

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 (Procedura de recunoaștere mutuală și procedura descentralizată in baza art. 743)	Situatie
1	Lopinavir/ Ritonavir Terapie 200 mg/50 mg	200 mg/ 50 mg	Comprimate filmate	Lopinavir/Ritonavir	Terapie S.A., Romania	R - art.738 (4) A - in baza art. 708 (1)	3/12/2018	FR/H/0545/002/R001	Trimis DLIGED 10.06.2019
2	Olynth 0,5 mg/ml	0,5 mg/ml	Spray nazal, solutie	Clorhidrat de xilometazolina	McNeil Healthcare (Ireland) Limited, Irlanda	R - art.738 (4) A - in baza art. 709	10/22/2018	LV/H/0119/001/R001	Trimis DLIGED 24.06.2019
3	Olynth 1 mg/ml	1 mg/ml	Spray nazal, solutie	Clorhidrat de xilometazolina	McNeil Healthcare (Ireland) Limited, Irlanda	R - art.738 (4) A - in baza art. 709	10/22/2018	LV/H/0119/002/R001	Trimis DLIGED 24.06.2019
4	Carbonat de Sevelamer Heaton 800 mg	800 mg	Comprimate filmate	Carbonat de sevelamer anhidru	Heaton k.s., Republica Ceha	R - art.738 (4) A - in baza art. 708 (3)	6/12/2018	CZ/H/0711/001/R001	Solicitare traduceri 29.05.2019
5	Carbonat de Sevelamer Sandoz 800 mg	800 mg	Comprimate filmate	Carbonat de sevelamer anhidru	Sandoz S.R.L., Romania	R - art.738 (4) A - in baza art. 708 (3)	6/11/2018	DK/H/1953/001/R001	Solicitare traduceri 29.05.2019
6	Cognomem 10 mg	10 mg	Comprimate filmate	Clorhidrat de memantina	Zentiva k.s., Republica Ceha	R - art.738 (4) A - in baza art. 708 (1)	1/22/2018	CZ/H/0225/001/R001	Trimis DLIGED mai 2019
7	Cognomem 20 mg	20 mg	Comprimate filmate	Clorhidrat de memantina	Zentiva k.s., Republica Ceha	R - art.738 (4) A - in baza art. 708 (1)	1/22/2018	CZ/H/0225/002/R001	Trimis DLIGED mai 2019
8	Biphozyl		Solutie pentru hemodializa/ hemofiltrare	Clorura de magneziu hexahidrat, clorura de sodiu, hidrogenocarbonat de sodiu, clorura de potasiu, fosfat disodic dihidrat	Gambro Lundia AB, Suedia	R - art.738 (4) A - in baza art. 709	1/18/2019	NL/H/3002/001/R001	Solicitare traduceri 29.05.2019
9	Velyn 100 mg	100 mg	Comprimate	Clostazol	Terapie S.A., Romania	R - art.738 (4) A - in baza art. 708 (1)	5/21/2018	EE/H/0189/002/R001	Trimis DLIGED 7.06.2019
10	Dipperam HCT 5 mg/160 mg/12,5 mg	5 mg/160 mg/12,5 mg	Comprimate filmate	Amlodipina/valsartan/hidroc lorotiazida	S.C. Sandoz S.R.L., Romania	A - in baza art. 708 (1)	1/3/2018	NL/H/4290/001/DC	Trimis DLIGED 5.06.2019
11	Dipperam HCT 10 mg/160 mg/12,5 mg	10 mg/160 mg/12,5 mg	Comprimate filmate	Amlodipina/valsartan/hidroc lorotiazida	S.C. Sandoz S.R.L., Romania	A - in baza art. 708 (1)	1/3/2018	NL/H/4290/002/DC	Trimis DLIGED 5.06.2019
12	Dipperam HCT 5 mg/160 mg/25 mg	5 mg/160 mg/25 mg	Comprimate filmate	Amlodipina/valsartan/hidroc lorotiazida	S.C. Sandoz S.R.L., Romania	A - in baza art. 708 (1)	1/3/2018	NL/H/4290/003/DC	Trimis DLIGED 5.06.2019
