 0.50 µg

ALPHA D3 0.50 µg 0.50 µg TEVA PHARMACEUTICALS SRL

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| **960** |**B01AB05**| **ENOXAPARINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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B01AB05 ENOXAPARINUM SOL. INJ. 2000 ui

anti-Xa/0.2 ml

CLEXANE 2000 ui 2000 ui anti-Xa/0.2 ml LAB. AVENTIS

anti-Xa/0.2 ml

B01AB05 ENOXAPARINUM SOL. INJ. 4000 ui

anti-Xa/0,4 ml

CLEXANE 4000 ui 4000 ui anti-Xa/0,4 ml LAB. AVENTIS

anti-Xa/0.4 ml

B01AB05 ENOXAPARINUM SOL. INJ. 6000 ui

anti-Xa/0.6 ml

CLEXANE 6000 ui 6000 ui anti-Xa/0.6 ml LAB. AVENTIS

anti-Xa/0.6 ml

B01AB05 ENOXAPARINUM SOL. INJ. 8000 ui

anti-Xa/0.8 ml

CLEXANE 8000 ui 8000 ui anti-Xa/0.8 ml LAB. AVENTIS

anti-Xa/0.8 ml

B01AB05 ENOXAPARINUM SOL. INJ. 2000 ui

anti-Xa/0.2 ml

CLEXANE 2000 ui 2000 ui anti-Xa/0.2 ml LAB. AVENTIS

anti-Xa/0.2 ml

B01AB05 ENOXAPARINUM SOL. INJ. 4000 ui

anti-Xa/0,4 ml

CLEXANE 4000 ui 4000 ui anti-Xa/0,4 ml LAB. AVENTIS

anti-Xa/0.4 ml

B01AB05 ENOXAPARINUM SOL. INJ. 6000 ui

anti-Xa/0.6 ml

CLEXANE 6000 ui 6000 ui anti-Xa/0.6 ml LAB. AVENTIS

anti-Xa/0.6 ml

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| **961** |**B01AB04**| **DALTEPARINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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B01AB04 DALTEPARINUM SOL. INJ. 10000 ui/ml

FRAGMIN 10000 UI/ml 10000 ui/ml PFIZER EUROPE MA EEIG

B01AB04 DALTEPARINUM SOL. INJ. 15000 ui/0.6 ml

FRAGMIN 15000 UI/0,6 ml 15000 ui/0.6 ml PFIZER EUROPE MA EEIG

B01AB04 DALTEPARINUM SOL. INJ. 2500 ui/0.2 ml

FRAGMIN 2500 UI/0,2 ml 2500 ui/0.2 ml PFIZER EUROPE MA EEIG

B01AB04 DALTEPARINUM SOL. INJ. 5000 ui/0.2 ml

FRAGMIN 5000 UI/0,2 ml 5000 ui/0.2 ml PFIZER EUROPE MA EEIG

B01AB04 DALTEPARINUM SOL. INJ. 7500 ui/0.3 ml

FRAGMIN 7500 UI/0,3 ml 7500 ui/0.3 ml PFIZER EUROPE MA EEIG

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| **962** |**B01AB08**| **REVIPARINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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B01AB08 REVIPARINUM SOL. INJ. 1432 ui/0.25 ml

CLIVARIN(R) 1432 UI/0,25 ml 1432 ui/0.25 ml ABBOTT GMBH & CO. KG

B01AB08 REVIPARINUM SOL. INJ. 3436 ui/0.6 ml

CLIVARIN(R) 3436 UI/0,6 ml 3436 ui/0.6 ml ABBOTT GMBH & CO. KG

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*|* ***963*** *| \*\*\* Abrogată |*

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*|* ***964*** *| \*\*\* Abrogată |*

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| **965** |**B05AA06**| **POLYGELINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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B05AA06 POLYGELINUM SOL. PERF. 3.5%

HAEMACCEL 3.5% THERASELECT GMBH

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| **966** |**H01CB02**| **OCTREOTIDUM\*\*** | **Protocol: H010C** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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H01CB02 OCTREOTIDUM SOL. INJ. 0.1 mg/ml

SANDOSTATIN(R) 0.1 mg/ml NOVARTIS PHARMA GMBH

H01CB02 OCTREOTIDUM PULB. + SOLV. PT. SUSP. 10 mg

INJ. (I.M.) CU ELIB.

PRELUNG.

SANDOSTATIN LAR 10 mg 10 mg NOVARTIS PHARMA GMBH

H01CB02 OCTREOTIDUM PULB. + SOLV. PT. SUSP. 20 mg

INJ. (I.M.) CU ELIB.

PRELUNG.

SANDOSTATIN LAR 20 mg 20 mg NOVARTIS PHARMA GMBH

H01CB02 OCTREOTIDUM PULB. + SOLV. PT. SUSP. 30 mg

INJ. (I.M.) CU ELIB.

PRELUNG.

SANDOSTATIN LAR 30 mg 30 mg NOVARTIS PHARMA GMBH

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| **967** |**J01CR05**| **PIPERACILLINUM + TAZOBACTAMUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01CR05 PIPERACILLINUM + LIOF. PT. SOL. INJ.

TAZOBACTAMUM

TAZOCIN 2,25 WYETH LEDERLE PHARMA GMBH

TAZOCIN 4,5 WYETH LEDERLE PHARMA GMBH

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| **968** |**J01XA02**| **TEICOPLANINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01XA02 TEICOPLANINUM LIOF. + SOLV. PT. SOL. 400 mg

INJ.

TARGOCID(R) 400 mg 400 mg AVENTIS PHARMA LTD.

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| **969** |**J01XX08**| **LINEZOLIDUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01XX08 LINEZOLIDUM GRAN. PT. SUSP. ORALA 100 mg/5 ml

ZYVOXID(R) 100 mg/5 ml PFIZER EUROPE MA EEIG

J01XX08 LINEZOLIDUM SOL. PERF. 2 mg/ml

ZYVOXID(R) 2 mg/ml PFIZER EUROPE MA EEIG

J01XX08 LINEZOLIDUM COMPR. FILM. 600 mg

ZYVOXID(R) 600 mg PFIZER EUROPE MA EEIG

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| **970** |**J02AB02**| **KETOCONAZOLUM** | |

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Prescriere limitată: **Candidoza genitală simptomatică recurentă după**

**tratamentul local a cel puţin două episoade.**

**Candidoza orală la persoanele imunocompromise sever la**

**care tratamentul local nu a avut rezultate**

**Micoze sistemice la care alte forme de terapie**

**antifungică nu au avut efect.**

A fost raportată hepatotoxicitate la ketoconazol.

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J02AB02 KETOCONAZOLUM COMPR. 200 mg

KEFUNGIN 200 mg ANTIBIOTICE SA

KETOCONAZOL 200 mg 200 mg MAGISTRA C & C

KETOSTIN 200 mg 200 mg AC HELCOR SRL

NIZORAL 200 mg JANSSEN PHARMACEUTICA NV

NIZORAL 200 mg 200 mg TERAPIA SA

J02AB02 KETOCONAZOLUM COMPR. 200 mg

KEFUNGIN 200 mg ANTIBIOTICE SA

KETOCONAZOL 200 mg 200 mg MAGISTRA C & C

KETOSTIN 200 mg 200 mg AC HELCOR SRL

NIZORAL 200 mg JANSSEN PHARMACEUTICA NV

NIZORAL 200 mg 200 mg TERAPIA SA

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| **971** |**J02AC01**| **FLUCONAZOLUM** | |

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Prescriere limitată: **Tratament de întreţinere la pacienţi cu meningită**

**criptococică şi imunosupresie.**

**Profilaxia secundară a candidozei orofaringiene la**

**pacienţi cu imunosupresie.**

**Tratamentul meningitei criptococice la pacienţii care**

**nu pot lua sau nu tolerează amfotericina.**

**Tratamentul candidozelor severe şi care pun în pericol**

**viaţa la pacienţi care nu tolerează amfotericina.**

**Tratamentul candidozei orofaringiene la pacienţi cu**

**imunosupresie.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J02AC01 FLUCONAZOLUM CAPS. 100 mg

DIFLAZON 100 mg 100 mg KRKA D.D.

FLUCONAZOLE TEVA 100 mg 100 mg TEVA PHARMACEUTICALS SRL

FLUCORIC 100 mg 100 mg TERAPIA S.A.

FLUCOVIM 100 100 mg VIM SPECTRUM SRL

FUNGOLON 100 mg 100 mg BALKANPHARMA RAZGRAD AD

J02AC01 FLUCONAZOLUM CAPS. 150 mg

DIFLAZON 150 mg 150 mg KRKA D.D.

DIFLUCAN 150 mg 150 mg PFIZER EUROPE MA EEIG

FLUCONAZOL 150 mg 150 mg OZONE LABORATORIES LTD.

FLUCONAZOL MEDICO UNO 150 mg 150 mg MEDICO UNO PHARMACEUTICAL

SRL

FLUCONAZOL MEDOCHEMIE 150 mg 150 mg MEDOCHEMIE ROMANIA SRL

FLUCONAZOL SANDOZ(R) 150 150 mg SANDOZ SRL

FLUCONAZOL TERAPIA 150 mg 150 mg TERAPIA SA

FLUCONAZOLE TEVA 150 mg 150 mg TEVA PHARMACEUTICALS SRL

FLUCORIC 150 mg 150 mg TERAPIA S.A.

FLUCOVIM 150 150 mg VIM SPECTRUM SRL

MYCOMAX 150 150 mg ZENTIVA AS

MYCOSYSTA(R) 150 mg 150 mg GEDEON RICHTER PLC.

J02AC01 FLUCONAZOLUM CAPS. 200 mg

DIFLAZON 200 mg 200 mg KRKA D.D.

FLUCONAZOLE TEVA 200 mg 200 mg TEVA PHARMACEUTICALS SRL

J02AC01 FLUCONAZOLUM SOL. PERF. 2 mg/ml

DIFLAZON(R) 2 mg/ml KRKA D.D.

DIFLUCAN(R) 2 mg/ml PFIZER EUROPE MA EEIG

MYCOMAX(R) INF 2 mg/ml ZENTIVA AS

J02AC01 FLUCONAZOLUM CAPS. 50 mg

DIFLAZON 50 mg 50 mg KRKA D.D.

DIFLUCAN 50 mg 50 mg PFIZER EUROPE MA EEIG

FLUCONAZOL 50 mg 50 mg ARENA GROUP SA

FLUCONAZOL MEDOCHEMIE 50 mg 50 mg MEDOCHEMIE ROMANIA SRL

FLUCONAZOL SANDOZ(R) 50 50 mg SANDOZ SRL

FLUCONAZOL TERAPIA 50 mg 50 mg TERAPIA S.A.

FLUCONAZOLE TEVA 50 mg 50 mg TEVA PHARMACEUTICALS SRL

FLUCORIC 50 mg 50 mg TERAPIA S.A.

FLUCOVIM 50 50 mg VIM SPECTRUM SRL

FUNGOLON 50 mg 50 mg BALKANPHARMA RAZGRAD AD

J02AC01 FLUCONAZOLUM PULB. PT. SUSP. ORALA 50 mg/5ml

DIFLUCAN(R) 50 mg/5 ml 50 mg/5 ml PFIZER EUROPE MA EEIG

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| **972** |**J02AC02**| **ITRACONAZOLUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J02AC02 ITRACONAZOLUM CAPS. 100 mg

ITRACONAZOL 100 mg 100 mg TERAPIA S.A.

OMICRAL 100 mg 100 mg MEDICO UNO PHARMACEUTICAL

S.R.L

ORUNGAL 100 mg JANSSEN PHARMACEUTICA NV

SPORILIN 100 mg 100 mg GEDEON RICHTER ROMANIA

S.A.

Prescriere limitată: **Sporotricoza sistemică**

Prescriere limitată: **Profilaxia secundară a candidozei orofaringiene la**

**pacienţi cu imunosupresie**

Prescriere limitată: **Tratamentul candidozei orofaringiene la pacienţi cu**

**imunosupresie**

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| **973** |**J02AC03**| **VORICONAZOLUM\*\*** | **Protocol: J012B** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J02AC03 VORICONAZOLUM COMPR. FILM. 200 mg

VFEND 200 mg 200 mg PFIZER LTD.

J02AC03 VORICONAZOLUM PULB. PT. SOL. PERF. 200 mg

VFEND 200 mg 200 mg PFIZER LTD.

J02AC03 VORICONAZOLUM PULB. PT. SUSP. ORALA 40 mg/ml

VFEND 40 mg/ml 40 mg/ml PFIZER LTD.

J02AC03 VORICONAZOLUM COMPR. FILM. 50 mg

VFEND 50 mg 50 mg PFIZER LTD.

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| **974** |**J02AX04**| **CASPOFUNGINUM\*\*** | **Protocol: J010D** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J02AX04 CASPOFUNGINUM PULB. PT. CONC. PT. 50 mg

SOL. PERF.

CANCIDAS 50 mg 50 mg MERCK SHARP & DOHME LTD

J02AX04 CASPOFUNGINUM PULB. PT. CONC. PT. 70 mg

SOL. PERF.

CANCIDAS 70 mg 70 mg MERCK SHARP & DOHME LTD

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| **976** |**J05AB01**| **ACICLOVIRUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J05AB01 ACICLOVIRUM CAPS. 200 mg

ACICLOVIR 200 mg 200 mg SLAVIA PHARM SRL

EUVIROX 200 mg 200 mg EUROPHARM SA

J05AB01 ACICLOVIRUM COMPR. 200 mg

ACICLOVIR 200 mg 200 mg TERAPIA SA

CLOVIRAL 200 mg 200 mg ANTIBIOTICE SA

ZOVIRAX 200 mg GLAXO WELLCOME FOUNDATION

LTD.

J05AB01 ACICLOVIRUM COMPR. DISP. 200 mg

ACICLOVIR 200 mg 200 mg OZONE LABORATORIES LTD.

LOVIR 200 mg 200 mg RANBAXY UK LIMITED

J05AB01 ACICLOVIRUM PULB. PT. SOL. 250 mg

INJ./PERF.

VIROLEX 250 mg KRKA D.D. NOVO MESTO

J05AB01 ACICLOVIRUM CAPS. 400 mg

ACICLOVIR 400 mg 400 mg ARENA GROUP S.A.

J05AB01 ACICLOVIRUM COMPR. 400 mg

ACICLOVIR 400 mg 400 mg EGIS PHARMACEUTICALS

P.L.C.

J05AB01 ACICLOVIRUM COMPR. FILM. 400 mg

ACIKLOVIR 400 mg A & G MED TRADING S.R.L.

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| **977** |**J05AB14**| **VALGANCICLOVIRUM\*\*** | |

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Prescriere limitată: **Tratamentul de iniţiere şi menţinere pentru retinita cu citomegalovirus (CMV) la pacienţi imunocompromişi.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J05AB14 VALGANCICLOVIRUM COMPR. FILM. 450 mg

VALCYTE(R) 450 mg 450 mg ROCHE ROMANIA SRL

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| **978** |**J05AB11**| **VALACYCLOVIRUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J05AB11 VALACYCLOVIRUM COMPR. FILM. 500 mg

VALTREX 500 mg 500 mg THE WELLCOME FOUNDATION

LTD.

Prescriere limitată: **Profilaxia infecţiei şi bolii cu citomegalovirus în urma transplantului renal la pacienţii cu risc de boală cu citomegalovirus**

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| **980** |**L01AA01**| **CYCLOPHOSPHAMIDUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L01AA01 CYCLOPHOSPHAMIDUM PULB. PT. SOL. 1 g

INJ./PERF.

ENDOXAN(R) 1 g 1 g BAXTER ONCOLOGY GMBH

L01AA01 CYCLOPHOSPHAMIDUM PULB. PT. SOL. 200 mg

PERF./INJ. I.V.

ENDOXAN 200 mg 200 mg ACTAVIS S.R.L.

L01AA01 CYCLOPHOSPHAMIDUM PULB. PT. SOL. 500 mg

INJ./PERF.

ENDOXAN(R) 500 mg 500 mg BAXTER ONCOLOGY GMBH

L01AA01 CYCLOPHOSPHAMIDUM DRAJ. 50 mg

ENDOXAN(R) 50 mg 50 mg BAXTER ONCOLOGY GMBH

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| **981** |**L03AA02**| **FILGRASTIMUM (G-CSF)** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L03AA02 FILGRASTIMUM (G-CSF) SOL. INJ. 30 MU/0.5 ml

NEUPOGEN(R) 30 MU/0.5 ml AMGEN EUROPE B.V.

L03AA02 FILGRASTIMUM (G-CSF) SOL. INJ. 48 MU/0.5 ml

NEUPOGEN(R) 48 MU/0.5 ml AMGEN EUROPE B.V.

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| **982** |**L04AA01**| **CICLOSPORINUM** | |

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Prescriere limitată: **Managementul rejectului de grefă la pacienţii supuşi procedurii de transplant.**

Monitorizarea atentă a pacienţilor este obligatorie.

