

DOSARE PROCEDURĂ EUROPEANĂ DISCUTATE ÎN CAPP ÎN LUNA OCTOMBRIE 2019

| Nr. Crt. | Denumire comerciala | Concentratia | Forma farmaceutica | DCI | Deținător APP | Statut A/R Baza legala- Legea 95/2006 cu modificari | Data intrării ANMDM | Tipul Procedurii | DATA CAPP | OBSERVAȚII |
|----------|--------------------------|------------------|---------------------------------|--|---------------------------------|---|---------------------|--------------------|-----------|------------|
| 1 | Dailiport 0,5 mg | 0,5 mg | Capsule cu eliberare prelungita | Tacrolimus monohidrat | SC Sandoz SRL, Romania | A - in baza art. 708 (1) | 8/3/2018 | NL/H/450 8/001/DC | 10/7/2019 | |
| 2 | Dailiport 1 mg | 1 mg | Capsule cu eliberare prelungita | Tacrolimus monohidrat | SC Sandoz SRL, Romania | A - in baza art. 708 (1) | 8/3/2018 | NL/H/450 8/002/DC | 10/7/2019 | |
| 3 | Dailiport 2 mg | 2 mg | Capsule cu eliberare prelungita | Tacrolimus monohidrat | SC Sandoz SRL, Romania | A - in baza art. 708 (1) | 8/3/2018 | NL/H/450 8/003/DC | 10/7/2019 | |
| 4 | Dailiport 3 mg | 3 mg | Capsule cu eliberare prelungita | Tacrolimus monohidrat | SC Sandoz SRL, Romania | A - in baza art. 708 (1) | 8/3/2018 | NL/H/450 8/004/DC | 10/7/2019 | |
| 5 | Dailiport 4 mg | 4 mg | Capsule cu eliberare prelungita | Tacrolimus monohidrat | SC Sandoz SRL, Romania | A - in baza art. 708 (1) | 8/3/2018 | NL/H/450 8/005/DC | 10/7/2019 | |
| 6 | Roxampex 10 mg/5 mg/4 mg | 10 mg/5 mg/ 4 mg | Comprimante filmate | Rosuvastatina sub forma de rosuvastatina calcica/Amlodipin a sub forma de besilat de amlodipina/Perind opril tert-butilamina | Krka d.d., Novo mesto, Slovenia | A - in baza art. 710 | 9/12/2018 | HU/H/05 98/001/D C | 10/7/2019 | |

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| 7 | Roxampex 10 mg/5 mg/8 mg | 10 mg/5 mg/ 4 mg | Comprimare filmate | Rosuvastatina sub forma de rosuvastatina calcica/Amlodipin a sub forma de besilat de amlodipina/Perind opril tert- butilamina | Krka d.d., Novo mesto, Slovenia | A - in baza art. 710 | 9/12/2018 | HU/H/05 98/002/D C | 10/7/2019 | |
| 8 | Roxampex 10 mg/10 mg/8 mg | 10 mg/10 mg/ 8 mg | Comprimare filmate | Rosuvastatina sub forma de rosuvastatina calcica/Amlodipin a sub forma de besilat de amlodipina/Perind opril tert- butilamina | Krka d.d., Novo mesto, Slovenia | A - in baza art. 710 | 9/12/2018 | HU/H/05 98/003/D C | 10/7/2019 | |
| 9 | Roxampex 20 mg/5 mg/4 mg | 20 mg/5 mg/ 4 mg | Comprimare filmate | Rosuvastatina sub forma de rosuvastatina calcica/Amlodipin a sub forma de besilat de amlodipina/Perind opril tert- butilamina | Krka d.d., Novo mesto, Slovenia | A - in baza art. 710 | 9/12/2018 | HU/H/05 98/004/D C | 10/7/2019 | |
| 10 | Roxampex 20 mg/5 mg/8 mg | 20 mg/5 mg/ 8 mg | Comprimare filmate | Rosuvastatina sub forma de rosuvastatina calcica/Amlodipin a sub forma de besilat de amlodipina/Perind opril tert- butilamina | Krka d.d., Novo mesto, Slovenia | A - in baza art. 710 | 9/12/2018 | HU/H/05 98/005/D C | 10/7/2019 | |