13	Dipperam HCT 10 mg/160 mg/25 mg	10 mg/160 mg/25 mg	Comprimate filmate	Amlodipina/valsartan/hidroc lorotiazida	S.C. Sandoz S.R.L., Romania	A - in baza art. 708 (1)	1/3/2018	NL/H/4290/004/DC	Trimis DLIGED 5.06.2019
14	Amarhyton 50 mg	50 mg	Capsule cu eliberare prelungita	Acetat de flecainida	Swyssi AG, Germania	A - in baza art. 708 (1)	4/5/2019	PT/H/2164/001/DC	Trimis DLIGED 7.06.2019
15	Amarhyton 100 mg	100 mg	Capsule cu eliberare prelungita	Acetat de flecainida	Swyssi AG, Germania	A - in baza art. 708 (1)	4/5/2019	PT/H/2164/002/DC	Trimis DLIGED 7.06.2019
16	Moxifloxacină MSN 400 mg	400 mg	Comprimate filmate	Moxifloxacin sub forma de clorhidrat de moxifloxacină	Vivanta Generics s.r.o., Republica Cehă	A - in baza art. 708 (1)	5/3/2018	NL/H/4360/001/DC	Trimis DLIGED 4.06.2019
17	Strattera 4 mg/ml	4 mg/ml	Solutie orala	Clorhidrat de atomoxetina	Eli Lilly Nederland B.V., Olanda	R - art.738 (4) A - in baza art. 706	12/21/2018	ES/H/0575/009/R003	Trimis DLIGED 13.06.2019
18	Kventiax EP 150 mg	150 mg	Comprimate cu eliberare prelungita	Fumarat de quetiapina	Krka d.d., Novo mesto, Slovenia	R - art.738 (4) A - in baza art. 708 (1)	2/21/2019	DK/H/1059/006/R002	Trimis DLIGED 4.06.2019
19	Kventiax EP 200 mg	200 mg	Comprimate cu eliberare prelungita	Fumarat de quetiapina	Krka d.d., Novo mesto, Slovenia	R - art.738 (4) A - in baza art. 708 (1)	2/21/2019	DK/H/1059/007/R002	Trimis DLIGED 4.06.2019
20	Kventiax EP 300 mg	300 mg	Comprimate cu eliberare prelungita	Fumarat de quetiapina	Krka d.d., Novo mesto, Slovenia	R - art.738 (4) A - in baza art. 708 (1)	2/21/2019	DK/H/1059/008/R002	Trimis DLIGED 4.06.2019
21	Kventiax EP 50 mg	50 mg	Comprimate cu eliberare prelungita	Fumarat de quetiapina	Krka d.d., Novo mesto, Slovenia	R - art.738 (4) A - in baza art. 708 (1)	2/21/2019	DK/H/1059/009/R002	Trimis DLIGED 4.06.2019

22	Kventiax EP 400 mg	400 mg	Comprimate cu eliberare prelungita	Fumarat de quetiapina	Krka d.d., Novo mesto, Slovenia	R - art.738 (4) art. 708 (1) A - in baza	2/21/2019	DK/H/1059/010/R002	Trimis DLIGED 4.06.2019
23	Aspendos 100 mg	100 mg	Comprimate	Modafinil	Medochemie Limited, Cipru	R - art.738 (4) art. 708 (1) A - in baza	1/3/2019	NL/H/1816/001/R002	Trimis DLIGED 10.06.2019
24	Cefepima MIP 1 g	1 g	Pulbere pentru solutie injectabila/perfuzabila	Cefepima sub forma de diclorhidrat de cefepima monohidrat	MIP Pharma GmbH., Germania	R - art.738 (4) art. 708 (1) A - in baza	2/21/2019	NL/H/2986/001/R001	APP emis
25	Cefepima MIP 2 g	1 g	Pulbere pentru solutie injectabila/perfuzabila	Cefepima sub forma de diclorhidrat de cefepima monohidrat	MIP Pharma GmbH., Germania	R - art.738 (4) art. 708 (1) A - in baza	2/21/2019	NL/H/2986/002/R001	APP emis
26	Ertapenem Villerton 1 g	1 g	Pulbere pentru concentrat pentru solutie perfuzabila	Ertapenem sodic	Villerton Invest S.A., Luxemburg	A - in baza art. 708 (1)	5/14/2018	NL/H/4383/001/DC	la aplicant 25.06.2019