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L04AA01 CICLOSPORINUM CAPS. MOI 100 mg

EQUORAL(R) 100 mg 100 mg IVAX - PHARMACEUTICALS

S.R.O.

L04AA01 CICLOSPORINUM SOL. ORALA 100 mg/ml

EQUORAL(R) 100 mg/ml IVAX - PHARMACEUTICALS

S.R.O.

SANDIMMUN NEORAL(R) 100 mg/ml NOVARTIS PHARMA GMBH

L04AA01 CICLOSPORINUM CAPS. MOI 25 mg

CICLORAL(R) HEXAL(R) 25 mg 25 mg HEXAL AG

EQUORAL(R) 25 mg 25 mg IVAX - PHARMACEUTICALS

S.R.O.

SANDIMMUN NEORAL(R) 25 mg NOVARTIS PHARMA GMBH

L04AA01 CICLOSPORINUM CAPS. MOI 50 mg

CICLORAL(R) HEXAL 50 mg 50 mg HEXAL AG

EQUORAL(R) 50 mg 50 mg IVAX - PHARMACEUTICALS

S.R.O.

SANDIMMUN NEORAL(R) 50 mg NOVARTIS PHARMA GMBH

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| **984** |**L04AA05**| **TACROLIMUSUM\*\*** | |

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Prescriere limitată: **Profilaxia rejetului de alogrefă la adulţii cu**

**transplant renal.**

**Tratamentul rejetului de alogrefă rezistent la alte**

**terapii imunosupresoare, la pacienţii adulţi.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L04AA05 TACROLIMUSUM CAPS. ELIB. PREL 0,5 mg

ADVAGRAF 0,5 mg 0,5 mg ASTELLAS PHARMA GMBH

L04AA05 TACROLIMUSUM CAPS. 0.5 mg

PROGRAF(R) 0,5 mg 0.5 mg ASTELLAS PHARMA GMBH

L04AA05 TACROLIMUSUM CAPS. 1 mg

PROGRAF(R) 1 mg 1 mg ASTELLAS IRELAND CO. LTD.

L04AA05 TACROLIMUSUM CAPS. ELIB. PREL. 1 mg

ADVAGRAF 1 mg 1 mg ASTELLAS PHARMA GMBH

L04AA05 TACROLIMUSUM CAPS. 5 mg

PROGRAF(R) 5 mg 5 mg ASTELLAS PHARMA GMBH

L04AA05 TACROLIMUSUM CAPS. ELIB. PREL. 5 mg

ADVAGRAF 5 mg 5 mg ASTELLAS PHARMA GMBH

L04AA05 TACROLIMUSUM CONC. PT. SOL. PERF. 5 mg/ml

PROGRAF(R) 5 mg/ml 5 mg/ml ASTELLAS PHARMA GMBH

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| **985** |**L04AA06**| **MYCOPHENOLATUM\*\*** | |

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Prescriere limitată: **Profilaxia rejetului acut de grefă la pacienţii care primesc transplant alogen renal.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L04AA06 MYCOPHENOLATUM COMPR. FILM. GASTROREZ. 180 mg

MYFORTIC 180 mg 180 mg NOVARTIS PHARMA GMBH

L04AA06 MYCOPHENOLATUM PULB. PT. SUSP. ORALA 1 g/5 ml

CELLCEPT 1 mg/5 ml 1 g/5 ml ROCHE REGISTRATION LTD.

L04AA06 MYCOPHENOLATUM CAPS. 250 mg

CELLCEPT 250 mg 250 mg ROCHE REGISTRATION LTD.

MYFENAX 250 mg 250 mg TEVA PHARMA BV

L04AA06 MYCOPHENOLATUM COMPR. FILM. GASTROREZ. 360 mg

MYFORTIC 360 mg 360 mg NOVARTIS PHARMA GMBH

L04AA06 MYCOPHENOLATUM CAPS. 500 mg

MYFENAX 500 mg 500 mg TEVA PHARMA BV

L04AA06 MYCOPHENOLATUM COMPR. FILM. 500 mg

CELLCEPT 500 mg 500 mg ROCHE REGISTRATION LTD.

L04AA06 MYCOPHENOLATUM PULB. PT. CONC. PT. 500 mg

SOL. PERF.

CELLCEPT 500 mg 500 mg ROCHE REGISTRATION LTD.

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| **986** |**L04AA08**| **DACLIZUMABUM\*\*** | |

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Prescriere limitată: **Profilaxia rejecţiei acute de organ în transplantul renal alogen de novo şi se utilizează concomitent cu o schemă de tratament cu imunosupresoare, incluzând ciclosporină şi glucocorticoizi, la pacienţii care nu sunt hiperimunizaţi.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L04AA08 DACLIZUMABUM CONC. PT. SOL. PERF. 5 mg/ml

ZENAPAX 5 mg/ml 5 mg/ml ROCHE REGISTRATION LTD.

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| **987** |**L04AA09**| **BASILIXIMABUM\*\*** | |

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Prescriere limitată: **Profilaxia rejetului acut de organ în transplantul renal alogen de novo la pacienţii adulţi şi copii. Se utilizează concomitent cu tratamentul imunosupresor cu ciclosporină microemulsionată şi corticosteroizi, la pacienţii cu mai puţin de 80% anticorpi reactivi, sau în tratament imunosupresor de întreţinere triplu cu ciclosporină microemulsionată, corticosteroizi şi azatioprină sau mofetil micofenolat.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L04AA09 BASILIXIMABUM LIOF. + SOLV. PT. SOL. 20 mg

INJ./PERF.

SIMULECT 20 mg 20 mg NOVARTIS EUROPHARM LTD.

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| **988** |**L04AA10**| **SIROLIMUS\*\*** | |

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Prescriere limitată: **Profilaxia rejetului de organ la pacienţii adulţi cu transplant renal şi risc imunologic mic sau moderat.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L04AA10 SIROLIMUS COMPR. FILM. 1 mg

RAPAMUNE 1 mg 1 mg WYETH EUROPA LTD.

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| **989** |**L04AX01**| **AZATHIOPRINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L04AX01 AZATHIOPRINUM COMPR. FILM. 50 mg

IMURAN(R) 50 mg THE WELLCOME FOUNDATION

LTD.

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| **990** |**M05BA04**| **ACIDUM ALENDRONICUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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M05BA04 ACIDUM ALENDRONICUM COMPR. 10 mg

FOSAMAX 10 mg 10 mg MERCK SHARP & DOHME S.R.L.

M05BA04 ACIDUM ALENDRONICUM COMPR. 70 mg

TEVA NAT 70 mg TEVA PHARMACEUTICALS SRL

M05BA04 ACIDUM ALENDRONICUM COMPR. 70 mg

FOSAMAX 70 mg 70 mg MERCK SHARP & DOHME S.R.L.

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| **991** |**N02AB02**| **PETHIDINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N02AB02 PETHIDINUM SOL. INJ. 50 mg/ml

MIALGIN(R) 100 mg/2 ml 50 mg/ml ZENTIVA SA

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| **993** |**B01AB08**| **REVIPARINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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B01AB08 REVIPARINUM SOL. INJ.

CLIVARIN (R) 1432 UI/0.25 ml 1432 ui/0.25 ml ABBOTT GMBH & CO. KG

CLIVARIN(R) 1432 UI/0.25 ml 1432 ui/0.25 ml ABBOTT GMBH & CO. KG

B01AB08 REVIPARINUM SOL. INJ.

CLIVARIN (R) 3436 UI/0,6 ml 3436 ui/0.6 ml ABBOTT GMBH & CO. KG

CLIVARIN(R) 3436 UI/0,6 ml 3436 ui/0.6 ml ABBOTT GMBH & CO. KG

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| **994** |**B05AA06**| **POLYGELINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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B05AA06 POLYGELINUM SOL. PERF. 3.5%

HAEMACCEL 3.5% THERASELECT GMBH

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| **995** |**J01XX08**| **LINEZOLIDUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01XX08 LINEZOLIDUM GRAN. PT. SUSP. ORALA

ZYVOXID(R) 100 mg/5 ml PFIZER EUROPE MA EEI

ZYVOXID(R) 100 mg/5 ml PFIZER EUROPE MA EEIG

J01XX08 LINEZOLIDUM SOL. PERF.

ZYVOXID(R) 2 mg/ml PFIZER EUROPE MA EEI

ZYVOXID(R) 2 mg/ml PFIZER EUROPE MA EEIG

J01XX08 LINEZOLIDUM COMPR. FILM.

ZYVOXID(R) 600 mg PFIZER EUROPE MA EEI

ZYVOXID(R) 600 mg PFIZER EUROPE MA EEIG

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| **996** |**J02AC03**| **VORICONAZOLUM\*\*** | **Protocol: J012B** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J02AC03 VORICONAZOLUM COMPR. FILM.

VFEND(R) 200 mg PFIZER LIMITED

VFEND 200 mg 200 mg PFIZER LTD.

J02AC03 VORICONAZOLUM PULB. PT. SOL. PERF.

VFEND(R) 200 mg PFIZER LIMITED

VFEND 200 mg 200 mg PFIZER LTD.

J02AC03 VORICONAZOLUM PULB. PT. SUSP. ORALA

VFEND(R) 40 mg/ml 40 mg/ml PFIZER LIMITED

VFEND 40 mg/ml 40 mg/ml PFIZER LTD.

J02AC03 VORICONAZOLUM COMPR. FILM.

VFEND(R) 50 mg PFIZER LIMITED

VFEND 50 mg 50 mg PFIZER LTD.

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| **998** |**J05AB14**| **VALGANCICLOVIRUM\*\*** | |

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Prescriere limitată: **Tratamentul de iniţiere şi menţinere pentru retinita cu citomegalovirus (CMV) la pacienţi imunocompromişi.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J05AB14 VALGANCICLOVIRUM COMPR. FILM. 450 mg

VALCYTE(R) 450 mg 450 mg ROCHE ROMANIA SRL

J05AB14 VALGANCICLOVIRUM COMPR. FILM.

VALCYTE(R) 450 mg 450 mg ROCHE ROMANIA SRL

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**SUBLISTA C2-P9: PROGRAM NAŢIONAL DE TRANSPLANT DE ORGANE, ŢESUTURI ŞI CELULE DE ORIGINE UMANĂ. P9.6 TRANSPLANT PULMONAR**

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| **999** |**B01AB05**| **ENOXAPARINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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B01AB05 ENOXAPARINUM SOL. INJ. 2000 ui

anti-Xa/0.2 ml

CLEXANE 2000 ui 2000 ui anti-Xa/0.2 ml LAB. AVENTIS

anti-Xa/0.2 ml

B01AB05 ENOXAPARINUM SOL. INJ. 4000 ui

anti-Xa/0,4ml

CLEXANE 4000 ui 4000 ui anti-Xa/0,4 ml LAB. AVENTIS

anti-Xa/0.4 ml

B01AB05 ENOXAPARINUM SOL. INJ. 6000 ui

anti-Xa/0.6 ml

CLEXANE 6000 ui 6000 ui anti-Xa/0.6 ml LAB. AVENTIS

anti-Xa/0.6 ml

B01AB05 ENOXAPARINUM SOL. INJ. 8000 ui

anti-Xa/0.8 ml

CLEXANE 8000 ui 8000 ui anti-Xa/0.8 ml LAB. AVENTIS

anti-Xa/0.8 ml

B01AB05 ENOXAPARINUM SOL. INJ. 2000 ui

anti-Xa/0.2 ml

CLEXANE 2000 ui 2000 ui anti-Xa/0.2 ml LAB. AVENTIS

anti-Xa/0.2 ml

B01AB05 ENOXAPARINUM SOL. INJ. 4000 ui

anti-Xa/0,4 ml

CLEXANE 4000 ui 4000 ui anti-Xa/0,4 ml LAB. AVENTIS

anti-Xa/0.4 ml

B01AB05 ENOXAPARINUM SOL. INJ. 6000 ui

anti-Xa/0.6 ml

CLEXANE 6000 ui 6000 ui anti-Xa/0.6 ml LAB. AVENTIS

anti-Xa/0.6 ml

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| **1000** |**B01AB08**| **REVIPARINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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B01AB08 REVIPARINUM SOL. INJ. 1432 ui/0.25 ml

CLIVARIN(R) 1432 UI/0.25 ml 1432 ui/0.25 ml ABBOTT GMBH & CO. KG

B01AB08 REVIPARINUM SOL. INJ. 3436 ui/0.6 ml

CLIVARIN(R) 3436 UI/0,6 ml 3436 ui/0.6 ml ABBOTT GMBH & CO. KG

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| **1002** |**C01CA24**| **EPINEPHRINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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C01CA24 EPINEPHRINUM SOL. INJ. 1 mg/ml

ADRENALINA 1 mg 1 mg/ml TERAPIA SA

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| **1003** |**J01CR05**| **PIPERACILLINUM + TAZOBACTAMUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01CR05 PIPERACILLINUM + LIOF. PT. SOL. INJ.

TAZOBACTAMUM

TAZOCIN 2,25 WYETH LEDERLE PHARMA GMBH

TAZOCIN 4,5 WYETH LEDERLE PHARMA GMBH

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| **1004** |**J01XX08**| **LINEZOLIDUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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J01XX08 LINEZOLIDUM GRAN. PT. SUSP. ORALA 100 mg/5 ml

ZYVOXID(R) 100 mg/5 ml PFIZER EUROPE MA EEIG

J01XX08 LINEZOLIDUM SOL. PERF. 2 mg/ml

ZYVOXID(R) 2 mg/ml PFIZER EUROPE MA EEIG

J01XX08 LINEZOLIDUM COMPR. FILM. 600 mg

ZYVOXID(R) 600 mg PFIZER EUROPE MA EEIG

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| **1005** |**J02AC01**| **FLUCONAZOLUM** | |

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Prescriere limitată: **Tratament de întreţinere la pacienţi cu meningită**

**criptococică şi imunosupresie.**

**Profilaxia secundară a candidozei orofaringiene la**

**pacienţi cu imunosupresie.**

**Tratamentul meningitei criptococice la pacienţii care**

**nu pot lua sau nu tolerează amfotericina.**

**Tratamentul candidozelor severe şi care pun în pericol**

**viaţa la pacienţi care nu tolerează amfotericina.**

**Tratamentul candidozei orofaringiene la pacienţi cu**

**imunosupresie.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J02AC01 FLUCONAZOLUM CAPS. 100 mg

DIFLAZON 100 mg 100 mg KRKA D.D.

FLUCONAZOLE TEVA 100 mg 100 mg TEVA PHARMACEUTICALS SRL

FLUCORIC 100 mg 100 mg TERAPIA S.A.

FLUCOVIM 100 100 mg VIM SPECTRUM SRL

FUNGOLON 100 mg 100 mg BALKANPHARMA RAZGRAD AD

J02AC01 FLUCONAZOLUM CAPS. 150 mg

DIFLAZON 150 mg 150 mg KRKA D.D.

DIFLUCAN 150 mg 150 mg PFIZER EUROPE MA EEIG

FLUCONAZOL 150 mg 150 mg OZONE LABORATORIES LTD.

FLUCONAZOL MEDICO UNO 150 mg 150 mg MEDICO UNO PHARMACEUTICAL

SRL

FLUCONAZOL MEDOCHEMIE 150 mg 150 mg MEDOCHEMIE ROMANIA SRL

FLUCONAZOL SANDOZ(R) 150 150 mg SANDOZ SRL

FLUCONAZOL TERAPIA 150 mg 150 mg TERAPIA SA

FLUCONAZOLE TEVA 150 mg 150 mg TEVA PHARMACEUTICALS SRL

FLUCORIC 150 mg 150 mg TERAPIA S.A.

FLUCOVIM 150 150 mg VIM SPECTRUM SRL

MYCOMAX 150 150 mg ZENTIVA AS

MYCOSYSTA(R) 150 mg 150 mg GEDEON RICHTER PLC.

J02AC01 FLUCONAZOLUM CAPS. 200 mg

DIFLAZON 200 mg 200 mg KRKA D.D.

FLUCONAZOLE TEVA 200 mg 200 mg TEVA PHARMACEUTICALS SRL

J02AC01 FLUCONAZOLUM SOL. PERF. 2 mg/ml

DIFLAZON(R) 2 mg/ml KRKA D.D.

DIFLUCAN(R) 2 mg/ml PFIZER EUROPE MA EEIG

MYCOMAX(R)INF 2 mg/ml ZENTIVA AS

J02AC01 FLUCONAZOLUM CAPS. 50 mg

DIFLAZON 50 mg 50 mg KRKA D.D.

DIFLUCAN 50 mg 50 mg PFIZER EUROPE MA EEIG

FLUCONAZOL 50 mg 50 mg ARENA GROUP SA

FLUCONAZOL MEDOCHEMIE 50 mg 50 mg MEDOCHEMIE ROMANIA SRL

FLUCONAZOL SANDOZ(R) 50 50 mg SANDOZ SRL

FLUCONAZOL TERAPIA 50 mg 50 mg TERAPIA S.A.