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| 11 | Roxampex 20 mg/10 mg/8 mg | 20 mg/10 mg/ 8 mg | Comprimate filmate | Rosuvastatina sub forma de rosuvastatina calcica/Amlodipin a sub forma de besilat de amlodipina/Perind opril tert-butilamina | Krka d.d., Novo mesto, Slovenia | A - in baza art. 710 | 9/12/2018 | HU/H/05 98/006/D C | 10/7/2019 | |
| 12 | Tiavella 50 mg | 50 mg | Comprimate filmate | Benfotiamina | G.L. Pharma GmbH, Austria | A - in baza art. 709 | 3/22/2018 | HU/H/05 71/001/D C | 10/7/2019 | |
| 13 | Tiavella 300 mg | 300 mg | Comprimate filmate | Benfotiamina | G.L. Pharma GmbH, Austria | A - in baza art. 709 | 3/22/2018 | HU/H/05 71/003/D C | 10/7/2019 | |
| 14 | Dexmedetomidi ne Kalceks 100 micrograme/ml | 100 micrograme/ml | Concentrat pentru solutie perfuzabila | Clorhidrat de dexmedetomidina | AS Kalceks, Letonia | A - in baza art. 708 (1) | 7/1/2019 | DK/H/28 91/001/E0 01 | 10/7/2019 | |
| 15 | Metobject PEN 7,5 mg | 7,5 mg | Solutie injectabila in stilou injector (pen) preumplut | Metotrexat | Medac Gesellschaft mbH, Germania | R - art.738 (4) A - in baza art. 708 (1) | 9/28/2017 | SE/H/064 3/002/R0 02 | 10/7/2019 | |
| 16 | Metobject PEN 10 mg | 10 mg | Solutie injectabila in stilou injector (pen) preumplut | Metotrexat | Medac Gesellschaft mbH, Germania | R - art.738 (4) A - in baza art. 708 (1) | 9/28/2017 | SE/H/064 3/003/R0 02 | 10/7/2019 | |
| 17 | Metobject PEN 12,5 mg | 12,5 mg | Solutie injectabila in stilou injector (pen) preumplut | Metotrexat | Medac Gesellschaft mbH, Germania | R - art.738 (4) A - in baza art. 708 (1) | 9/28/2017 | SE/H/064 3/004/R0 02 | 10/7/2019 | |
| 18 | Metobject PEN 15 mg | 15 mg | Solutie injectabila in stilou injector (pen) preumplut | Metotrexat | Medac Gesellschaft mbH, Germania | R - art.738 (4) A - in baza art. 708 (1) | 9/28/2017 | SE/H/064 3/005/R0 02 | 10/7/2019 | |
| 19 | Metobject PEN 17,5 mg | 17,5 mg | Solutie injectabila in stilou injector (pen) preumplut | Metotrexat | Medac Gesellschaft mbH, Germania | R - art.738 (4) A - in baza art. 708 (1) | 9/28/2017 | SE/H/064 3/006/R0 02 | 10/7/2019 | |

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|----|--|-------------------------------|--|--|----------------------------------|---|-----------|----------------------------|-----------|--|
| 20 | Metoject PEN 20 mg | 20 mg | Solutie injectabila in stilou injector (pen) preumplut | Metotrexat | Medac Gesellschaft mbH, Germania | R - art.738 (4) A - in baza art. 708 (1) | 9/28/2017 | SE/H/064 3/007/R0 02 | 10/7/2019 | |
| 21 | Metoject PEN 22,5 mg | 22,5 mg | Solutie injectabila in stilou injector (pen) preumplut | Metotrexat | Medac Gesellschaft mbH, Germania | R - art.738 (4) A - in baza art. 708 (1) | 9/28/2017 | SE/H/064 3/008/R0 02 | 10/7/2019 | |