27	Olmesartan medoxomil/Amlodipina Krka 20 mg/5 mg	20 mg/5 mg	Comprimate filmate	Olmesartan medoxomil/Amlodipina sub forma de besilat de amlodipina	Krka d.d., Novo Mesto, Slovenia	A - in baza art. 708 (1)	11/22/2018	HU/H/0487/001/E001	Trimis DLIGED 24.06.2019
28	Olmesartan medoxomil/Amlodipina Krka 40 mg/5 mg	40 mg/5 mg	Comprimate filmate	Olmesartan medoxomil/Amlodipina sub forma de besilat de amlodipina	Krka d.d., Novo Mesto, Slovenia	A - in baza art. 708 (1)	11/22/2018	HU/H/0487/002/E001	Trimis DLIGED 24.06.2019
29	Olmesartan medoxomil/Amlodipina Krka 40 mg/10 mg	40 mg/10 mg	Comprimate filmate	Olmesartan medoxomil/Amlodipina sub forma de besilat de amlodipina	Krka d.d., Novo Mesto, Slovenia	A - in baza art. 708 (1)	11/22/2018	HU/H/0487/003/E001	Trimis DLIGED 24.06.2019
30	Norditropin NordiFlex 10 mg/1,5 ml	10 mg/1,5 ml	Solutie injectabila in stilou preumplut	Somatropina	Novo Nordisk A/S, Danemarca	A - in baza art. 706	10/30/2018	DK/H/0001/012/E006	Trimis DLIGED 20.06.2019
31	Netiapin 50 mg	50 mg	Comprimate cu eliberare prelungita	Quetiapina sub forma de fumarat de quetiapina	S.C. Sandoz S.R.L., Romania	R - art.738 (4) art. 706 A - in baza	2/8/2019	DK/H/2334/001/R001	Trimis DLIGED 24.06.2019
32	Netiapin 150 mg	150 mg	Comprimate cu eliberare prelungita	Quetiapina sub forma de fumarat de quetiapina	S.C. Sandoz S.R.L., Romania	R - art.738 (4) art. 706 A - in baza	2/8/2019	DK/H/2334/002/R001	Trimis DLIGED 24.06.2019
33	Netiapin 200 mg	200 mg	Comprimate cu eliberare prelungita	Quetiapina sub forma de fumarat de quetiapina	S.C. Sandoz S.R.L., Romania	R - art.738 (4) art. 706 A - in baza	2/8/2019	DK/H/2334/003/R001	Trimis DLIGED 24.06.2019
34	Netiapin 300 mg	300 mg	Comprimate cu eliberare prelungita	Quetiapina sub forma de fumarat de quetiapina	S.C. Sandoz S.R.L., Romania	R - art.738 (4) art. 706 A - in baza	2/8/2019	DK/H/2334/004/R001	Trimis DLIGED 24.06.2019
35	Netiapin 400 mg	400 mg	Comprimate cu eliberare prelungita	Quetiapina sub forma de fumarat de quetiapina	S.C. Sandoz S.R.L., Romania	R - art.738 (4) art. 706 A - in baza	2/8/2019	DK/H/2334/005/R001	Trimis DLIGED 24.06.2019
36	Voriconazol Zentiva 200 mg	200 mg	Comprimate filmate	Voriconazol	Zentiva k.s., Republica Ceha	R - art.738 (4) art. 708 (1) A - in baza	3/19/2019	DE/H/3920/002/R001	Trimis DLIGED 18.06.2019
37	Dutasterida Cipla 0,5 mg	0,5 mg	Capsule moi	Dutasterida	Cipla (EU) Limited, Marea Britanie	R - art.738 (4) art. 708 (1) A - in baza	10/26/2018	ES/H/0580/001/R001	Solicitareaplicant 5.06.2019
38	Diclopram 75 mg/20 mg	75 mg/20 mg	Capsule cu eliberare modificata	Diclofenac sodic/Omeprazol	PharmaSwiss Ceska republica s.r.o., Republica Ceha	R - art.738 (4) art. 710 A - in baza	12/6/2019	EE/H/0266/001/R001	In lucru