FLUCONAZOLE TEVA 50 mg 50 mg TEVA PHARMACEUTICALS SRL

FLUCORIC 50 mg 50 mg TERAPIA S.A.

FLUCOVIM 50 50 mg VIM SPECTRUM SRL

FUNGOLON 50 mg 50 mg BALKANPHARMA RAZGRAD AD

J02AC01 FLUCONAZOLUM PULB. PT. SUSP. ORALA 50 mg/5 ml

DIFLUCAN(R) 50 mg/5 ml 50 mg/5 ml PFIZER EUROPE MA EEIG

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| **1006** |**J02AC03**| **VORICONAZOLUM\*\*** | **Protocol: J012B** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J02AC03 VORICONAZOLUM COMPR. FILM. 200 mg

VFEND 200 mg 200 mg PFIZER LTD.

J02AC03 VORICONAZOLUM PULB. PT. SOL. PERF. 200 mg

VFEND 200 mg 200 mg PFIZER LTD.

J02AC03 VORICONAZOLUM PULB. PT. SUSP. ORALA 40 mg/ml

VFEND 40 mg/ml 40 mg/ml PFIZER LTD.

J02AC03 VORICONAZOLUM COMPR. FILM. 50 mg

VFEND 50 mg 50 mg PFIZER LTD.

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| **1008** |**J05AB01**| **ACICLOVIRUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J05AB01 ACICLOVIRUM CAPS. 200 mg

ACICLOVIR 200 mg 200 mg ARENA GROUP SA

EUVIROX 200 mg 200 mg EUROPHARM SA

J05AB01 ACICLOVIRUM COMPR. 200 mg

ACICLOVIR 200 mg 200 mg TERAPIA SA

CLOVIRAL 200 mg 200 mg ANTIBIOTICE SA

ZOVIRAX 200 mg GLAXO WELLCOME FOUNDATION

LTD.

J05AB01 ACICLOVIRUM COMPR. DISP. 200 mg

ACICLOVIR 200 mg 200 mg OZONE LABORATORIES LTD.

LOVIR 200 mg 200 mg RANBAXY UK LIMITED

J05AB01 ACICLOVIRUM PULB. PT. SOL. 250 mg

INJ./PERF.

VIROLEX 250 mg KRKA D.D. NOVO MESTO

J05AB01 ACICLOVIRUM CAPS. 400 mg

ACICLOVIR 400 mg 400 mg ARENA GROUP SA

J05AB01 ACICLOVIRUM COMPR. 400 mg

ACICLOVIR 400 mg 400 mg EGIS PHARMACEUTICALS

P.L.C.

J05AB01 ACICLOVIRUM COMPR. FILM. 400 mg

ACIKLOVIR 400 mg A & G MED TRADING S.R.L.

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| **1009** |**J05AB14**| **VALGANCICLOVIRUM\*\*** | |

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Prescriere limitată: **Tratamentul de iniţiere şi menţinere pentru retinita cu citomegalovirus (CMV) la pacienţi imunocompromişi.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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J05AB14 VALGANCICLOVIRUM COMPR. FILM. 450 mg

VALCYTE(R) 450 mg 450 mg ROCHE ROMANIA SRL

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| **1010** |**L04AA01**| **CICLOSPORINUM** | |

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Prescriere limitată: **Managementul rejectului de grefă la pacienţii supuşi procedurii de transplant.**

Monitorizarea atentă a pacienţilor este obligatorie.

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L04AA01 CICLOSPORINUM CAPS. MOI 100 mg

EQUORAL(R) 100 mg 100 mg IVAX - PHARMACEUTICALS

S.R.O.

L04AA01 CICLOSPORINUM SOL. ORALA 100 mg/ml

EQUORAL(R) 100 mg/ml IVAX - PHARMACEUTICALS

S.R.O.

SANDIMMUN NEORAL(R) 100 mg/ml NOVARTIS PHARMA GMBH

L04AA01 CICLOSPORINUM CAPS. MOI 25 mg

CICLORAL(R) HEXAL(R) 25 mg 25 mg HEXAL AG

EQUORAL(R) 25 mg 25 mg IVAX - PHARMACEUTICALS

S.R.O.

SANDIMMUN NEORAL(R) 25 mg NOVARTIS PHARMA GMBH

L04AA01 CICLOSPORINUM CAPS. MOI 50 mg

CICLORAL(R) HEXAL 50 mg 50 mg HEXAL AG

EQUORAL(R) 50 mg 50 mg IVAX - PHARMACEUTICALS

S.R.O.

SANDIMMUN NEORAL(R) 50 mg NOVARTIS PHARMA GMBH

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| **1012** |**L04AA06**| **MYCOPHENOLATUM\*\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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L04AA06 MYCOPHENOLATUM COMPR. FILM. GASTROREZ. 180 mg

MYFORTIC 180 mg 180 mg NOVARTIS PHARMA GMBH

L04AA06 MYCOPHENOLATUM PULB. PT. SUSP. ORALA 1 g/5 ml

CELLCEPT 1 mg/5 ml 1 g/5 ml ROCHE REGISTRATION LTD.

L04AA06 MYCOPHENOLATUM CAPS. 250 mg

CELLCEPT 250 mg 250 mg ROCHE REGISTRATION LTD.

MYFENAX 250 mg 250 mg TEVA PHARMA BV

L04AA06 MYCOPHENOLATUM COMPR. FILM. GASTROREZ. 360 mg

MYFORTIC 360 mg 360 mg NOVARTIS PHARMA GMBH

L04AA06 MYCOPHENOLATUM CAPS. 500 mg

MYFENAX 500 mg 500 mg TEVA PHARMA BV

L04AA06 MYCOPHENOLATUM COMPR. FILM. 500 mg

CELLCEPT 500 mg 500 mg ROCHE REGISTRATION LTD.

L04AA06 MYCOPHENOLATUM PULB. PT. CONC. PT. 500 mg

SOL. PERF.

CELLCEPT 500 mg 500 mg ROCHE REGISTRATION LTD.

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| **1013** |**L04AA09**| **BASILIXIMABUM\*\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L04AA09 BASILIXIMABUM LIOF. + SOLV. PT. SOL. 20 mg

INJ./PERF.

SIMULECT 20 mg 20 mg NOVARTIS EUROPHARM LTD.

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| **1014** |**L04AX01**| **AZATHIOPRINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L04AX01 AZATHIOPRINUM COMPR. FILM. 50 mg

IMURAN(R) 50 mg THE WELLCOME FOUNDATION

LTD.

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| **1015** |**N02AX02**| **TRAMADOLUM** | |

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Prescriere limitată: **Durere severă, care nu răspunde la analgezice**

**non-opioide.**

**Pentru durere acută la care tratamentul cu aspirină**

**şi/sau paracetamol este contraindicat sau nu a dat**

**rezultate.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N02AX02 TRAMADOLUM COMPR. ELIB. MODIF. 100 mg

TRAMADOLOR(R) 100 ID 100 mg HEXAL AG

N02AX02 TRAMADOLUM COMPR. ELIB. PREL. 100 mg

NOAX UNO 100 mg 100 mg LABOPHARM EUROPE LIMITED

TRALGIT SR 100 100 mg ZENTIVA AS

TRAMADOL(R) RETARD 100 mg KRKA D.D.

N02AX02 TRAMADOLUM COMPR. FILM. ELIB. 100 mg

PREL.

TRAMAL RETARD 100 mg 100 mg GRUNENTHAL GMBH

N02AX02 TRAMADOLUM SOL. INJ. 100 mg

MABRON 100 mg MEDOCHEMIE LTD.

TRADOLAN 100 mg LANNACHER HEILMITTEL GMBH

Prescriere limitată: **Tratamentul de scurtă durată al durerii acute.**

N02AX02 TRAMADOLUM SUPOZ. 100 mg

TRADOLAN 100 mg LANNACHER HEILMITTEL GMBH

TRAMADOL 100 mg KRKA D.D.

TRAMAG 100 100 mg MAGISTRA C & C

TRAMAL(R) 100 mg GRUNENTHAL GMBH

N02AX02 TRAMADOLUM SOL. INJ. 100 mg/2 ml

TRALGIT 100 100 mg/2 ml ZENTIVA A.S.

Prescriere limitată: **Tratamentul de scurtă durată al durerii acute.**

N02AX02 TRAMADOLUM PIC. ORALE, SOL. 100 mg/ml

TRALGIT 100 mg/ml ZENTIVA A.S.

N02AX02 TRAMADOLUM SOL. ORALA 100 mg/ml

TRADOLAN 100 mg/ml LANNACHER HEILMITTEL GMBH

N02AX02 TRAMADOLUM COMPR. ELIB. PREL. 150 mg

TRALGIT SR 150 150 mg ZENTIVA AS

N02AX02 TRAMADOLUM COMPR. FILM. ELIB. 150 mg

PREL.

TRAMADOL RETARD 150 mg 150 mg KRKA D.D. NOVO MESTO

TRAMAL RETARD 150 mg 150 mg GRUNENTHAL GMBH

N02AX02 TRAMADOLUM COMPR. ELIB. PREL. 200 mg

NOAX UNO 200 mg 200 mg LABOPHARM EUROPE LIMITED

TRALGIT SR 200 200 mg ZENTIVA AS

N02AX02 TRAMADOLUM COMPR. FILM. ELIB. 200 mg

PREL.

TRAMADOL RETARD 200 mg 200 mg KRKA D.D. NOVO MESTO

TRAMAL RETARD 200 mg 200 mg GRUNENTHAL GMBH

N02AX02 TRAMADOLUM COMPR. ELIB. PREL. 300 mg

NOAX UNO 300 mg 300 mg LABOPHARM EUROPE LIMITED

N02AX02 TRAMADOLUM CAPS. 50 mg

K-ALMA(R) 50 mg ANTIBIOTICE SA

MABRON 50 mg 50 mg MEDOCHEMIE LTD.

TRALGIT 50 50 mg ZENTIVA A.S.

TRAMACALM 50 mg AC HELCOR SRL

TRAMADOL 50 mg KRKA D.D.

TRAMADOL LPH 50 mg 50 mg LABORMED PHARMA SA

TRAMADOL AL 50 50 mg ALIUD(R) PHARMA

GMBH & CO. KG

TRAMADOL ARENA 50 mg ARENA GROUP S.A.

TRAMAL(R) 50 mg GRUNENTHAL GMBH

URGENDOL 50 mg MEDICAROM GROUP SRL

N02AX02 TRAMADOLUM COMPR. 50 mg

TRAMADOL 50 mg 50 mg OZONE LABORATORIES LTD.

TRAMADOL EEL 50 mg BIO EEL SRL

TRAMAG 50 50 mg MAGISTRA C & C

N02AX02 TRAMADOLUM COMPR. FILM. 50 mg

TRADOLAN 50 mg 50 mg LANNACHER HEILMITTEL GMBH

N02AX02 TRAMADOLUM SOL. INJ. 50 mg

TRADOLAN 50 mg 50 mg LANNACHER HEILMITTEL GMBH

Prescriere limitată: **Tratamentul de scurtă durată al durerii acute**

N02AX02 TRAMADOLUM SOL. INJ. 50 mg/ml

TRALGIT 50 50 mg/ml ZENTIVA A.S.

TRAMADOL 50 mg/ml KRKA D.D.

TRAMADOL(R) AL 100 Fiole 50 mg/ml ALIUD(R) PHARMA

GMBH & CO. KG

TRAMAL(R) 100 50 mg/ml GRUNENTHAL GMBH

TRAMAL(R) 50 50 mg/ml GRUNENTHAL GMBH

URGENDOL 50 mg/ml MEDICAROM GROUP SRL

Prescriere limitată: **Tratamentul de scurtă durată al durerii acute**

N02AX02 TRAMADOLUM PIC. ORALE, SOL.

TRAMADOL AL PICATURI ALIUD PHARMA GMBH & CO. KG

N02AX02 TRAMADOLUM PICATURI ORALE - SOL 100 mg/ml

TRAMAL(R) 100 mg/ml GRUNENTHAL GMBH

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**SUBLISTA C2 - P9: PROGRAM NAŢIONAL DE TRANSPLANT DE ORGANE, ŢESUTURI ŞI CELULE DE ORIGINE UMANĂ. P9.7 TRATAMENTUL STĂRII POSTTRANSPLANT ÎN AMBULATORIU A PACIENŢILOR TRANSPLANTAT!**

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| **1016** |**A05AA02**| **ACIDUM URSODEOXYCHOLICUM** | |

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NOTĂ:

**Nu se va prescrie în regim compensat pentru tratamentul litiazei biliare.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A05AA02 ACIDUM CAPS. 250 mg

URSODEOXYCHOLICUM

URSOFALK(R) 250 mg DR. FALK PHARMA GMBH

URSOSAN 250 mg PRO. MED. CS PRAHA AS

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*|* ***1017*** *| \*\*\* Abrogată |*

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*|* ***1018*** *| \*\*\* Abrogată |*

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*|* ***1019*** *| \*\*\* Abrogată |*

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| **1021** |**H02AB04**| **METHYLPREDNISOLONUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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H02AB04 METHYLPREDNISOLONUM LIOF. PT. SOL. INJ. 125 mg

LEMOD SOLU 125 mg 125 mg HEMOFARM S.R.L.

H02AB04 METHYLPREDNISOLONUM LIOF. SI SOLV. PT. SOL. 125 mg/2 ml

INJ.

SOLU-MEDROL ACT-O-VIAL 125 mg/2 ml PFIZER EUROPE MA EEIG

H02AB04 METHYLPREDNISOLONUM COMPR. 16 mg

MEDROL A 16 16 mg PFIZER EUROPE MA EEIG

H02AB04 METHYLPREDNISOLONUM LIOF. PT. SOL. INJ. 20 mg

LEMOD SOLU 20 mg 20 mg HEMOFARM S.R.L.

H02AB04 METHYLPREDNISOLONUM LIOF. SI SOLV. PT. SOL. 250 mg/4 ml

INJ.

SOLU-MEDROL ACT-O-VIAL 250 mg/4 ml PFIZER EUROPE MA EEIG

H02AB04 METHYLPREDNISOLONUM COMPR. 32 mg

MEDROL 32 32 mg PFIZER EUROPE MA EEIG

H02AB04 METHYLPREDNISOLONUM LIOF. PT. SOL. INJ. 40 mg

LEMOD SOLU 40 mg 40 mg HEMOFARM S.R.L.

H02AB04 METHYLPREDNISOLONUM LIOF. SI SOLV. PT. SOL. 40 mg/1 ml

INJ.

SOLU-MEDROL ACT-O-VIAL 40 mg/1 ml PFIZER EUROPE MA EEIG

H02AB04 METHYLPREDNISOLONUM COMPR. 4 mg

MEDROL 4 mg 4 mg PFIZER EUROPE MA EEIG

H02AB04 METHYLPREDNISOLONUM LIOF. PT. SOL. INJ. 500 mg

LEMOD SOLU 500 mg 500 mg HEMOFARM S.R.L.

H02AB04 METHYLPREDNISOLONUM LIOF. + SOLV. PT. SOL. 500 mg/7.8 ml

INJ.

SOLU-MEDROL 500 mg/7,8 ml 500 mg/7.8 ml PFIZER EUROPE MA EEIG

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| **1022** |**H02AB07**| **PREDNISONUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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H02AB07 PREDNISONUM COMPR. 5 mg

N-PREDNISON 5 mg MEDUMAN SA

PREDNISON 5 mg 5 mg SINTOFARM SA

PREDNISON ARENA 5 mg 5 mg ARENA GROUP SA

PREDNISON GEDEON RICHTER 5 mg 5 mg GEDEON RICHTER ROMANIA SA

PREDNISON MAGISTRA 5 mg 5 mg MAGISTRA C & C

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| **1023** |**J01EE01**| **SULFAMETHOXAZOLUM + TRIMETHOPRIMUM** | |

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Există un risc crescut de reacţie adversă severă la administrarea acestui medicament la persoane în vârstă.

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01EE01 SULFAMETHOXAZOLUM + SUSP. ORALA 200 mg/40 mg/5 ml

TRIMETHOPRIMUM

EPITRIM 200 mg/40 mg/5 ml E.I.P.I.CO. MED S.R.L.

J01EE01 SULFAMETHOXAZOLUM + SIROP 25 mg/5 mg/ml

TRIMETHOPRIMUM

SUMETROLIM 25 mg/5 mg/ml EGIS PHARMACEUTICALS

P.L.C.

J01EE01 SULFAMETHOXAZOLUM + COMPR. 400 mg/80 mg

TRIMETHOPRIMUM

BISEPTRIM 400 mg/80 mg EUROPHARM SA

CO-TRIMELL 400 mg/80 mg BIO EEL SRL

SUMETROLIM 400 mg/80 mg EGIS PHARMACEUTICALS

P.L.C.