| 22 | Metoject PEN 25 mg | 25 mg | Solutie injectabila in stilou injector (pen) preumplut | Metotrexat | Medac Gesellschaft mbH, Germania | R - art.738 (4) A - in baza art. 708 (1) | 9/28/2017 | SE/H/064 3/009/R0 02 | 10/7/2019 | |
| 23 | Metoject PEN 27,5 mg | 27,5 mg | Solutie injectabila in stilou injector (pen) preumplut | Metotrexat | Medac Gesellschaft mbH, Germania | R - art.738 (4) A - in baza art. 708 (1) | 9/28/2017 | SE/H/064 3/010/R0 02 | 10/7/2019 | |
| 24 | Metoject PEN 30 mg | 30 mg | Solutie injectabila in stilou injector (pen) preumplut | Metotrexat | Medac Gesellschaft mbH, Germania | R - art.738 (4) A - in baza art. 708 (1) | 9/28/2017 | SE/H/064 3/011/R0 02 | 10/7/2019 | |
| 25 | Pavtide Diskus 50 micrograme/ 100 micrograme | 50 micrograme/100 micrograme | Pulbere de inhalat | Xinafoat de salmeterol/Propionat de fluticazona | GlaxoSmithkline SRL, Romania | R - art.738 (4) A - in baza art. 706 | 3/28/2019 | SE/H/017 0/001/R0 03 | 10/7/2019 | |
| 26 | Pavtide Diskus 50 micrograme/250 micrograme | 50 micrograme/250 micrograme | Pulbere de inhalat | Xinafoat de salmeterol/propionat de fluticazona | GlaxoSmithkline SRL, Romania | R - art.738 (4) A - in baza art. 706 | 3/28/2019 | SE/H/017 0/002/R0 03 | 10/7/2019 | |
| 27 | Pavtide Diskus 50 micrograme/500 micrograme | 50 micrograme/ 500 micrograme | Pulbere de inhalat | Xinafoat de salmeterol/propionat de fluticazona | GlaxoSmithkline SRL, Romania | R - art.738 (4) A - in baza art. 706 | 3/28/2019 | SE/H/017 0/003/R0 03 | 10/7/2019 | |
| 28 | Elicea Q-Tab 5 mg | 5 mg | Comprimat orodispersabile | Escitalopram sub forma de oxalat de excitalopram | Krka d.d., Novo mesto, Slovenia | R - art.738 (4) A - in baza art. 708 (1) | 8/21/2019 | CZ/H/027 7/004/R0 01 | 10/7/2019 | |
| 29 | Elicea Q-Tab 10 mg | 10 mg | Comprimat orodispersabile | Escitalopram sub forma de oxalat de excitalopram | Krka d.d., Novo mesto, Slovenia | R - art.738 (4) A - in baza art. 708 (1) | 8/21/2019 | CZ/H/027 7/005/R0 01 | 10/7/2019 | |

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| 30 | Elicea Q-Tab 15 mg | 15 mg | Comprimate orodispersabile | Escitalopram sub forma de oxalat de excitalopram | Krka d.d., Novo mesto, Slovenia | R - art.738 (4) A - in baza art. 708 (1) | 8/21/2019 | CZ/H/027 7/006/R0 01 | 10/7/2019 | |
| 31 | Elicea Q-Tab 20 mg | 20 mg | Comprimate orodispersabile | Escitalopram sub forma de oxalat de excitalopram | Krka d.d., Novo mesto, Slovenia | R - art.738 (4) A - in baza art. 708 (1) | 8/21/2019 | CZ/H/027 7/007/R0 01 | 10/7/2019 | |
| 32 | Sobycombi 5 mg/5 mg | 5 mg/5 mg | Comprimate | Fumarat de bisoprolul/Amlodi pina sub forma de besilat de amlodipina | Krka d.d., Novo mesto, Slovenia | R - art.738 (4) A - in baza art. 706 | 10/18/2018 | HU/H/03 48/001/R 001 | 10/7/2019 | |