39	Ibuprofen Chanell Medical 200 mg	200 mg	Capsule moi	Ibuprofen sub forma de lizinat de ibuprofen	Chanelle Medical, Irlanda	A - in baza art. 708 (1)	4/20/2018	NL/H/4402/001/DC	Trimis DLIGED 27.06.2019
40	Ibuprofen Chanell Medical 400 mg	400 mg	Capsule moi	Ibuprofen sub forma de lizinat de ibuprofen	Chanelle Medical, Irlanda	A - in baza art. 708 (1)	4/20/2018	NL/H/4402/002/DC	Trimis DLIGED 27.06.2019
41	Exoderil SET 50mg/ml	50 mg/ml	Lac de unghii medicamentos	Amorolfina sub forma de clorhidrat de amorolfina	Laboratoires Gerda, Franta	A - in baza art. 708 (3)	1/16/2017	AT/H/0734/001/DC	Trimis DLIGED iunie 2019
42	Duodopa 20 mg/ml + 5 mg/ml	20 mg/ml + 5 mg/ml	Gel intestinal	Levodopa/Carbidopa sub forma monohidrat	AbbVie Deutschland GmbH & Co. KG, Germania	R - art.738 (4) art. 706 A - in baza	10/30/2018	SE/H/0415/001/R002	Trimis DLIGED 21.06.2019
43	Gliclazida Zentiva 60 mg	60 mg	Comprimate cu eliberare modificata	Gliclazida	Zentiva k.s., Republica Ceha	R - art.738 (4) art. 708 (1) A - in baza	9/26/2018	LV/H/0145/002/R001	Trimis DLIGED 25.06.2019
44	APO-go 10 mg/ml	10 mg/ml	Solutie injectabila in pen multidoza	Clorhidrat de apomorfina hemihidrat	Britannia Pharmaceuticals Ltd., Marea Britanie	R - art.738 (4) art. 706 A - in baza	11/7/2017	UK/H/0342/001/R005	Trimis DLIGED 6.06.2019
45	APO-go 10 mg/ml	10 mg/ml	Solutie injectabila/perfuzabila	Clorhidrat de apomorfina hemihidrat	Britannia Pharmaceuticals Ltd., Marea Britanie	R - art.738 (4) art. 706 A - in baza	11/7/2017	UK/H/0342/002/R005	Trimis DLIGED 6.06.2019

46	APO-go 10 mg/ml	10 mg/ml	Solutie perfuzabila in seringa preumpluta unidoza	Clorhidrat de apomorfină hemihidrat	Britannia Pharmaceuticals Ltd., Marea Britanie	R - art.738 (4) A - in baza art. 708 (1)	11/7/2017	UK/H/0342/003/R005	Trimis DLIGED 6.06.2019
47	Temelor 4 mg/ml	4 mg/ml	Solutie injectabila	Lorazepam	Medochemie Iberia S.A., Portugalia	A - in baza art. 708 (1)	4/2/2018	NL/H/4352/001/DC	In lucru
48	Darunavir Aurobindo 400 mg	400 mg	Comprimate filmate	Darunavir sub forma de darunavir propilen glicolat	Aurobindo Pharma Romania S.R.L.	A - in baza art. 708 (1)	3/22/2018	PT/H/1932/001/DC	la aplicant 24.06.2019
49	Darunavir Aurobindo 600 mg	600 mg	Comprimate filmate	Darunavir sub forma de darunavir propilen glicolat	Aurobindo Pharma Romania S.R.L.	A - in baza art. 708 (1)	3/22/2018	PT/H/1932/002/DC	la aplicant 24.06.2019
50	Xeomin 50 unitati	50 unitati	Pulbere pentru solutie injectabila	Neurotoxina Clostridium botulinum tip A	Merz Pharmaceuticals GmbH, Germania	A - in baza art. 706	1/31/2018	DE/H/0722/001/X/085	Solicitare aplicant 25.06.2019