TAGREMIN 400 mg/80 mg ZENTIVA S.A.

J01EE01 SULFAMETHOXAZOLUM + SOL. PERF. 400 mg/80 mg

TRIMETHOPRIMUM

SEPTRIN 400 mg/80 mg THE WELLCOME FOUNDATION

LTD.

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| **1024** |**J02AC01**| **FLUCONAZOLUM** | |

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Prescriere limitată: **Tratament de întreţinere la pacienţi cu meningită**

**criptococică şi imunosupresie.**

**Profilaxia secundară a candidozei orofaringiene la**

**pacienţi cu imunosupresie.**

**Tratamentul meningitei criptococice la pacienţii care**

**nu pot lua sau nu tolerează amfotericina.**

**Tratamentul candidozelor severe şi care pun în pericol**

**viaţa la pacienţi care nu tolerează amfotericina.**

**Tratamentul candidozei orofaringiene la pacienţi cu**

**imunosupresie.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J02AC01 FLUCONAZOLUM CAPS. 100 mg

DIFLAZON 100 mg 100 mg KRKA D.D.

FLUCONAZOLE TEVA 100 mg 100 mg TEVA PHARMACEUTICALS SRL

FLUCORIC 100 mg 100 mg TERAPIA S.A.

FLUCOVIM 100 100 mg VIM SPECTRUM SRL

FUNGOLON 100 mg 100 mg BALKANPHARMA RAZGRAD AD

J02AC01 FLUCONAZOLUM CAPS. 150 mg

DIFLAZON 150 mg 150 mg KRKA D.D.

DIFLUCAN 150 mg 150 mg PFIZER EUROPE MA EEIG

FLUCONAZOL 150 mg 150 mg OZONE LABORATORIES LTD.

FLUCONAZOL MEDICO UNO 150 mg 150 mg MEDICO UNO PHARMACEUTICAL

SRL

FLUCONAZOL MEDOCHEMIE 150 mg 150 mg MEDOCHEMIE ROMANIA SRL

FLUCONAZOL SANDOZ(R) 150 150 mg SANDOZ SRL

FLUCONAZOL TERAPIA 150 mg 150 mg TERAPIA SA

FLUCONAZOLE TEVA 150 mg 150 mg TEVA PHARMACEUTICALS SRL

FLUCORIC 150 mg 150 mg TERAPIA S.A.

FLUCOVIM 150 150 mg VIM SPECTRUM SRL

MYCOMAX 150 150 mg ZENTIVA AS

MYCOSYSTA(R) 150 mg 150 mg GEDEON RICHTER PLC.

J02AC01 FLUCONAZOLUM CAPS. 200 mg

DIFLAZON 200 mg 200 mg KRKA D.D.

FLUCONAZOLE TEVA 200 mg 200 mg TEVA PHARMACEUTICALS SRL

J02AC01 FLUCONAZOLUM SOL. PERF. 2 mg/ml

DIFLAZON(R) 2 mg/ml KRKA D.D.

DIFLUCAN(R) 2 mg/ml PFIZER EUROPE MA EEIG

MYCOMAX(R) INF 2 mg/ml ZENTIVA AS

J02AC01 FLUCONAZOLUM CAPS. 50 mg

DIFLAZON 50 mg 50 mg KRKA D.D.

DIFLUCAN 50 mg 50 mg PFIZER EUROPE MA EEIG

FLUCONAZOL 50 mg 50 mg ARENA GROUP SA

FLUCONAZOL MEDOCHEMIE 50 mg 50 mg MEDOCHEMIE ROMANIA SRL

FLUCONAZOL SANDOZ(R) 50 50 mg SANDOZ SRL

FLUCONAZOL TERAPIA 50 mg 50 mg TERAPIA S.A.

FLUCONAZOLE TEVA 50 mg 50 mg TEVA PHARMACEUTICALS SRL

FLUCORIC 50 mg 50 mg TERAPIA S.A.

FLUCOVIM 50 50 mg VIM SPECTRUM SRL

FUNGOLON 50 mg 50 mg BALKANPHARMA RAZGRAD AD

J02AC01 FLUCONAZOLUM PULB. PT. SUSP. ORALA 50 mg/5 ml

DIFLUCAN(R) 50 mg/5 ml 50 mg/5 ml PFIZER EUROPE MA EEIG

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| **1025** |**J02AC03**| **VORICONAZOLUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J02AC03 VORICONAZOLUM PULB. PT. SOL. PERF.

VFEND(R) 200 mg PFIZER LIMITED

VFEND 200 mg 200 mg PFIZER LTD.

J02AC03 VORICONAZOLUM COMPR. FILM. 50 mg

VFEND 50 mg 50 mg PFIZER LTD.

J02AC03 VORICONAZOLUM PULB. PT. SUSP. ORALA

VFEND(R) 40 mg/ml 40 mg/ml PFIZER LIMITED

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| **1026** |**J02AC04**| **POSACONAZOLUM\*\*** | |

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Prescriere limitată: **Profilaxia şi tratamentul infecţiilor fungice invazive**

**la pacienţii aflaţi sub chimioterapie de**

**inducţie-remisie pentru LAM sau pentru sindroame**

**mielodisplazice şi care prezintă risc înalt de a**

**dezvolta infecţii fungice masive.**

**Profilaxia şi tratamentul infecţiilor fungice invazive**

**la pacienţii în procedura de transplant medular şi**

**aflaţi sub terapie imunosupresoare cu doze mari, cu**

**risc mare de a dezvolta infecţii fungice masive.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J02AC04 POSACONAZOLUM SUSP. ORALA 40 mg/ml

NOXAFIL SP 40 mg/ml 40 mg/ml SP EUROPE

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| **1027** |**J05AB01**| **ACICLOVIRUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J05AB01 ACICLOVIRUM CAPS. 200 mg

ACICLOVIR 200 mg 200 mg SLAVIA PHARM SRL

EUVIROX 200 mg 200 mg EUROPHARM SA

J05AB01 ACICLOVIRUM COMPR. 200 mg

ACICLOVIR 200 mg 200 mg EGIS PHARMACEUTICALS

P.L.C.

CLOVIRAL 200 mg 200 mg ANTIBIOTICE SA

ZOVIRAX 200 mg GLAXO WELLCOME FOUNDATION

LTD.

J05AB01 ACICLOVIRUM COMPR. DISP. 200 mg

ACICLOVIR 200 mg 200 mg OZONE LABORATORIES LTD.

LOVIR 200 mg 200 mg RANBAXY UK LIMITED

J05AB01 ACICLOVIRUM PULB. PT. SOL. 250 mg

INJ./PERF.

VIROLEX 250 mg KRKA D.D. NOVO MESTO

J05AB01 ACICLOVIRUM CAPS. 400 mg

ACICLOVIR 400 mg 400 mg ARENA GROUP SA

J05AB01 ACICLOVIRUM COMPR. 400 mg

ACICLOVIR 400 mg 400 mg EGIS PHARMACEUTICALS

P.L.C.

J05AB01 ACICLOVIRUM COMPR. FILM. 400 mg

ACIKLOVIR 400 mg A & G MEDTRADING S.R.L.

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| **1028** |**J05AB14**| **VALGANCICLOVIRUM\*\*** | |

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Prescriere limitată: **Tratamentul de iniţiere şi menţinere pentru retinita cu citomegalovirus (CMV) la pacienţi imunocompromişi.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J05AB14 VALGANCICLOVIRUM COMPR. FILM. 450 mg

VALCYTE(R) 450 mg 450 mg ROCHE ROMANIA SRL

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| **1029** |**J05AF05**| **LAMIVUDINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J05AF05 LAMIVUDINUM COMPR. FILM. 100 mg

ZEFFIX 100 mg 100 mg GLAXO GROUP LTD.

J05AF05 LAMIVUDINUM SOL. ORALA 10 mg/ml

EPIVIR 10 mg/ml 10 mg/ml GLAXO GROUP LTD.

J05AF05 LAMIVUDINUM COMPR. FILM. 150 mg

EPIVIR 150 mg 150 mg GLAXO GROUP LTD.

J05AF05 LAMIVUDINUM SOL. ORALA 5 mg/ml

ZEFFIX 5 mg/ml 5 mg/ml GLAXO GROUP LTD.

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| **1030** |**L04AA01**| **CICLOSPORINUM** | |

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Prescriere limitată: **Managementul rejectului de grefă la pacienţii supuşi procedurii de transplant.**

Monitorizarea atentă a pacienţilor este obligatorie.

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L04AA01 CICLOSPORINUM CAPS. MOI 100 mg

EQUORAL(R) 100 mg 100 mg IVAX - PHARMACEUTICALS

S.R.O.

L04AA01 CICLOSPORINUM SOL. ORALA 100 mg/ml

EQUORAL(R) 100 mg/ml IVAX - PHARMACEUTICALS

S.R.O.

SANDIMMUN NEORAL(R) 100 mg/ml NOVARTIS PHARMA GMBH

L04AA01 CICLOSPORINUM CAPS. MOI 25 mg

CICLORAL(R) HEXAL(R) 25 mg 25 mg HEXAL AG

EQUORAL(R) 25 mg 25 mg IVAX - PHARMACEUTICALS

S.R.O.

SANDIMMUN NEORAL(R) 25 mg NOVARTIS PHARMA GMBH

L04AA01 CICLOSPORINUM CAPS. MOI 50 mg

CICLORAL(R) HEXAL 50 mg 50 mg HEXAL AG

EQUORAL(R) 50 mg 50 mg IVAX - PHARMACEUTICALS

S.R.O.

SANDIMMUN NEORAL(R) 50 mg NOVARTIS PHARMA GMBH

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| **1031** |**L04AA05**| **TACROLIMUSUM\*\*** | |

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Prescriere limitată: **Terapie de menţinere consecutivă iniţierii şi**

**stabilizării tratamentului cu mycophenolatum la**

**pacienţii cu transplant alogen renal.**

**Terapie de menţinere consecutivă iniţierii şi**

**stabilizării tratamentului cu mycophenolatum la**

**pacienţii cu transplant alogen cardiac.**

**Terapie de menţinere consecutivă iniţierii şi**

**stabilizării tratamentului cu mycophenolatum la**

**pacienţii cu transplant alogen hepatic.**

Monitorizarea atentă a pacienţilor este obligatorie.

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L04AA05 TACROLIMUSUM CAPS. ELIB. PREL 0,5 mg

ADVAGRAF 0,5 mg 0,5 mg ASTELLAS PHARMA GMBH

L04AA05 TACROLIMUSUM CAPS. 0.5 mg

PROGRAF(R) 0,5 mg 0.5 mg ASTELLAS PHARMA GMBH

L04AA05 TACROLIMUSUM CAPS. 1 mg

PROGRAF(R) 1 mg 1 mg ASTELLAS IRELAND CO. LTD.

L04AA05 TACROLIMUSUM CAPS. ELIB. PREL. 1 mg

ADVAGRAF 1 mg 1 mg ASTELLAS PHARMA GMBH

L04AA05 TACROLIMUSUM CAPS. 5 mg

PROGRAF(R) 5 mg 5 mg ASTELLAS PHARMA GMBH

L04AA05 TACROLIMUSUM CAPS. ELIB. PREL. 5 mg

ADVAGRAF 5 mg 5 mg ASTELLAS PHARMA GMBH

L04AA05 TACROLIMUSUM CONC. PT. SOL. PERF. 5 mg/ml

PROGRAF(R) 5 mg/ml 5 mg/ml ASTELLAS PHARMA GMBH

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| **1032** |**L04AA06**| **MYCOPHENOLATUM\*\*** | |

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Prescriere limitată: **Terapie de menţinere consecutivă iniţierii şi**

**stabilizării tratamentului cu mycophenolatum la**

**pacienţii cu transplant alogen renal.**

**Terapie de menţinere consecutivă iniţierii şi**

**stabilizării tratamentului cu mycophenolatum la**

**pacienţii cu transplant alogen cardiac.**

**Terapie de menţinere consecutivă iniţierii şi**

**stabilizării tratamentului cu mycophenolatum la**

**pacienţii cu transplant alogen hepatic.**

Monitorizarea atentă a pacienţilor este obligatorie.

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L04AA06 MYCOPHENOLATUM COMPR. FILM. GASTROREZ. 180 mg

MYFORTIC 180 mg 180 mg NOVARTIS PHARMA GMBH

L04AA06 MYCOPHENOLATUM PULB. PT. SUSP. ORALA 1 g/5 ml

CELLCEPT 1 mg/5 ml 1 g/5 ml ROCHE REGISTRATION LTD.

L04AA06 MYCOPHENOLATUM CAPS. 250 mg

CELLCEPT 250 mg 250 mg ROCHE REGISTRATION LTD.

MYFENAX 250 mg 250 mg TEVA PHARMA BV

L04AA06 MYCOPHENOLATUM COMPR. FILM. GASTROREZ. 360 mg

MYFORTIC 360 mg 360 mg NOVARTIS PHARMA GMBH

L04AA06 MYCOPHENOLATUM CAPS. 500 mg

MYFENAX 500 mg 500 mg TEVA PHARMA BV

L04AA06 MYCOPHENOLATUM COMPR. FILM. 500 mg

CELLCEPT 500 mg 500 mg ROCHE REGISTRATION LTD.

L04AA06 MYCOPHENOLATUM PULB. PT. CONC. PT. 500 mg

SOL. PERF.

CELLCEPT 500 mg 500 mg ROCHE REGISTRATION LTD.

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| **1033** |**L04AA10**| **SIROLIMUS\*\*** | |

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Prescriere limitată: **Terapie de menţinere, urmare a iniţierii şi stabilizării tratamentului cu sirolimus. Monitorizarea şi revizuirea terapiei va fi efectuată în unităţi de transplant.**

Monitorizarea atentă a pacienţilor este obligatorie.

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L04AA10 SIROLIMUS COMPR. FILM. 1 mg

RAPAMUNE 1 mg 1 mg WYETH EUROPA LTD.

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| **1034** |**L04AX01**| **AZATHIOPRINUM\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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L04AX01 AZATHIOPRINUM COMPR. FILM. 50 mg

IMURAN(R) 50 mg THE WELLCOME FOUNDATION

LTD.

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**SUBLISTA C2 - P10: PROGRAM NAŢIONAL DE SUPLEERE A FUNCŢIEI RENALE LA BOLNAVII CU INSUFICIENŢĂ RENALĂ CRONICĂ.**

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| **1035** |**A11CC03**| **ALFACALCIDOLUM** | **Protocol: A007E** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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A11CC03 ALFACALCIDOLUM CAPS. MOI 0.25 µg

ALPHA D3 0,25 µg 0.25 µg TEVA PHARMACEUTICALS SRL

A11CC03 ALFACALCIDOLUM CAPS. MOI 0.50 µg

ALPHA D3 0.50 µg 0.50 µg TEVA PHARMACEUTICALS SRL

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| **1036** |**A11CC04**| **CALCITRIOLUM\*\*** | **Protocol: A006E** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A11CC04 CALCITRIOLUM CAPS. MOI 0.25 µg

ROCALTROL 0.25 µg ROCHE ROMANIA S.R.L.

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| **1037** |**A11CC07**| **PARICALCITOLUM\*\*** | **Protocol: A005E** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A11CC07 PARICALCITOLUM SOL. INJ. 5 µg/ml

ZEMPLAR 5 µg/ml ABBOTT LABORATORIES S.A.

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| **1038** |**B01AB01**| **HEPARINUM\*\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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B01AB01 HEPARINUM SOL. INJ. 5000 ui/ml

HEPARIN 5000 ui/ml POLIPHARMA INDUSTRIES

S.R.L.