| 33 | Sobycombi 5 mg/10 mg | 5 mg/10 mg | Comprimate | Fumarat de bisoprolul/Amlodi pina sub forma de besilat de amlodipina | Krka d.d., Novo mesto, Slovenia | R - art.738 (4) A - in baza art. 706 | 10/18/2018 | HU/H/03 48/002/R 001 | 10/7/2019 | |
| 34 | Sobycombi 10 mg/5 mg | 10 mg/5 mg | Comprimate | Fumarat de bisoprolul/Amlodi pina sub forma de besilat de amlodipina | Krka d.d., Novo mesto, Slovenia | R - art.738 (4) A - in baza art. 706 | 10/18/2018 | HU/H/03 48/003/R 001 | 10/7/2019 | |
| 35 | Sobycombi 10 mg/10 mg | 10 mg/10 mg | Comprimate | Fumarat de bisoprolul/Amlodi pina sub forma de besilat de amlodipina | Krka d.d., Novo mesto, Slovenia | R - art.738 (4) A - in baza art. 706 | 10/18/2018 | HU/H/03 48/004/R 001 | 10/7/2019 | |
| 36 | Abacavir Aurobindo 300 mg | 300 mg | Comprimate filmate | Abacavir sub forma de sulfat de abacavir | Aurobindo Pharma Romania S.R.L. | A - in baza art. 708 (1) | 8/3/2018 | PT/H/195 1/001/DC | 10/14/2019 | |
| 37 | Posaconazol Stada 100 mg | 100 mg | Comprimate gastrorezistente | Posaconazol | Stada M&D S.R.L., Romania | A - in baza art. 708 (1) | 4/2/2018 | DE/H/557 3/001/DC | 10/14/2019 | |
| 38 | Posaconazol Zentiva 100 mg | 100 mg | Comprimate gastrorezistente | Posaconazol | Zentiva k.s., Republica Cehia | A - in baza art. 708 (1) | 4/2/2018 | DE/H/557 4/001/DC | 10/14/2019 | |
| 39 | Posaconazol Mylan 100 mg | 100 mg | Comprimate gastrorezistente | Posaconazol | Mylan S.A.S., Franta | A - in baza art. 708 (1) | 4/2/2018 | DE/H/557 5/001/DC | 10/14/2019 | |

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| 40 | Socont 100 mg | 100 mg | Comprimate gastrorezistente | Posaconazol | Egis Pharmaceutica Is PLC, Ungaria | A - in baza art. 708 (1) | 4/2/2018 | DE/H/559 9/001/DC | 10/14/2019 | |
| 41 | Posaconazol Alvogen 100 mg | 100 mg | Comprimate gastrorezistente | Posaconazol | Alvogen Malta Operations (ROW) Limited, Malta | A - in baza art. 708 (1) | 12/21/2018 | DE/H/613 5/001/DC | 10/14/2019 | |
| 42 | Strepsils Intensiv cirese si menta 8,75 mg/doza | 8,75 mg/doza | Spray bucofaringian, solutie | Flurbiprofen | Reckitt Benckiser Romania SRL | A - in baza art. 706 | 8/13/2018 | NL/H/450 6/001/DC | 10/14/2019 | |
| 43 | Biorphen 0,1 mg/ml | 0,1 mg/ml | Solutie perfuzabila | Clorhidrat de fenilefrina | Sintetica GmbH, Germania | A - in baza art. 708 (3) | 5/7/2019 | DE/H/440 7/001/E00 1 | 10/14/2019 | |
| 44 | Biorphen 10 mg/ml | 10 mg/ml | Solutie injectabila | Clorhidrat de fenilefrina | Sintetica GmbH, Germania | A - in baza art. 708 (3) | 5/7/2019 | DE/H/440 7/002/E00 1 | 10/14/2019 | |
| 45 | Daptomicina Accordpharma 350 mg | 350 mg | Pulbere si solutie injectabila/perfuzabila | Daptomicina | Accord Healthcare Polska Sp. Z.o.o., Polonia | A - in baza art. 708 (1) | 5/8/2018 | PT/H/217 3/001/DC | 10/21/2019 | |