51	Xeomin 100 unitati	100 unitati	Pulbere pentru solutie injectabila	Neurotoxina Clostridium botulinum tip A	Merz Pharmaceuticals GmbH, Germania	A - in baza art. 706	1/31/2018	DE/H/0722/002/X/085	Solicitare aplicant 25.06.2019
52	Xeomin 200 unitati	200 unitati	Pulbere pentru solutie injectabila	Neurotoxina Clostridium botulinum tip A	Merz Pharmaceuticals GmbH, Germania	A - in baza art. 706	1/31/2018	DE/H/0722/003/X/085	Solicitare aplicant 25.06.2019
53	Pelafen		Sirup	Extract uscat din radacina de pelargonium	Phytopharm Kleka S.A., Polonia	A - in baza art. 718	3/1/2019	AT/H/0783/001/E001	Trimis DLIGED 25.06.2019
54	Physioneal 35 Glucose CLEAR-FLEX 13,6 mg/ml	13,6 mg/ml	Solutie pentru dializa peritoneala	Glucosa anhidra sub forma de glucoza monohidrat, clorura de sodiu, clorura de calciu dihidrat, clorura de magneziu hexahidrat, bicarbonat de sodiu, solutie de (S)lactat de sodiu	Baxter Healthcare SRL, Romania	R - art.738 (4) A - in baza art. 709	12/3/2018	DK/H/0590/001/DC	In lucru
55	Physioneal 35 Glucose CLEAR-FLEX 22,7 mg/ml	22,7 mg/ml	Solutie pentru dializa peritoneala	Glucosa anhidra sub forma de glucoza monohidrat, clorura de sodiu, clorura de calciu dihidrat, clorura de magneziu hexahidrat, bicarbonat de sodiu, solutie de (S)lactat de sodiu	Baxter Healthcare SRL, Romania	R - art.738 (4) A - in baza art. 709	12/3/2018	DK/H/0590/002/DC	In lucru
56	Physioneal 35 Glucose CLEAR-FLEX 38,6 mg/ml	38,6 mg/ml	Solutie pentru dializa peritoneala	Glucosa anhidra sub forma de glucoza monohidrat, clorura de sodiu, clorura de calciu dihidrat, clorura de magneziu hexahidrat, bicarbonat de sodiu, solutie de (S)lactat de sodiu	Baxter Healthcare SRL, Romania	R - art.738 (4) A - in baza art. 709	12/3/2018	DK/H/0590/003/DC	In lucru
57	Physioneal 40 Glucose CLEAR-FLEX 13,6 mg/ml	13,6 mg/ml	Solutie pentru dializa peritoneala	Glucosa anhidra sub forma de glucoza monohidrat, clorura de sodiu, clorura de calciu dihidrat, clorura de magneziu hexahidrat, bicarbonat de sodiu, solutie de (S)lactat de sodiu	Baxter Healthcare SRL, Romania	R - art.738 (4) A - in baza art. 709	12/3/2018	DK/H/0590/004/DC	In lucru

58	Physioneal 40 Glucose CLEAR-FLEX 22,7 mg/ml	22,7 mg/ml	Solutie pentru dializa peritoneala	Glucoza anhidra sub forma de glucoza monohidrat, clorura de sodiu, clorura de calciu dihidrat, clorura de magneziu hexahidrat, bicarbonat de sodiu, solutie de (S)lactat de sodiu	Baxter Healthcare SRL, Romania	R - art.738 (4) A - in baza art. 709	12/3/2018	DK/H/0590/005/DC	In lucru
59	Physioneal 40 Glucose CLEAR-FLEX 38,6 mg/ml	38,6 mg/ml	Solutie pentru dializa peritoneala	Glucoza anhidra sub forma de glucoza monohidrat, clorura de sodiu, clorura de calciu dihidrat, clorura de magneziu hexahidrat, bicarbonat de sodiu, solutie de (S)lactat de sodiu	Baxter Healthcare SRL, Romania	R - art.738 (4) A - in baza art. 709	12/3/2018	DK/H/0590/006/DC	In lucru