HEPARIN SANDOZ(R) 5000 ui/ml SANDOZ GMBH

25000 UI/5 ml

HEPARINE SODIQUE PANPHARMA 5000 ui/ml LAB. PANPHARMA

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| **1039** |**B01AB05**| **ENOXAPARINUM\*\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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B01AB05 ENOXAPARINUM SOL. INJ. 2000 ui

anti - Xa/0.2 ml

CLEXANE 2000 ui

anti - Xa/0.2 ml 2000 ui LAB. AVENTIS

anti - Xa/0.2 ml

B01AB05 ENOXAPARINUM SOL. INJ. 4000 ui

anti - Xa/0,4 ml

CLEXANE 4000 ui

anti - Xa/0.4 ml 4000 ui LAB. AVENTIS

anti - Xa/0,4 ml

B01AB05 ENOXAPARINUM SOL. INJ. 6000 ui

anti - Xa/0.6 ml

CLEXANE 6000 ui 6000 ui LAB. AVENTIS

anti - Xa/0.6 ml anti - Xa/0.6 ml

B01AB05 ENOXAPARINUM SOL. INJ. 8000 ui

anti - Xa/0.8 ml

CLEXANE 8000 ui 8000 ui LAB. AVENTIS

anti - Xa/0.8 ml anti - Xa/0.8 ml

B01AB05 ENOXAPARINUM SOL. INJ. 2000 ui

anti - Xa/0.2 ml

CLEXANE 2000 ui 2000 ui LAB. AVENTIS

anti - Xa/0.2 ml anti - Xa/0.2 ml

B01AB05 ENOXAPARINUM SOL. INJ. 4000 ui

anti - Xa/0,4 ml

CLEXANE 4000 ui 4000 ui LAB. AVENTIS

anti - Xa/0.4 ml anti - Xa/0,4 ml

B01AB05 ENOXAPARINUM SOL. INJ. 6000 ui

anti - Xa/0.6 ml

CLEXANE 6000 ui 6000 ui LAB. AVENTIS

anti - Xa/0.6 ml anti - Xa/0.6 ml

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| **1040** |**B01AB06**| **NADROPARINUM\*\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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B01AB06 NADROPARINUM SOL. INJ. 11400 ui AXa/0.6 ml

FRAXODI 11400 UI 11400 ui AXa/0.6 ml GLAXO GROUP LTD.

anti - factor Xa/0,6 ml

B01AB06 NADROPARINUM SOL. INJ. 15200 ui AXa/0.8 ml

FRAXODI 15200 UI 15200 ui AXa/0.8 ml GLAXO GROUP LTD.

anti - factor Xa/0,8 ml

B01AB06 NADROPARINUM SOL. INJ. 2850 ui AFXa/0.3 ml

FRAXIPARINE(R) 2850 UI 2850 ui AFXa/0.3 ml GLAXO GROUP LTD.

anti - factor Xa/0,3 ml

B01AB06 NADROPARINUM SOL. INJ. 3800 ui AFXa/0.4 ml

FRAXIPARINE(R) 3800 UI 3800 ui AFXa/0.4 ml GLAXO GROUP LTD.

anti - factor Xa/0,4 ml

B01AB06 NADROPARINUM SOL. INJ. 5700 ui AFXa/0.6 ml

FRAXIPARINE(R) 5700 UI 5700 ui AFXa/0.6 ml GLAXO GROUP LTD.

anti - factor Xa/0,6 ml

B01AB06 NADROPARINUM SOL. INJ. 7600 ui AXa/0.8 ml

FRAXIPARINE(R) 7600 UI 7600 ui AXa/0.8 ml GLAXO GROUP LTD.

anti - factor Xa/0,8 ml

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| **1041** |**B01AB08**| **REVIPARINUM\*\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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B01AB08 REVIPARINUM SOL. INJ. 1432 ui/0.25 ml

CLIVARIN(R) 1432 UI/0.25 ml 1432 ui/0.25 ml ABBOTT GMBH & CO. KG

B01AB08 REVIPARINUM SOL. INJ. 3436 ui/0.6 ml

CLIVARIN(R) 3436 UI/0,6 ml 3436 ui/0.6 ml ABBOTT GMBH & CO. KG

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| **1042** |**B01AB10**| **TINZAPARINUM\*\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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B01AB10 TINZAPARINUM SOL. INJ. 10000 u ANTIF. Xa/ml

INNOHEP 10000 U ANTIF. Xa/ml LEO PHARMACEUTICAL

PRODUCTS

B01AB10 TINZAPARINUM SOL. INJ. 20000 u ANTIF. Xa/ml

INNOHEP 20000 U ANTIF. Xa/ml LEO PHARMACEUTICAL

PRODUCTS

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| **1043** |**B03AC02**| **COMPLEX DE HIDROXID DE FER (III) SUCROZA** | **Protocol: A010N** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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B03AC02 COMPLEX DE HIDROXID SOL. INJ./PERF. 20 mg/ml

DE FER (III) SUCROZA

VENOFER(R) 20 mg/ml VIFOR FRANCE S.A.

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| **1044** |**B03XA01**| **EPOETINUM ALFA\*\*** | **Protocol: B010N** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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B03XA01 EPOETINUM ALFA SOL. INJ. 10000 ui/ml

EPREX(R) 10000 UI 10000 ui/ml JOHNSON & JOHNSON D.O.O.

B03XA01 EPOETINUM ALFA SOL. INJ. IN SERINGA 1000 UI/0,3 ml

PREUMPLUTA

EPREX(R) 1000 UI 1000 ui/0.5 ml JOHNSON & JOHNSON D.O.O.

B03XA01 EPOETINUM ALFA SOL. INJ. IN SERINGA 1000 UI/0,5 ml

PREUMPLUTA

BINOCRIT 1000 UI/0,5 ml 1000 UI/0,5 ml SANDOZ GMBH

EPOKINE 1000 UI/0,5 ml 1000 UI/0.5 ml RENAMED FARMA S.R.L.

B03XA01 EPOETINUM ALFA SOL. INJ. IN SERINGA 20000 UI/0,5 ml

PREUMPLUTA

EPOKINE 2000 UI/0,5 ml 2000 UI/0.5 ml RENAMED FARMA S.R.L.

B03XA01 EPOETINUM ALFA SOL. INJ. 2000 UI

EPOPHAR 2000 U.I. 2000 UI GULF PHARMACEUTICAL IND.

S.R.L.

EPREX(R) 2000 UI 2000 ui/0.5 ml JOHNSON & JOHNSON D.O.O.

B03XA01 EPOETINUM ALFA SOL. INJ. IN SERINGA 2000 UI/1,0 ml

PREUMPLUTA

BINOCRIT 2000 UI/1,0 ml 2000 UI/1,0 ml SANDOZ GMBH

EPOKINE 2000 UI/1 ml 2000 UI/1 ml RENAMED FARMA S.R.L.

B03XA01 EPOETINUM ALFA SOL. INJ. IN SERINGA 3000 UI/0,3 ml

PREUMPLUTA

BINOCRIT 3000 UI/0,3 ml 3000 UI/0,3 ml SANDOZ GMBH

B03XA01 EPOETINUM ALFA SOL. INJ. 3000 ui/0.3 ml

EPREX(R) 3000 UI 3000 ui/0.3 ml JOHNSON & JOHNSON D.O.O.

B03XA01 EPOETINUM ALFA SOL. INJ. 40000 UI

EPREX(R) 40000 UI 40000 UI JOHNSON & JOHNSON D.O.O.

B03XA01 EPOETINUM ALFA SOL. INJ. 4000 UI

EPOPHAR 4000 UI 4000 UI GULF PHARMACEUTICAL IND.

S.R.L.

B03XA01 EPOETINUM ALFA SOL. INJ. IN SERINGA 4000 UI/0,4 ml

PREUMPLUTA

BINOCRIT 4000 UI/0,4 ml 4000 UI/0,4 ml SANDOZ GMBH

EPOKINE 4000 UI/0,4 ml 4000 UI/0.4 ml RENAMED FARMA S.R.L.

EPREX(R) 4000 UI 4000 ui/0.4 ml JOHNSON & JOHNSON D.O.O.

B03XA01 EPOETINUM ALFA SOL. INJ. 4000 UI/1 ml

EPOKINE 4000 UI/1 ml 4000 UI/1 ml RENAMED FARMA S.R.L.

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| **1045** |**B03XA01**| **EPOETINUM BETA\*\*** | **Protocol: B009N** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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B03XA01 EPOETINUM BETA SOL. INJ. IN SERINGA 10000 UI/0,6 ml

PREUMPLUTA

NEORECORMON 10000 UI/0,6 ml 10000 UI/0,6 ml ROCHE REGISTRATION LTD.

B03XA01 EPOETINUM BETA SOL. INJ. IN SERINGA 1000 UI/0,3 ml

PREUMPLUTA

NEORECORMON 1000 UI/0,3 ml 1000 UI/0,3 ml ROCHE REGISTRATION LTD.

B03XA01 EPOETINUM BETA SOL. INJ. IN SERINGA 2000 UI/0,3 ml

PREUMPLUTA

NEORECORMON 2000 UI/0,3 ml 2000 UI/0,3 ml ROCHE REGISTRATION LTD.

B03XA01 EPOETINUM BETA SOL. INJ. IN SERINGA 4000 UI/0,3 ml

PREUMPLUTA

NEORECORMON 4000 UI/0,3 ml 4000 UI/0,3 ml ROCHE REGISTRATION LTD.

B03XA01 EPOETINUM BETA SOL. INJ. IN SERINGA 5000 UI/0,3 ml

PREUMPLUTA

NEORECORMON 5000 UI/0,3 ml 5000 UI/0,3 ml ROCHE REGISTRATION LTD.

B03XA01 EPOETINUM BETA SOL. INJ. IN SERINGA 500 UI/0,3 ml

PREUMPLUTA

NEORECORMON 500 UI/0,3 ml 500 UI/0,3 ml ROCHE REGISTRATION LTD.

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| **1046** |**B03XA02**| **DARBEPOETINUM ALFA\*\*** | **Protocol: B011N** |

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CONCENTRAŢIE FIRMA

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B03XA02 DARBEPOETINUM ALFA SOL. INJ. IN SERINGA 10 µg/0,4 ml

PREUMPLUTA

ARANESP 10 µg/0.4 ml 10 µg/0.4 ml AMGEN EUROPE BV

B03XA02 DARBEPOETINUM ALFA SOL. INJ. IN SERINGA 100 µg/0,5 ml

PREUMPLUTA

ARANESP 100 µg/0.5 ml 100 µg/0.5 ml AMGEN EUROPE BV

B03XA02 DARBEPOETINUM ALFA SOL. INJ. IN SERINGA 15 µg/0.375 ml

PREUMPLUTA

ARANESP 15 µg/0.375 ml 15 µg/0.375 ml AMGEN EUROPE BV

B03XA02 DARBEPOETINUM ALFA SOL. INJ. IN SERINGA 150 µg/0,3 ml

PREUMPLUTA

ARANESP 150 µg/0.3 ml 150 µg/0.3 ml AMGEN EUROPE BV

B03XA02 DARBEPOETINUM ALFA SOL. INJ. IN SERINGA 20 µg/0.5 ml

PREUMPLUTA

ARANESP 20 µg/0.5 ml 20 µg/0.5 ml AMGEN EUROPE BV

B03XA02 DARBEPOETINUM ALFA SOL. INJ. IN SERINGA 30 µg/0.3 ml

PREUMPLUTA

ARANESP 30 µg/0.3 ml 30 µg/0.3 ml AMGEN EUROPE BV

B03XA02 DARBEPOETINUM ALFA SOL. INJ. IN SERINGA 300 µg/0.6 ml

PREUMPLUTA

ARANESP 300 µg/0.6 ml 300 µg/0.6 ml AMGEN EUROPE BV

B03XA02 DARBEPOETINUM ALFA SOL. INJ. IN SERINGA 40 µg/0.4 ml

PREUMPLUTA

ARANESP 40 µg/0.4 ml 40 µg/0.4 ml AMGEN EUROPE BV

B03XA02 DARBEPOETINUM ALFA SOL. INJ. IN SERINGA 50 µg/0.5 ml

PREUMPLUTA

ARANESP 50 µg/0.5 ml 50 µg/0.5 ml AMGEN EUROPE BV

B03XA02 DARBEPOETINUM ALFA SOL. INJ. IN SERINGA 500 µg/ml

PREUMPLUTA

ARANESP 500 µg/ml 500 µg/ml AMGEN EUROPE BV

B03XA02 DARBEPOETINUM ALFA SOL. INJ. IN SERINGA 60 µg/0.3 ml

PREUMPLUTA

ARANESP 60 µg/0.3 ml 60 µg/0.3 ml AMGEN EUROPE BV

B03XA02 DARBEPOETINUM ALFA SOL. INJ. IN SERINGA 80 µg/0.4 ml

PREUMPLUTA

ARANESP 80 µg/0.4 ml 80 µg/0.4 ml AMGEN EUROPE BV

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| **1049** |**V03AE02**| **SEVELAMER\*\*** | **Protocol: V003D** |

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CONCENTRAŢIE FIRMA

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V03AE02 SEVELAMER COMPR. FILM. 800 mg

RENAGEL 800 mg 800 mg GENZYME EUROPE BV

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| **1050** |**H05BX01**| **CINACALCETUM\*\*\*\*** | **Protocol: H003N** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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H05BX01 CINACALCETUM COMPR. FILM. 30 mg

MIMPARA 30 mg 30 mg AMGEN EUROPE B.V.

H05BX01 CINACALCETUM COMPR. FILM. 60 mg

MIMPARA 60 mg 60 mg AMGEN EUROPE B.V.

H05BX01 CINACALCETUM COMPR. FILM. 90 mg

MIMPARA 90 mg 90 mg AMGEN EUROPE B. V.

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**SUBLISTA C2 - P11: PROGRAM NAŢIONAL DE SĂNĂTATE MINTALĂ. SUBPROGRAMUL TRATAMENTUL TOXICODEPENDENŢELOR**

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| **1051** |**N07BB04**| **NALTREXONUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N07BB04 NALTREXONUM COMPR. FILM. 50 mg

REVIA 50 mg TORREX CHIESI PHARMA GMBH

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Naltrexone hydrochloride este contraindicată la pacienţii trataţi cu medicamente opioide

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| **1052** |**N07BC02**| **METHADONUM** | |

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Risc înalt de apariţie a dependenţei.

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N07BC02 METHADONUM COMPR. 2.5 mg

SINTALGON 2,5 mg 2.5 mg ZENTIVA S.A.

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| **1053** |**N07BC51**| **COMBINATII (BUPRENORPHINUM + NALAXONE)** | |

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Prescriere limitată: **Tratamentul dependenţei de opioide în cadrul terapiei medicale, sociale şi psihologice.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N07BC51 COMBINATII COMPR. SUBLING. 2 mg/0,5 mg

(BUPRENORPHINUM +

NALAXONE)

SUBOXONE 2 mg/0,5 mg 2 mg/0,5 mg SP EUROPE

N07BC51 COMBINATII COMPR. SUBLING. 8 mg/2 mg

(BUPRENORPHINUM +

NALAXONE)

SUBOXONE 8 mg/2 mg 8 mg/2 mg SP EUROPE

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**SUBLISTA C3 - DCI-URI CORESPUNZĂTOARE MEDICAMENTELOR DE CARE BENEFICIAZĂ COPIII PANĂ LA 18 ANI, TINERII DE LA 18 LA 26 ANI DACĂ SUNT ELEVI, UCENICI SAU STUDENŢI DACĂ NU REALIZEAZĂ VENITURI PRECUM ŞI GRAVIDE ŞI LEHUZE, ÎN TRATAMENTUL AMBULATORIU ÎN REGIM DE COMPENSARE 100% DIN PREŢUL DE REFERINŢĂ**

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| **1056** |**A03AD02**| **DROTAVERINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A03AD02 DROTAVERINUM SOL. INJ. 40 mg/2 ml

NO-SPA 40 mg/2 ml 40 mg/2 ml CHINOIN PRIVATE CO. LTD.

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| **1057** |**A03BA01**| **ATROPINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A03BA01 ATROPINUM SOL. INJ. 1 mg/ml

SULFAT DE ATROPINA 1 mg/ml ZENTIVA S.A.

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| **1058** |**A03BB01**| **BUTYLSCOPOLAMMONII BROMIDUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A03BB01 BUTYLSCOPOLAMMONII SOL. INJ. 10 mg/ml

BROMIDUM

SCOBUTIL 10 mg/ml 10 mg/ml ZENTIVA SA

A03BB01 BUTYLSCOPOLAMMONII SOL. INJ. 20 mg/ml

BROMIDUM

BUSCOPAN 20 mg/ml 20 mg/ml BOEHRINGER INGELHEIM

INT. GMBH

FARCORELAXIN 20 mg/ml PHARCO IMPEX 93 S.R.L.

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| **1059** |**A03DA02**| **COMBINAŢII** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A03DA02 COMBINATII COMPR.

ALGIFEN COMPRIMATE ZENTIVA SA

PIAFEN ANTIBIOTICE SA

A03DA02 COMBINATII SOL. INJ.

ALGIFEN SOLUTIE INJECTABILA ZENTIVA SA

A03DA02 COMBINATII SUPOZ.

PIAFEN ANTIBIOTICE SA

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| **1060** |**A05BAN3**| **COMBINAŢII** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A05BAN3 COMBINATII SOL. INJ.

ASPATOFORT(R) TERAPIA SA

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| **1061** |**A06AD65**| **COMBINAŢII** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A06AD65 COMBINATII PULB. PT. SOL. ORALA

ENDOFALK DR. FALK PHARMA GMBH

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| **1062** |**A07AX03**| **NIFUROXAZIDUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A07AX03 NIFUROXAZIDUM CAPS. 200 mg

ERCEFURYL(R) 200 mg 200 mg SANOFI - SYNTHELABO OTC

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| **1063** |**A11CA01**| **RETINOLUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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A11CA01 RETINOLUM PIC. ORALE, SOL. 1500000 ui/g

VITAMINA A 1500000 ui/g BIOFARM SA

A11CA01 RETINOLUM CAPS. MOI 50000 ui

VITAMINA A FORTE 50000 ui BIOFARM SA

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| **1064** |**A11CC02**| **DIHYDROTACHYSTEROLUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A11CC02 DIHYDROTACHYSTEROLUM PICATURI ORALE - SOL. 0.1 mg/ml

TACHYSTIN 0.1 mg/ml CHAUVIN ANKERPHARM GMBH

A11CC02 DIHYDROTACHYSTEROLUM PICATURI ORALE - SOL. 1 mg/ml

A.T.10(R) 1 mg/ml MERCK KGAA

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| **1065** |**A11CC04**| **CALCITRIOLUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A11CC04 CALCITRIOLUM CAPS. MOI 0.25 µg

ROCALTROL 0.25 µg ROCHE ROMANIA S.R.L.