| 46 | Daptomicina Accordpharma 500 mg | 500 mg | Pulbere si solutie injectabila/perfuzabila | Daptomicina | Accord Healthcare Polska Sp. Z.o.o., Polonia | A - in baza art. 708 (1) | 5/8/2018 | PT/H/217 3/002/DC | 10/21/2019 | |
| 47 | Lornoxicam Rompharm 8 mg | 8 mg | Pulbere si solvent pentru solutie injectabila | Lornoxicam | S.C. Rompharm Company SRL, Romania | A - in baza art. 708 (1) | 9/27/2018 | HU/H/06 09/001/D C | 10/21/2019 | |
| 48 | Acarizax 12 SQ-HDM | | Liofilizat oral | Extrakte alergene standardizate de acarieni din praf de casa | ALK-Abello A/S, Danemarca | A - in baza art. 708 (3) | 7/1/2019 | DE/H/195 0/001/E00 1 | 10/21/2019 | |
| 49 | Ibaldin Express 200 mg | 200 mg | Capsule moi | Ibuprofen | Sanofi Romania SRL | R - art.738 (4) A - in baza art. 708 (1) | 10/3/2018 | HU/H/04 51/001/R 001 | 10/21/2019 | |

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| 50 | Ibalgin Express 400 mg | 400 mg | Capsule moi | Ibuprofen | Sanofi Romania SRL | R - art.738 (4) A - in baza art. 708 (1) | 10/3/2018 | HU/H/0451/002/R001 | 10/21/2019 | |
| 51 | Bortezomib Mylan 1 mg | 1 mg | Pulbere pentru solutie injectabila | Bortezomib | Mylan S.A.S., Franta | R - art.738 (4) A - in baza art. 708 (1) | 8/13/2019 | NL/H/4174/001/R001 | 10/21/2019 | |
| 52 | Bortezomib Mylan 3,5 mg | 3,5 mg | Pulbere pentru solutie injectabila | Bortezomib | Mylan S.A.S., Franta | R - art.738 (4) A - in baza art. 708 (1) | 8/13/2019 | NL/H/4174/002/R001 | 10/21/2019 | |
| 53 | Garganta 1,5 mg/ml | 1,5 mg/ml | Spray bucofaringian, solutie | Clorhidrat de benzidamina | PharmaSwiss Ceska republika s.r.o., Republica Ceha | R - art.738 (4) A - in baza art. 708 (3) | 5/9/2019 | PL/H/0211/001/R001 | 10/21/2019 | |
| 54 | Leptoprol 5 mg | 5 mg | Implant in seringa preumpluta | Leuprorelina sub forma de acetat de leuprorelina | S.C. Sandoz S.R.L., Romania | R - art.738 (4) A - in baza art. 708 (3) | 1/11/2019 | DE/H/3873/001/R001 | 10/21/2019 | |
| 55 | Darunavir MSN Laboratories 400 mg | 400 mg | Comprimate filmate | Darunavir | Vivanta Generics s.r.o., Republica Ceha | R - art.738 (4) A - in baza art. 708 (1) | 8/3/2018 | NL/H/4523/001/DC | 10/21/2019 | Procedura respinsa conform deciziei consensuale SMR si SMI |
| 56 | Darunavir MSN Laboratories 600 mg | 600 mg | Comprimate filmate | Darunavir | Vivanta Generics s.r.o., Republica Ceha | R - art.738 (4) A - in baza art. 708 (1) | 8/3/2018 | NL/H/4523/002/DC | 10/21/2019 | Procedura respinsa conform deciziei consensuale SMR si SMI |
| 57 | Darunavir MSN Laboratories 800 mg | 800 mg | Comprimate filmate | Darunavir | Vivanta Generics s.r.o., Republica Ceha | R - art.738 (4) A - in baza art. 708 (1) | 8/3/2018 | NL/H/4523/003/DC | 10/21/2019 | Procedura respinsa conform deciziei consensuale SMR si SMI |
| 58 | Talidomida Accord 50 mg | 50 mg | Capsule | Talidomida | Accord Healthcare Ltd., Polonia | A - in baza art. 708 (1) | 8/3/2018 | MT/H/0312/001/D C | 10/28/2019 | |