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| **1066** |**A11CC05**| **COLECALCIFEROLUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A11CC05 COLECALCIFEROLUM PIC. ORALE, SOL. 0,45 mg/ml

VITAMINA D3 0,45 µg/ml BIOFARM S.A.

A11CC05 COLECALCIFEROLUM PIC. ORALE, SOL. 0.5 mg/ml

VIGANTOL OIL 0.5 mg/ml MERCK KGAA

A11CC05 COLECALCIFEROLUM COMPR. 1000 UI

VIGANTOLETTEN 1000 1000 UI MERCK KGAA

A11CC05 COLECALCIFEROLUM COMPR. 500 UI

VIGANTOLETTEN 500 500 UI MERCK KGAA

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| **1067** |**A11CC20**| **COMBINAŢII** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A11CC20 COMBINATII COMPR.

FLUOR VIGANTOLETTEN 1000 MERCK KGAA

FLUOR VIGANTOLETTEN 500 MERCK KGAA

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| **1068** |**A11DA01**| **THIAMINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A11DA01 THIAMINUM SOL. INJ. 100 mg/2 ml

SICOVIT(R) B1 100 mg/2 ml 100 mg/2 ml ZENTIVA S.A.

A11DA01 THIAMINUM COMPR. 10 mg

SICOVIT(R) B1 10 mg 10 mg ZENTIVA S.A.

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| **1069** |**A11DA03**| **BENFOTIAMINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A11DA03 BENFOTIAMINUM DRAJ. 50 mg

BENFOGAMMA 50 mg WORWAG PHARMA

GMBH & CO. KG

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| **1070** |**A11DBN1**| **COMBINAŢII** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A11DBN1 COMBINATII CAPS. MOI

MILGAMMA(R) N WORWAG PHARMA

GMBH & CO. KG

A11DBN1 COMBINATII SOL. INJ.

MILGAMMA(R) N WORWAG PHARMA

GMBH & CO. KG

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| **1071** |**A11DBN2**| **COMBINAŢII** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A11DBN2 COMBINATII COMPR. FILM.

NEUROMULTIVIT(R) LANNACHER HEILMITTEL GMBH

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| **1072** |**A11GA01**| **ACIDUM ASCORBICUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A11GA01 ACIDUM ASCORBICUM SOL. INJ. 750 mg

VITAMINA C ARENA 750 mg 750 mg ARENA GROUP SA

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| **1073** |**A11HA02**| **PYRIDOXINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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A11HA02 PYRIDOXINUM COMPR. 250 mg

VITAMINA B6 250 mg 250 mg ARENA GROUP SA

A11HA02 PYRIDOXINUM COMPR. 250 mg

SICOVIT B6 250 mg 250 mg ZENTIVA SA

A11HA02 PYRIDOXINUM SOL. INJ. 250 mg/5 ml

SICOVIT B6 250 mg/5 ml 250 mg/5 ml ZENTIVA SA

A11HA02 PYRIDOXINUM SOL. INJ. 50 mg/2 ml

SICOVIT B6 50 mg/2 ml 50 mg/2 ml ZENTIVA SA

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| **1074** |**A11HA03**| **TOCOFEROLUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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A11HA03 TOCOFEROLUM CAPS. MOI 200 mg

VITAMIN E 200 200 mg ZENTIVA AS

A11HA03 TOCOFEROLUM CAPS. MOI 400 mg

VITAMIN E 400 400 mg ZENTIVA AS

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| **1076** |**A12AA03**| **CALCII GLUCONAS** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A12AA03 CALCII GLUCONAS SOL. INJ.

GLUCONAT DE CALCIU ZENTIVA SA

GLUCONAT DE CALCIU 10% 10% B. BRAUN MELSUNGEN AG

A12AA03 CALCII GLUCONAS SOL. INJ. 10,00%

GLUCONAT DE CALCIU ZENTIVA SA

GLUCONAT DE CALCIU 10% 10% B. BRAUN MELSUNGEN AG

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| **1077** |**A14AA03**| **METANDIENONUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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A14AA03 METANDIENONUM COMPR. 5 mg

NAPOSIM 5 mg 5 mg TERAPIA SA

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| **1078** |**A16AA01**| **LEVOCARNITINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A16AA01 LEVOCARNITINUM SOL. ORALA 100 mg/ml

CARNIL(R) 100 mg/ml ANFARM HELLAS S.A.

PHARMACEUTICALS

A16AA01 LEVOCARNITINUM SOL. ORALA 10%

MIOCOR 10% ECOBI PHARMACEUTICI

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| **1079** |**A16AXN1**| **DIVERSE** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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A16AXN1 DIVERSE DRAJ. 200 mg

ACTOVEGIN(R) 200 mg NYCOMED AUSTRIA GMBH

A16AXN1 DIVERSE SOL. INJ. 200 mg/5 ml

ACTOVEGIN(R) 200 mg/5 ml NYCOMED AUSTRIA GMBH

A16AXN1 DIVERSE SOL. INJ. 80 mg/2 ml

ACTOVEGIN(R) 80 mg/2 ml NYCOMED AUSTRIA GMBH

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| **1080** |**B02BX01**| **ETAMSYLATUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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B02BX01 ETAMSYLATUM SOL. INJ. 250 mg/2 ml

ETAMSILAT 250 mg/2 ml 250 mg/2 ml ZENTIVA S.A.

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| **1081** |**B02BX02**| **CARBAZOCHROMI SALICYLAS** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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B02BX02 CARBAZOCHROMI SOL. INJ. 0.3 mg/ml

SALICYLAS

ADRENOSTAZIN 0.3 mg/ml TERAPIA SA

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| **1082** |**B03AA02**| **FERROSI FUMARAS** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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B03AA02 FERROSI FUMARAS SUSP. ORALA 3,00%

FERRONAT(R) 3% IVAX - PHARMACEUTICALS

S.R.O.

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| **1083** |**B03AA03**| **FERROSI GLUCONAS** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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B03AA03 FERROSI GLUCONAS COMPR.

ASCOFER ARENA GROUP SA

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| **1084** |**B03ABN1**| **FERROCHOLINATUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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B03ABN1 FERROCHOLINATUM SOL. ORALA IN PICATURI 24 mg Fe/ml

FER-SOL 24 mg Fe/ml E.I.P.I.CO. MED S.R.L.

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| **1085** |**B03AD02**| **COMBINAŢII** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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B03AD02 COMBINATII CAPS. ELIB. PREL

FERRETAB(R) LANNACHER HEILMITTEL GMBH

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| **1086** |**B03AD03**| **COMBINAŢII** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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B03AD03 COMBINATII CAPS.

FERRO SANOL GYN SCHWARZ PHARMA AG

B03AD03 COMBINATII DRAJ. ELIB. PREL.

TARDYFERON FOL(R) LAB. PIERRE FABRE

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| **1087** |**B03AD04**| **COMBINAŢII** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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B03AD04 COMBINATII COMPR. MAST.

MALTOFER FOL VIFOR FRANCE SA

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| **1088** |**B03AE01**| **COMBINAŢII** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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B03AE01 COMBINATII CAPS. MOI

FERRO - FOLGAMMA(R) WORWAG PHARMA

GMBH & CO. KG

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| **1089** |**B03AE10**| **COMBINAŢII** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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B03AE10 COMBINATII SOL. ORALA

TOTHEMA LAB. INNOTHERA

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| **1090** |**B03BA01**| **CYANOCOBALAMINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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B03BA01 CYANOCOBALAMINUM SOL. INJ. 1000 µg/ml

SICOVIT(R) B12 1000 µg/ml 1000 µg/ml ZENTIVA S.A.

B03BA01 CYANOCOBALAMINUM SOL. INJ. 50 µg/ml

SICOVIT B12 50 µg/ml 50 µg/ml ZENTIVA S.A.

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| **1091** |**B03BA51**| **COMBINAŢII** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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B03BA51 COMBINATII DRAJ.

MILGAMMA(R) WORWAG PHARMA

GMBH & CO. KG

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| **1092** |**C01EA01**| **ALPROSTADILUM\*\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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C01EA01 ALPROSTADILUM CONC. PT. SOL. PERF. 500 µg

ALPROSTADIL "PINT" 500 µg 500 µg PINT - PHARMA GMBH

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| **1093** |**C02LA51**| **COMBINAŢII** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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C02LA51 COMBINATII DRAJ.

NEOCRYSTEPIN ZENTIVA AS

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| **1094** |**C04AE01**| **CODERGOCRINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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C04AE01 CODERGOCRINUM SOL. ORALA IN PICATURI 0.1%

CO-DERGOCRIN 0.1% TERAPIA SA

C04AE01 CODERGOCRINUM SOL. ORALA IN PICATURI 1 mg/ml

SECATOXIN 1 mg/ml IVAX - PHARMACEUTICALS

S.R.O.

C04AE01 CODERGOCRINUM PICATURI ORALE - SOL. 0.1%

REDERGIN 1 mg/ml 0.1% LEK PHARMACEUTICALS D.D.

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| **1095** |**C05AA01**| **COMBINAŢII** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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C05AA01 COMBINATII UNGUENT

HEMORZON ANTIBIOTICE SA

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| **1096** |**C05AA08**| **COMBINAŢII** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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C05AA08 COMBINATII SUPOZ.

ULTRAPROCT(R) INTENDIS GmbH

C05AA08 COMBINATII UNGUENT RECTAL

ULTRAPROCT(R) INTENDIS GmbH

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| **1097** |**C05AD01**| **COMBINAŢII** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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C05AD01 COMBINATII UNGUENT RECTAL

DOXIPROCT OM PORTUGUESA S.A.

DOXIPROCT PLUS OM PORTUGUESA S.A.

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| **1098** |**C05BX01**| **CALCII DOBESILAS** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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C05BX01 CALCII DOBESILAS CAPS. 500 mg

DOXILEK 500 mg LEK PHARMACEUTICALS D.D.

DOXIUM 500 500 mg OM PORTUGUESA S.A.

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| **1099** |**C05CA54**| **TROXERUTINUM (COMBINAŢII)** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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C05CA54 TROXERUTINUM CAPS.

(COMBINATII)

GINKOR FORT BEAUFOUR IPSEN PHARMA

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| **1100** |**C07AB08**| **CELIPROLOLUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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C07AB08 CELIPROLOLUM COMPR. FILM. 100 mg

CELIPRES(R) 100 mg RANBAXY U.K. LIMITED

C07AB08 CELIPROLOLUM COMPR. FILM. 200 mg

CELIPRES(R) 200 mg RANBAXY U.K. LIMITED

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| **1101** |**C07NAN1**| **COMBINAŢII** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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C07NAN1 COMBINATII CAPS.

CALMOGEN EUROPHARM SA

C07NAN1 COMBINATII COMPR.

DISTONOVAL FABIOL S.A.

C07NAN1 COMBINATII COMPR. FILM.

DISTONOCALM(R) ZENTIVA S.A.

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| **1102** |**C08CA06**| **NIMODIPINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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C08CA06 NIMODIPINUM SOL. PERF. 10 mg/50 ml

DILCEREN(R) 10 mg/50 ml SLOVAKOFARMA

NIMOTOP(R) 10 mg/50 ml BAYER HEALTHCARE AG

C08CA06 NIMODIPINUM COMPR. FILM. 30 mg

NIMOTOP(R) 30 mg BAYER HEALTHCARE AG

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| **1103** |**C10AD02**| **ACIDUM NICOTINICUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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C10AD02 ACIDUM NICOTINICUM COMPR. ELIB. PREL 1000 mg

NIASPAN 1000 mg 1000 mg MERCK KGAA

C10AD02 ACIDUM NICOTINICUM COMPR. ELIB. PREL. 375 mg

NIASPAN 375 mg 375 mg MERCK KGAA

C10AD02 ACIDUM NICOTINICUM COMPR. ELIB. PREL. 500 mg

NIASPAN 500 mg 500 mg MERCK KGAA

C10AD02 ACIDUM NICOTINICUM COMPR. ELIB. PREL. 750 mg

NIASPAN 750 mg 750 mg MERCK KGAA

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| **1104** |**D01AC05**| **ISOCONAZOLUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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D01AC05 ISOCONAZOLUM CREMA 10 mg/1 g

TRAVOGEN 10 mg/1 g INTENDIS GmbH

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| **1105** |**D01AC08**| **KETOCONAZOLUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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D01AC08 KETOCONAZOLUM CREMA 20 mg/g

KETOCONAZOL CREMA 20 mg/g SC HYPERION SA

D01AC08 KETOCONAZOLUM CREMA 2 mg/100 mg

KEFUNGIN 2 mg/100 mg 2 mg/100 mg ANTIBIOTICE S.A.

D01AC08 KETOCONAZOLUM CREMA 2%

KETOCONAZOL 2% TIS FARMACEUTIC SA

NIZORAL 2% JANSSEN PHARMACEUTICA NV

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| **1106** |**D01AC52**| **COMBINAŢII** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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D01AC52 COMBINATII CREMA

MYCOHEAL(R) HC DAR AL DAWA PHARMA S.R.L.

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| **1108** |**D05AC01**| **DITHRANOLUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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D05AC01 DITHRANOLUM UNGUENT 0.5%

PSORIANOL 0,5% 0.5% HYPERION SA

D05AC01 DITHRANOLUM UNGUENT 1%

PSORIANOL 1% 1% HYPERION SA

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| **1109** |**D05AXN1**| **COMBINAŢII** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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D05AXN1 COMBINATII SOL. CUT.

ASORIAN BIOFARM SA

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| **1110** |**D07AB10**| **ALCLOMETAZONUM** | **Protocol: D001L** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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D07AB10 ALCLOMETAZONUM CREMA 0.5 mg/g

AFLODERM 0.5 mg/g A & G MED TRADING S.R.L.

D07AB10 ALCLOMETAZONUM UNGUENT 0.5 mg/g

AFLODERM 0.5 mg/g A & G MED TRADING S.R.L.

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| **1111** |**D07AC04**| **FLUOCINOLONI ACETONIDUM** | **Protocol: D001L** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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D07AC04 FLUOCINOLONI UNGUENT 25,00%

ACETONIDUM

FLUOCINOLON ACETONID 0,025% 0.025% LAROPHARM SRL

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| **1112** |**D07AC05**| **FLUOCORTOLONUM** | **Protocol: D001L** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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D07AC05 FLUOCORTOLONUM CREMA 0.25%

ULTRALAN CREMA 0.25% INTENDIS GMBH

D07AC05 FLUOCORTOLONUM UNGUENT 0.25%

ULTRALAN UNGUENT 0.25% SCHERING AG

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| **1113** |**D07CB01**| **COMBINAŢII** | **Protocol: D001L** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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D07CB01 COMBINATII CREMA

NIDOFLOR ANTIBIOTICE SA

D07CB01 COMBINATII UNGUENT

PANDERM GULF PHARMACEUTICAL

INDUSTRIES S.R.L.

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| **1114** |**D07CC02**| **COMBINAŢII** | **Protocol: D001L** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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D07CC02 COMBINATII UNGUENT

FLUOCINOLON N ANTIBIOTICE SA

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| **1115** |**D07XB02**| **COMBINAŢII** | **Protocol: D001L** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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D07XB02 COMBINATII CREMA

TRIAMCINOLON S ANTIBIOTICE SA

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| **1116** |**D07XC01**| **COMBINAŢII** | **Protocol: D001L** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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D07XC01 COMBINATII SOL. CUT.

BELOSALIC A & G MED TRADING S.R.L.

DIPROSALIC SCHERING-PLOUGH EUROPE

D07XC01 COMBINATII UNGUENT

BELOSALIC A & G MED TRADING S.R.L.

DIPROSALIC SCHERING-PLOUGH EUROPE

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| **1117** |**D07XC04**| **COMBINAŢII** | **Protocol: D001L** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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D07XC04 COMBINATII CREMA

TRAVOCORT INTENDIS GmbH

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| **1119** |**D10AD01**| **TRETINOINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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D10AD01 TRETINOINUM CREMA 0.05%

RETIN-A(R) 0.05% JOHNSON & JOHNSON D.O.O.

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| **1121** |**D10AF02**| **ERYTHROMYCINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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D10AF02 ERYTHROMYCINUM SOL. CUT. 4 g

ERYFLUID 4 g PIERRE FABRE DERMATOLOGIE

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| **1122** |**D10AF52**| **COMBINAŢII** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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D10AF52 COMBINATII PULB. + SOLV. SOL. CUT. 40 mg/12 mg/ml

ZINERYT 40 mg/12 mg/ml ASTELLAS PHARMA EUROPE

B.V.

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| **1124** |**G01AF01**| **METRONIDAZOLUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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G01AF01 METRONIDAZOLUM OVULE 500 mg

FLAGYL 500 mg LAB. AVENTIS

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| **1126** |**G01AXN1**| **COMBINAŢII** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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G01AXN1 COMBINATII COMPR. VAG.

COLPOSEPTINE(R) LAB. THERAMEX

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| **1127** |**G01BDN1**| **COMBINAŢII** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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G01BDN1 COMBINATII COMPR. VAG.

TERGYNAN LAB. BOUCHARA-RECORDATI

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| **1128** |**G03AC06**| **MEDROXYPROGESTERONUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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G03AC06 MEDROXYPROGESTERONUM SUSP. INJ. 150 mg

DEPO-PROVERA 150 mg PFIZER EUROPE MA EEIG

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| **1129** |**G03DB04**| **NOMEGESTROLUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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G03DB04 NOMEGESTROLUM COMPR. 5 mg

LUTENYL(R) 5 mg LAB. THERAMEX

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| **1130** |**G03GA01**| **GONADOTROPHINUM CHORIONICUM** | |

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Prescriere limitată: **Infertilitate anovulatorie.**

**Pentru tratamentul infertilităţii masculine ca urmare a**

**hipogonadismului hipogonadotrop;**

**Pentru tratamentul infertilităţii masculine asociată cu**

**deficit de LH;**

**Pentru tratamentul bărbaţilor care au insuficienţă**

**combinată de GH şi gonadotropine şi la care absenţa**

**caracterelor sexuale secundare indică o întârziere de**

**maturare.**

**Pentru tratamentul băieţilor de peste 16 ani care au**

**manifestări clinice ale hipogonadismului sau ale**

**pubertăţii întârziate. Tratamentul nu trebuie să**

**depăşească 6 luni.**

NOTĂ:

**Cu excepţia cazurilor de hipopituitarism sau amenoree primară, pacienta trebuie să fi fost tratată anterior cu citrat de clomifen şi/sau gonadorelin, iar tratamentul să fi rămas fără efect (sarcina nu a fost obţinută). Femeile care au urmat tratament pentru inducerea ovulaţiei cu alte clase de medicamente şi nu au obţinut o sarcină necesită evaluare laparoscopică pentru a exclude alte cauze care împiedică apariţia unei sarcini. Oligomenoreea trebuie să fie prezentă de cel puţin douăsprezece luni sau amenoreea să fie prezentă de cel puţin şase luni înaintea tratamentului. Înaintea acestui tratament pacientele cu hiperprolactinemie trebuie să fi urmat tratament specific medical sau chirurgical.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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G03GA01 GONADOTROPHINUM LIOF. + SOLV. PT. 5000 ui/ml

CHORIONICUM SOL. INJ.

PREGNYL 5000 5000 ui/ml NV ORGANON

G03GA01 GONADOTROPHINUM LIOF. + SOLV. PT. 500 ui/ml

CHORIONICUM SOL. INJ.

PREGNYL 500 500 ui/ml ORGANON NV

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| **1131** |**G03GA02**| **MENOTROPINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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G03GA02 MENOTROPINUM LIOF. SI SOLV. PT. 75 ui FSH/75 ui LH

SOL. INJ.

MENOGON 75 ui FSH/75 ui LH FERING GMBH

G03GA02 MENOTROPINUM LIOF. + SOLV. PT.

SOL. INJ.

MENOPUR FERRING LAEGEMIDLER A/S

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| **1132** |**G04BCN1**| **COMBINAŢII** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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G04BCN1 COMBINATII GRAN. ORALE

URALYT-U MADAUS GMBH

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| **1133** |**H03AA03**| **COMBINAŢII** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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H03AA03 COMBINATII COMPR. 100 µg + 20 µg

NOVOTHYRAL(R) 100 100 µg + 20 µg MERCK KGAA

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| **1134** |**J01CR50**| **COMBINAŢII** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01CR50 COMBINATII PULB. PT. SOL. INJ. 1 g + 1 g

SULPERAZON(R) 2 g 1 g + 1 g PFIZER EUROPE MA EEIG

J01CR50 COMBINATII CAPS. 250 mg + 250 mg

AMPICLOX 250 mg + 250 mg EUROPHARM SA

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| **1135** |**J01DB04**| **CEFAZOLINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01DB04 CEFAZOLINUM PULB. PT. SOL. INJ. 1 g

LYZOLIN 1 g MEDICAROM GROUP S.R.L.

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| **1136** |**J01DE02**| **CEFPIROMUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01DE02 CEFPIROMUM PULB. PT. SOL. 1 g

INJ./PERF.

CEFROM(R) 1 g 1 g LAB. AVENTIS

J01DE02 CEFPIROMUM PULB. PT. SOL.

INJ./PERF. 2 g

CEFROM(R) 2 g 2 g LAB. AVENTIS

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| **1137** |**J01EB05**| **SULFAFURAZOLUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01EB05 SULFAFURAZOLUM COMPR. 500 mg

NEOXAZOL(R) 500 mg 500 mg ZENTIVA S.A.

SULFAFURAZOL 500 mg ARENA GROUP SA

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| **1138** |**J01FA06**| **ROXITHROMYCINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01FA06 ROXITHROMYCINUM COMPR. FILM. 150 mg

ROXAMED(R) 150 150 mg DAR AL DAWA PHARMA S.R.L.

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| **1139** |**J01GB03**| **GENTAMICINUM** | |

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Prescriere limitată: **Infecţii cu agent patogen sensibil confirmat pentru**

**acest tip de antibiotic.**

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01GB03 GENTAMICINUM SOL. INJ. 40 mg/ml

GENTAMICIN KRKA 40 mg/ml KRKA D.D. NOVO MESTO

GENTAMICINA SANDOZ(R)

40 mg/ml 40 mg/ml SANDOZ GMBH

J01GB03 GENTAMICINUM SOL. INJ. 40 mg/ml

GENTAMICIN KRKA 40 mg/ml KRKA D.D. NOVO MESTO

GENTAMICINA SANDOZ(R)

40 mg/ml 40 mg/ml SANDOZ GMBH

J01GB03 GENTAMICINUM SOL. PARENT. 40 mg/ml

LYRAMYCIN 40 mg/ml MEDICAROM GROUP S.R.L.

J01GB03 GENTAMICINUM SOL. INJ. 80 mg/2 ml

GENTAMICIN KRKA 80 mg/2 ml KRKA D.D. NOVO MESTO

J01GB03 GENTAMICINUM SOL INJ. 80 mg/2 ml

PAN-GENTAMICINE 80 mg/2 ml LAB. PANPHARMA

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| **1140** |**J01GB07**| **NETILMICINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J01GB07 NETILMICINUM SOL. INJ. 150 mg/1.5 ml

NETROMYCINE(R) 150 mg/1.5 ml SCHERING PLOUGH EUROPE

J01GB07 NETILMICINUM SOL. INJ. 200 mg/2 ml

NETROMYCINE(R) 200 mg/2 ml SCHERING PLOUGH EUROPE

J01GB07 NETILMICINUM SOL. INJ. 50 mg/2 ml

NETROMYCINE(R) 50 mg/2 ml SCHERING PLOUGH EUROPE

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| **1143** |**J02AC03**| **VORICONAZOLUM\*\*** | **Protocol: J012B** |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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J02AC03 VORICONAZOLUM COMPR. FILM. 200 mg

VFEND 200 mg 200 mg PFIZER LTD.

J02AC03 VORICONAZOLUM PULB. PT. SUSP. ORALA 40 mg/ml

VFEND 40 mg/ml 40 mg/ml PFIZER LTD.

J02AC03 VORICONAZOLUM COMPR. FILM. 50 mg

VFEND 50 mg 50 mg PFIZER LTD.

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| **1144** |**M01AB55**| **COMBINAŢII** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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M01AB55 COMBINATII COMPR. GASTROREZ.

ARTHROTEC 75 PFIZER EUROPE MA EEIG

M01AB55 COMBINATII SOL. PERF.

NEODOLPASSE FRESENIUS KABI AUSTRIA

GMBH

M01AB55 COMBINATII SUPOZ.

ACECLOFEN ANTIBIOTICE SA

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| **1145** |**M01AE01**| **IBUPROFENUM** | |

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A se administra cu precauţie la pacienţii cu istoric de factori de risc sau afecţiuni gastrointestinale.

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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M01AE01 IBUPROFENUM SUSP. ORALA 100 mg/5 ml

IBALGIN BABY 100 mg/5 ml ZENTIVA AS

IBUGESIC(R) 100 mg/5 ml DAR AL DAWA PHARMA S.R.L.

NUROFEN(R) PENTRU COPII, cu 100 mg/5 ml RECKITT BENCKISER

aromă de căpşuni HEALTHCARE INTERNATIONAL

LIMITED

NUROFEN(R) PENTRU COPII, cu 100 mg/5 ml RECKITT BENCKISER

aromă de portocală HEALTHCARE INTERNATIONAL

LIMITED

M01AE01 IBUPROFENUM CAPS. ELIB. PREL 300 mg

PADUDEN(R) SR 300 mg 300 mg TERAPIA SA

M01AE01 IBUPROFENUM CAPS. 400 mg

MARCOFEN(R) 400 mg EUROPHARM SA

M01AE01 IBUPROFENUM COMPR. FILM. 400 mg

IBUPROFEN 400 400 mg CIPLA (UK) LIMITED

PROFINAL 400 mg GULF PHARMACEUTICAL

INDUSTRIES S.R.L.

REUPROFEN(R) 400 mg 400 mg AC HELCOR SRL

M01AE01 IBUPROFENUM DRAJ. 400 mg

NUROFEN FORTE 400 mg RECKITT BENCKISER

HEALTHCARE INT. LTD.

M01AE01 IBUPROFENUM COMPR. FILM. 600 mg

IBUPROFEN 600 600 mg CIPLA (UK) LIMITED

PROFINAL 600 mg GULF PHARMACEUTICAL

INDUSTRIES S.R.L.

M01AE01 IBUPROFENUM CAPS. 400 mg

MARCOFEN(R) 400 mg EUROPHARM SA

M01AE01 IBUPROFENUM COMPR. FILM. 400 mg

IBUPROFEN 400 400 mg CIPLA (UK) LIMITED

PROFINAL 400 mg GULF PHARMACEUTICAL

INDUSTRIES S.R.L.

REUPROFEN(R) 400 mg 400 mg AC HELCOR SRL

M01AE01 IBUPROFENUM DRAJ. 400 mg

NUROFEN FORTE 400 mg RECKITT BENCKISER

HEALTHCARE INT. LTD.

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| **1146** |**M01AE02**| **NAPROXENUM** | |

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A se administra cu precauţie la pacienţii cu istoric de factori de risc sau afecţiuni gastrointestinale.

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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M01AE02 NAPROXENUM COMPR. 250 mg

REUXEN 250 mg 250 mg AC HELCOR PHARMA SRL

M01AE02 NAPROXENUM COMPR. 500 mg

REUXEN 500 mg 500 mg AC HELCOR PHARMA SRL

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| **1147** |**M01AG01**| **ACIDUM MEFENAMICUM** | |

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A se administra cu precauţie la pacienţii cu istoric de factori de risc sau afecţiuni gastrointestinale.

**Se aplică tuturor denumirilor comerciale, formelor farmaceutice şi concentraţiilor corespunzătoare DCI-ului.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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M01AG01 ACIDUM MEFENAMICUM COMPR. FILM. 500 mg

VIDAN 500 mg VIANEX SA

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| **1148** |**M01AH04**| **PARECOXIBUM** | |

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Prescriere limitată: **Tratamentul simptomatic antiinflamator la pacienţii cu intoleranţă la AINS neselective.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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M01AH04 PARECOXIBUM PULB. + SOLV. PT. 40 mg

SOL. INJ.

DYNASTAT 40 mg 40 mg PFIZER LIMITED

M01AH04 PARECOXIBUM PULB. PT. SOL. INJ. 40 mg

DYNASTAT 40 mg 40 mg PFIZER LIMITED

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| **1149** |**M01AX02**| **ACIDUM NIFLUMICUM** | |

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A se administra cu precauţie la pacienţii cu istoric de factori de risc sau afecţiuni gastrointestinale.

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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M01AX02 ACIDUM NIFLUMICUM CAPS. 250 mg

NIFLURIL 250 mg BRISTOL MYERS SQUIBB KFT

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| **1150** |**M01AA01**| **PHENYLBUTAZONUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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M01AA01 PHENYLBUTAZONUM SUPOZ. 250 mg

FENILBUTAZONA 250 mg 250 mg SINTOFARM SA

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| **1155** |**M02ACN3**| **COMBINAŢII** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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M02ACN3 COMBINATII GEL

PERCUTALGINE LABORATOIRES CHEMINEAU

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| **1156** |**M03BB03**| **CHLORZOXAZONUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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M03BB03 CHLORZOXAZONUM COMPR. 250 mg

CLORZOXAZON 250 mg 250 mg GEDEON RICHTER ROMANIA SA

CLORZOXAZONA 250 mg SINTOFARM SA

CLORZOXAZONA 250 mg 250 mg ARENA GROUP SA

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| **1157** |**M03BX04**| **TOLPERISONUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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M03BX04 TOLPERISONUM SOL. INJ. 100 mg/ml

MYDOCALM 100 mg/ml GEDEON RICHTER LTD.

M03BX04 TOLPERISONUM COMPR. FILM. 150 mg

MYDOCALM 150 mg GEDEON RICHTER LTD.

M03BX04 TOLPERISONUM COMPR. FILM. 50 mg

MYDOCALM 50 mg GEDEON RICHTER LTD.

M03BX04 TOLPERISONUM DRAJ. 50 mg

TOLPERISON 50 mg 50 mg TERAPIA SA

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| **1158** |**M09AX01**| **ACIDUM HIALURONICUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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M09AX01 ACIDUM HIALURONICUM SOL. INJ. 20 mg/2 ml

HYALGAN(R) 20 mg/2 ml CSC PHARMACEUTICALS

HANDELS GMBH

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| **1159** |**N02AA59**| **COMBINAŢII** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N02AA59 COMBINATII COMPR. 30 mg + 500 mg

PARADOREN 500 mg/30 mg 30 mg + 500 mg ARENA GROUP SA

N02AA59 COMBINATII COMPR. 60 mg + 500 mg

PARADOREN 500 mg/60 mg 60 mg + 500 mg ARENA GROUP SA

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| **1160** |**N02BA71**| **COMBINAŢII** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N02BA71 COMBINATII COMPR.

FASCONAL P GEDEON RICHTER ROMANIA SA

FASCOREM REMEDIA SRL

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| **1161** |**N02BB02**| **METAMIZOLUM NATRIUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N02BB02 METAMIZOLUM NATRIUM SOL. INJ. 1 g/2 ml

ALGOCALMIN(R) 1 g/2 ml 1 g/2 ml ZENTIVA SA

N02BB02 METAMIZOLUM NATRIUM PIC. ORALE, SOL. 500 mg/ml

NEVRALGIN 500 mg/ml TERAPIA S.A.

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| **1162** |**N05BA05**| **CLORAZEPAS DIKALII** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N05BA05 CLORAZEPAS DIKALII CAPS. 10 mg

TRANXENE 10 mg 10 mg SANOFI-AVENTIS FRANCE

N05BA05 CLORAZEPAS DIKALII CAPS. 5 mg

TRANXENE 5 mg 5 mg SANOFI-AVENTIS FRANCE

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| **1163** |**N05BA23**| **TOFISOPAMUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N05BA23 TOFISOPAMUM COMPR. 50 mg

GRANDAXIN 50 mg EGIS PHARMACEUTICALS LTD.

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| **1164** |**N05CD08**| **MIDAZOLAMUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N05CD08 MIDAZOLAMUM SOL. INJ. 1 mg/ml

DORMICUM(R) 1 mg/ml ROCHE ROMANIA S.R.L.

MIDAZOLAM TORREX 1 mg/ml 1 mg/ml TORREX CHIESI PHARMA GMBH

N05CD08 MIDAZOLAMUM SOL. INJ. 5 mg/ml

FULSED 5 mg/ml 5 mg/ml TERAPIA S.A.

MIDAZOLAM 5 mg/ml 5 mg/ml TERAPIA SA

MIDAZOLAM TORREX 5 mg/ml 5 mg/ml TORREX CHIESI PHARMA GMBH

N05CD08 MIDAZOLAMUM COMPR. FILM. 7.5 mg

DORMICUM(R) 7.5 mg ROCHE ROMANIA S.R.L.