| 59 | Rosuvastatina MSN Laboratories 5 mg | 5 mg | Comprimate filmate | Rosuvastatina sub forma de rosuvastatina calcica | Vivanta Generics s.r.o., Republica Ceha | A - in baza art. 708 (1) | 8/24/2018 | NL/H/4582/001/DC | 10/28/2019 | |

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| 60 | Rosuvastatina MSN Laboratories 10 mg | 10 mg | Comprimate filmate | Rosuvastatina sub forma de rosuvastatina calcica | Vivanta Generics s.r.o., Republica Ceha | A - in baza art. 708 (1) | 8/24/2018 | NL/H/458 2/001/DC | 10/28/2019 | |
| 61 | Rosuvastatina MSN Laboratories 20 mg | 20 mg | Comprimate filmate | Rosuvastatina sub forma de rosuvastatina calcica | Vivanta Generics s.r.o., Republica Ceha | A - in baza art. 708 (1) | 8/24/2018 | NL/H/458 2/001/DC | 10/28/2019 | |
| 62 | Rosuvastatina MSN Laboratories 40 mg | 40 mg | Comprimate filmate | Rosuvastatina sub forma de rosuvastatina calcica | Vivanta Generics s.r.o., Republica Ceha | A - in baza art. 708 (1) | 8/24/2018 | NL/H/458 2/001/DC | 10/28/2019 | |
| 63 | Aripiprazol Aurobindo 10 mg | 10 mg | Comprimate | Aripiprazol | Aurobindo Pharma (Malta) Limited, Malta | R - art.738 (4) A - in baza art. 708 (1) | 7/22/2019 | PT/H/130 4/002/R0 01 | 10/28/2019 | |
| 64 | Aripiprazol Aurobindo 15 mg | 15 mg | Comprimate | Aripiprazol | Aurobindo Pharma (Malta) Limited, Malta | R - art.738 (4) A - in baza art. 708 (1) | 7/22/2019 | PT/H/130 4/003/R0 01 | 10/28/2019 | |
| 65 | Copaxone 40 mg/ml | 40 mg/ml | Solutie injectabila in seringa preumpluta | Acetat de glatiramer | Teva Pharmaceutica ls S.R.L., Romania | R - art.738 (4) A - in baza art. 706 | 3/1/2019 | DE/H/528 3/004/R0 01 | 10/28/2019 | |
| 66 | Levetiracetam Accord 100 mg/ml | 100 mg/ml | Solutie orala | Levetiracetam | Accord Healthcare Polska Sp.z.o.o., Polonia | R - art.738 (4) A - in baza art. 708 (1) | 3/19/2019 | PT/H/120 6/001/R0 01 | 10/28/2019 | |
| 67 | Rosi 10 mg | 10 mg | Comprimate filmate | Rosuvastatina sub forma de rosuvastatina calcica | Swyssi AG, Germania | R - art.738 (4) A - in baza art. 708 (1) | 3/22/2019 | CZ/H/048 3/002/R0 01 | 10/28/2019 | |
| 68 | Rosi 20 mg | 20 mg | Comprimate filmate | Rosuvastatina sub forma de rosuvastatina calcica | Swyssi AG, Germania | R - art.738 (4) A - in baza art. 708 (1) | 3/22/2019 | CZ/H/048 3/003/R0 01 | 10/28/2019 | |

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|-----------|------------|-------|--------------------|---|------------------------|--|-----------|----------------------------|------------|--|
| 69 | Rosi 40 mg | 40 mg | Comprimete filmate | Rosuvastatina sub forma de rosuvastatina calcica | Swyssi AG, Germania | R - art.738 (4) A - in baza art. 708 (1) | 3/22/2019 | CZ/H/048 3/004/R0 01 | 10/28/2019 | |
|-----------|------------|-------|--------------------|---|------------------------|--|-----------|----------------------------|------------|--|