DORMICUM(R) 7,5 mg 7.5 mg TERAPIA SA

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| **1165** |**N05CD13**| **CINOLAZEPAMUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N05CD13 CINOLAZEPAMUM COMPR. 40 mg

GERODORM(R) 40 mg GEROT PHARMAZEUTIKA GMBH

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| **1166** |**N06BA04**| **METHYLFENIDATUM\*\*\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N06BA04 METHYLFENIDATUM COMPR. FILM. 18 mg

ELIB. PREL.

CONCERTA XL 18 mg 18 mg JANSSEN PHARMACEUTICA N.V.

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Prescriere limitată: **Utilizare în tulburare cu deficit de atenţie şi hiperactivitate.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N06BA04 METHYLFENIDATUM COMPR. FILM. 36 mg

ELIB. PREL.

CONCERTA XL 36 mg 36 mg JANSSEN PHARMACEUTICA N.V.

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Prescriere limitată: **Utilizare în tulburare cu deficit de atenţie şi hiperactivitate.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N06BA04 METHYLFENIDATUM COMPR. FILM. 54 mg

ELIB. PREL.

CONCERTA XL 54 mg 54 mg JANSSEN PHARMACEUTICA N.V.

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Prescriere limitată: **Utilizare în tulburare cu deficit de atenţie şi hiperactivitate.**

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| **1167** |**N06BA09**| **ATOMOXETINUM\*\*\*** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N06BA09 ATOMOXETINUM CAPS. 10 mg

STRATTERA 10 mg 10 mg ELI LILLY AND

COMPANY LIMITED

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Prescriere limitată: **Utilizare în tulburare cu deficit de atenţie şi hiperactivitate.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N06BA09 ATOMOXETINUM CAPS. 18 mg

STRATTERA 18 mg 18 mg ELI LILLY AND

COMPANY LIMITED

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Prescriere limitată: **Utilizare în tulburare cu deficit de atenţie şi hiperactivitate.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N06BA09 ATOMOXETINUM CAPS. 25 mg

STRATTERA 25 mg 25 mg ELI LILLY AND

COMPANY LIMITED

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Prescriere limitată: **Utilizare în tulburare cu deficit de atenţie şi hiperactivitate.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N06BA09 ATOMOXETINUM CAPS. 40 mg

STRATTERA 40 mg 40 mg ELI LILLY AND

COMPANY LIMITED

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Prescriere limitată: **Utilizare în tulburare cu deficit de atenţie şi hiperactivitate.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N06BA09 ATOMOXETINUM CAPS. 60 mg

STRATTERA 60 mg 60 mg ELI LILLY AND

COMPANY LIMITED

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Prescriere limitată: **Utilizare în tulburare cu deficit de atenţie şi hiperactivitate.**

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| **1168** |**N06BX02**| **PYRITINOLUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N06BX02 PYRITINOLUM DRAJ. 100 mg

ENCEPHABOL(R) 100 mg 100 mg MERCK KGAA

N06BX02 PYRITINOLUM DRAJ. 200 mg

ENCEPHABOL(R) FORTE 200 mg MERCK KGAA

N06BX02 PYRITINOLUM SUSP. ORALA 80.5 mg/5 ml

ENCEPHABOL(R) SUSPENSIE 80.5 mg/5 ml MERCK KGAA

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| **1169** |**N06BX03**| **PIRACETAMUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N06BX03 PIRACETAMUM COMPR. FILM. 1200 mg

LUCETAM(R) 1200 mg 1200 mg EGIS PHARMACEUTICALS LTD.

NOOTROPIL(R) 1200 mg 1200 mg U.C.B. SA

N06BX03 PIRACETAMUM SOL. PERF. 12 g

NOOTROPIL 12 g U.C.B. SA

N06BX03 PIRACETAMUM SOL. INJ. 1 g

NOOTROPIL 1 g U.C.B. SA

N06BX03 PIRACETAMUM SOL. INJ. 1 g/5 ml

LUCETAM(R) 1 g 1 g/5 ml EGIS PHARMACEUTICALS LTD.

MEMOTAL 1 g/5 ml 1 g/5 ml ZENTIVA SA

N06BX03 PIRACETAMUM SOL. INJ. 3 g/15 ml

LUCETAM(R) 3 g 3 g/15 ml EGIS PHARMACEUTICALS LTD.

N06BX03 PIRACETAMUM COMPR. 400 mg

PIRACETAM 400 mg 400 mg ANTIBIOTICE SA

N06BX03 PIRACETAMUM COMPR. 400 mg

MEMOTAL 400 mg 400 mg ZENTIVA S.A.

N-PIRACETAM 400 mg MEDUMAN SA

PIRACETAM 400 mg MAGISTRA C & C

PIRACETAM 400 mg 400 mg LAROPHARM SRL

PIRACETAM FARMEX 400 mg 400 mg FARMEX COMPANY SRL

N06BX03 PIRACETAMUM COMPR. FILM. 400 mg

LUCETAM 400 mg EGIS PHARMACEUTICALS PLC

PIRACETAM 400 mg 400 mg GEDEON RICHTER ROMANIA SA

PIRACETAM LPH(R) 400 mg 400 mg LABORMED PHARMA SA

N06BX03 PIRACETAMUM COMPR. FILM. 800 mg

LUCETAM 800 mg EGIS PHARMACEUTICALS PLC

NOOTROPIL(R) 800 mg 800 mg U.C.B. SA

PIRACETAM 800 mg 800 mg GEDEON RICHTER ROMANIA SA

PIRACETAM LPH 800 mg 800 mg LABORMED PHARMA SA

N06BX03 PIRACETAMUM SOL. ORALA 20%

NOOTROPIL(R) 20% U.C.B. SA

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| **1170** |**N07CA02**| **CINNARIZINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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N07CA02 CINNARIZINUM COMPR. 25 mg

CINARIZIN 25 mg 25 mg LAROPHARM SRL

CINARIZINA 25 mg 25 mg OZONE LABORATORIES

N-CINARIZINA 25 mg MEDUMAN SA

STUGERON 25 mg 25 mg TERAPIA SA

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| **1172** |**P01AX08**| **TENONITROZOLUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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P01AX08 TENONITROZOLUM CAPS. MOI GASTROREZ. 250 mg

ATRICAN 250 mg 250 mg LAB. INNOTECH INT.

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| **1173** |**P02CC01**| **PYRANTELUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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P02CC01 PYRANTELUM COMPR. FILM. 125 mg

HELMINTOX(R) 125 mg 125 mg LAB. INNOTECH INT.

P02CC01 PYRANTELUM COMPR. FILM. 250 mg

HELMINTOX(R) 250 mg 250 mg LAB. INNOTECH INT.

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| **1174** |**P03AAN1**| **SULFUR** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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P03AAN1 SULFUR UNGUENT 8,00%

UNGUENT CU SULF 8% 8% GEDEON RICHTER ROMANIA SA

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| **1175** |**P03AC04**| **PERMETHRINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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P03AC04 PERMETHRINUM CREMA CAPILARA 1,00%

NIX 1% GLAXO WELLCOME UK LTD.

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| **1176** |**P03AX01**| **BENZYLUM BENZOICUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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P03AX01 BENZYLUM BENZOICUM CREMA 25,00%

BENZOAT DE BENZIL MK 25% FITERMAN PHARMA S.R.L.

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| **1177** |**R01AD07**| **TIXOCORTOLUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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R01AD07 TIXOCORTOLUM SUSP. NAZALA 1,00%

PIVALONE 1% 1% PFIZER EUROPE MA EEG

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| **1178** |**R01ADN1**| **COMBINAŢII** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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R01ADN1 COMBINATII SPRAY NAZ. SUSP.

BIORINIL FARMILA FARMACEUTICI

MILANO SPA

R01ADN1 COMBINATII SUSP. INHAL.

FLUORORINIL FARMILA - THEA

FARMACEUTICI SPA

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| **1179** |**R01BA52**| **COMBINAŢII** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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R01BA52 COMBINATII COMPR. ELIB. MODIF.

CLARINASE(R) SCHERING PLOUGH EUROPE

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| **1180** |**R02AB03**| **FUSAFUNGINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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R02AB03 FUSAFUNGINUM SPRAY BUCOFARINGIAN 50 mg/10 ml

SI NAZAL - SOL.

BIOPAROX 50 mg/10 ml LES LABORATOIRES SERVER

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| **1181** |**R03CA02**| **EPHEDRINI HYDROCHLORIDUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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R03CA02 EPHEDRINI SOL. INJ. 10 mg/ml

HYDROCHLORIDUM

EFEDRINA 10 mg/ml 10 mg/ml ZENTIVA S.A.

R03CA02 EPHEDRINI SOL. INJ. 50 mg/ml

HYDROCHLORIDUM

EFEDRINA 50 mg/ml 50 mg/ml ZENTIVA S.A.

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| **1182** |**R03CC03**| **TERBUTALINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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R03CC03 TERBUTALINUM SIROP 1.5 mg/5 ml

AIRONYL 1.5 mg/5 ml SEDICO IMPEX S.R.L.

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| **1183** |**R05CB01**| **ACETYLCYSTEINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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R05CB01 ACETYLCYSTEINUM SOL. INJ. 300 mg/3 ml

ACC INJECT 300 mg/3 ml 300 mg/3 ml HEXAL AG

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| **1184** |**R05CB03**| **CARBOCISTEINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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R05CB03 CARBOCISTEINUM SIROP 100 mg/5 ml

HUMEX EXPECTORANT PENTRU 100 mg/5 ml LAB. URGO

COPII SI SUGARI

R05CB03 CARBOCISTEINUM SOL. ORALA 100 mg/5 ml

FLUIDOL 100 mg/5 ml 100 mg/5 ml TIS FARMACEUTIC SA

R05CB03 CARBOCISTEINUM SIROP 20 mg/ml

MUCOTREIS 20 mg/ml ECOBI PHARMACEUTICI SAS

R05CB03 CARBOCISTEINUM SIROP 2%

RHINATHIOL 2% pentru copii 2% SANOFI - AVENTIS OTC

şi sugari

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| **1186** |**R06AD02**| **PROMETHAZINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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R06AD02 PROMETHAZINUM COMPR. FILM. 30 mg

PROMETAZINA ARENA 30 mg 30 mg ARENA GROUP S.A.

Pot apărea efecte secundare semnificative

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| **1187** |**R06AD07**| **MEQUITAZINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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R06AD07 MEQUITAZINUM COMPR. 10 mg

PRIMALAN(R) 10 mg 10 mg LAB. PIERRE FABRE

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| **1188** |**R06AE05**| **MECLOZINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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R06AE05 MECLOZINUM COMPR. 30 mg

EMETOSTOP 30 mg SPECIFAR SA

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| **1189** |**R06AX02**| **CYPROHEPTADINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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R06AX02 CYPROHEPTADINUM SIROP 2 mg/5 ml

BIOHEPT 2 mg/5 ml BIOFARM S.A.

PERITOL 2 mg/5 ml EGIS PHARMACEUTICALS LTD.

R06AX02 CYPROHEPTADINUM COMPR. 4 mg

PERITOL 4 mg EGIS PHARMACEUTICALS LTD.

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| **1190** |**R06AX13**| **LORATADINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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R06AX13 LORATADINUM SIROP 1 mg/ml

CLARITINE 1 mg/ml SCHERING-PLOUGH EUROPE

SYMPHORAL(R) 1 mg/ml 1 mg/ml GEDEON RICHTER ROMANIA SA

R06AX13 LORATADINUM SIROP 5 mg/5 ml

LORATADINA BIOFARM 5 mg/5 ml 5 mg/5 ml BIOFARM S.A.

R06AX13 LORATADINUM SUSP. ORALA 5 mg/5 ml

FLONIDAN 5 mg/5 ml LEK PHARMACEUTICALS D.D.

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| **1191** |**S01AA01**| **CHLORAMPHENICOLUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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S01AA01 CHLORAMPHENICOLUM PULB. + SOLV. PT. 0.4%

SOL. OFT.

SIFICETINA 0.4% S.I.F.I. SPA

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| **1192** |**S01AA13**| **ACIDUM FUSIDICUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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S01AA13 ACIDUM FUSIDICUM GEL OFT. 1,00%

FUCITHALMIC(R) 1% LEO PHARMACEUTICAL

PRODUCTS

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| **1193** |**S01AA24**| **KANAMYCINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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S01AA24 KANAMYCINUM UNG. OFT. 1,00%

KANAMICINA SULFAT 1% 1% ANTIBIOTICE SA

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| **1194** |**S01AA30**| **COMBINAŢII** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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S01AA30 COMBINATII PICATURI OFT. - SOL.

ANTIBIOPTAL FARMILA FARMACEUTICI

S01AA30 COMBINATII PULB. + SOLV. PT.

SOL. OFT.

COLBIOCIN S.I.F.I. SPA

S01AA30 COMBINATII UNG. OFT.

ENBECIN POLIPHARMA INDUSTRIES

S.R.L.

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| **1195** |**S01BA07**| **FLUOROMETHOLONUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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S01BA07 FLUOROMETHOLONUM UNG. OFT. 1 mg/g

FLUMETOL S UNGUENT OFTALMIC 1 mg/g FARMILA - THEA

FARMACEUTICI SPA

S01BA07 FLUOROMETHOLONUM PICATURI OFT. SUSP. 2 mg/ml

FLUMETOL S 2 mg/ml FARMILA - THEA

FARMACEUTICI SPA

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| **1196** |**S01BA11**| **DESONIDUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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S01BA11 DESONIDUM PICATURI OFT. - SOL. 0.25%

PRENACID 0.25% S.I.F.I. SPA

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| **1197** |**S01BC01**| **INDOMETACINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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S01BC01 INDOMETACINUM PICATURI OFT. - SOL. 0.1%

INDOCOLLYRE(R) 0.1% 0.1% LAB. CHAUVIN

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| **1198** |**S01BC06**| **PIROXICAMUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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S01BC06 PIROXICAMUM PIC. OFT., SOL. 0.5%

BRUXICAM 0.5% 0.5% BRUSCHETTINI S.R.L.

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| **1199** |**S01EB01**| **PILOCARPINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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S01EB01 PILOCARPINUM PICATURI OFT. - SOL. 2,00%

DROPIL(R) 2% BRUSCHETTINI

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| **1200** |**S01GX06**| **EMEDASTINUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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S01GX06 EMEDASTINUM PICATURI OFT. - SOL. 0.5 mg/ml

EMADINE 0.05% 0.5 mg/ml ALCON LABORATORIES LTD.

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| **1201** |**S01GX08**| **KETOTIFENUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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S01GX08 KETOTIFENUM PICATURI OFT. - SOL. 0.25 mg/ml

ZADITEN 0,25 mg/ml 0.25 mg/ml NOVARTIS PHARMA GMBH

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| **1203** |**S01XA11**| **NANDROLONUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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S01XA11 NANDROLONUM PICATURI OFT. - SOL. 1,00%

KERATYL(R) 1% 1% LAB. CHAUVIN

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| **1204** |**S01XA12**| **DEXPANTHENOLUM** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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S01XA12 DEXPANTHENOLUM GEL OFT. 5,00%

CORNEREGEL(R) 5% DR. GERHARD MANN

CHEM-PHARM. FABRIK GMBH

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| **1205** |**S02CA05**| **COMBINAŢII** | |

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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S02CA05 COMBINATII SOL. AURICULARA

SOLUTIE AURICULARA CU BIOFARM SA

CLORAMFENICOL SI FLUOCINOLON

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| **1206** |**R03DX05**| **OMALIZUMABUM\*\*** | |

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Prescriere limitată: **Tratamentul adjuvant pentru îmbunătăţirea controlului astmului bronşic la pacienţii adulţi şi adolescenţi (cu vârsta de 12 ani şi peste) cu astm alergic persistent sever care prezintă test cutanat pozitiv sau hiperreactivitate in vitro la un alergen permanent şi care au funcţia pulmonară redusă (FEV1 < 80%), precum şi simptome frecvente în timpul zilei sau treziri bruşte în cursul nopţii şi care au avut multiple exacerbări astmatice confirmate, în ciuda administrării pe cale inhalatorie de doze mari de corticosteroizi şi agonişti beta2-adrenergici cu acţiune de lungă durată.**

NOTĂ:

**Tratamentul cu Xolair trebuie avut în vedere la pacienţii cu astm bronşic mediat cu certitudine prin intermediul IgE.**

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DCI/DENUMIRE COMERCIALĂ FORMA FARM.

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CONCENTRAŢIE FIRMA

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R03DX05 OMALIZUMABUM PULB. + SOLV. PT. 150 mg

SOL. INJ.

XOLAIR 150 mg 150 mg NOVARTIS EUROPHARM LTD.

R03DX05 OMALIZUMABUM PULB. + SOLV. PT.

SOL. INJ. 75 mg

XOLAIR 150 mg 150 mg NOVARTIS EUROPHARM LTD.

XOLAIR 75 mg 75 mg NOVARTIS EUROPHARM LTD.

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