

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	Tadalafil AOP 20 mg	20 mg	Comprimate filmate	Tadalafil	AOP Orphan Pharmaceuticals AG., Austria	A - in baza art. 708 (1)	2/8/2019	NL/H/4322/001/DC	APP emis
2	Cutaquig 165 mg/ml	165 mg/ml	Solutie injectabila	Imunoglobulina umana normala	Octapharma (IP) SPRL, Belgia	A - in baza art. 706	2/8/2019	DE/H/4903/001/DC	Finalizat CIM DPE
3	Omevod 10 mg	10 mg	Capsule gastrorezisten te	Omeprazol	Esteve Pharmaceuticals S.A., Spania	A - in baza art. 708 (1)	2/8/2019	DE/H/5865/001/MR	APP emis
4	Omevod 20 mg	20 mg	Capsule gastrorezisten te	Omeprazol	Esteve Pharmaceuticals S.A., Spania	A - in baza art. 708 (1)	2/8/2019	DE/H/5865/002/MR	APP emis
5	Omevod 40 mg	40 mg	Capsule gastrorezisten te	Omeprazol	Esteve Pharmaceuticals S.A., Spania	A - in baza art. 708 (1)	2/8/2019	DE/H/5865/003/MR	APP emis
6	Prindex Plus 2 mg/0,625 mg	2 mg/ 0,625 mg	Comprimate	Perindopril tert- butilamina/Indapamida	Glenmark Pharmaceuticals s.r.o., Republica Ceha	R - art.738 (4) A - in baza art. 708 (1)	2/8/2019	UK/H/2632/001/R001	APP emis
7	Prindex Plus 4 mg/1,25 mg	4 mg/ 1,25 mg	Comprimate	Perindopril tert- butilamina/Indapamida	Glenmark Pharmaceuticals s.r.o., Republica Ceha	R - art.738 (4) A - in baza art. 708 (1)	2/8/2019	UK/H/2632/002/R001	APP emis
8	Fluorouracil Accord 50 mg/ml	50 mg/ml	Solutie injectabila/ perfuzabila	Fluorouracil	Accord Healthcare Limited, Marea Britanie	R - art.738 (4) A - in baza art. 708 (1)	2/8/2019	UK/H/1185/001/R001	Solicitare traducerii
9	Zerlinda 4 mg/100 ml	4 mg/100 ml	Solutie perfuzabila	Acid zoledronic sub forma de acid zoledronic monohidrat	Actavis Group PTC ehf., Islanda	R - art.738 (4) A - in baza art. 708 (1)	2/28/2019	DK/H/2265/001/R001	APP emis
10	Metotrexat Ebewe 10 mg/ml	10 mg/ml	Solutie injectabila in seringa preumpluta	Metotrexat sub forma de metotrexat disodic	Ebewe Pharma, Austria	R - art.738 (4) A - in baza art. 708 (3)	2/28/2019	AT/H/0222/001/R002	APP emis
11	Diafer 50 mg/ml	50 mg/ml	Solutie injectabila	Fier izomaltozat	Pharmacosmos A/S, Danemarca	R - art.738 (4) A - in baza art. 706	2/28/2019	SE/H/1164/001/R001	APP emis
12	Suvezen 10 mg/ 10 mg	10 mg/ 10 mg	Comprimate filmate	Rosuvastatina sub forma de rosuvastatina calcica/Ezetimib	Sanofi Romania SRL	A - in baza art. 710	2/15/2019	CZ/H/0696/001/DC	APP emis
13	Suvezen 20 mg/10 mg	20 mg/10 mg	Comprimate filmate	Rosuvastatina sub forma de rosuvastatina calcica/Ezetimib	Sanofi Romania SRL	A - in baza art. 710	2/15/2019	CZ/H/0696/002/DC	APP emis
14	Suvezen 40 mg/10 mg	40 mg/10 mg	Comprimate filmate	Rosuvastatina sub forma de rosuvastatina calcica/ Ezetimib	Sanofi Romania SRL	A - in baza art. 710	2/15/2019	CZ/H/0696/003/DC	APP emis
15	Amorolfina Laboratoires Gerda 50 mg/ml	50 mg/ml	Lac de unghii medicamentos	Amorolfina sub forma de clorhidrat de amorolfina	Laboratoires Gerda, Franta	A - in baza art. 708 (3)	2/15/2019	AT/H/0733/001/DC	APP emis
16	Fentanil YES Pharmaceuticals 200 micrograme	200 micrograme	Comprimate de supt cu aplicator bucofaringian integrat	Citrat de fentanil	YES Pharmaceuticals Development Services GmbH, Germania	A - in baza art. 708 (3)	2/15/2019	NL/H/4053/001/DC	APP emis
17	Fentanil YES Pharmaceuticals 400 micrograme	400 micrograme	Comprimate de supt cu aplicator bucofaringian integrat	Citrat de fentanil	YES Pharmaceuticals Development Services GmbH, Germania	A - in baza art. 708 (3)	2/15/2019	NL/H/4053/002/DC	APP emis
18	Fentanil YES Pharmaceuticals 600 micrograme	600 micrograme	Comprimate de supt cu aplicator bucofaringian integrat	Citrat de fentanil	YES Pharmaceuticals Development Services GmbH, Germania	A - in baza art. 708 (3)	2/15/2019	NL/H/4053/003/DC	APP emis
19	Fentanil YES Pharmaceuticals 800 micrograme	800 micrograme	Comprimate de supt cu aplicator bucofaringian integrat	Citrat de fentanil	YES Pharmaceuticals Development Services GmbH, Germania	A - in baza art. 708 (3)	2/15/2019	NL/H/4053/004/DC	APP emis

20	Fentanil YES Pharmaceuticals	1200 micrograme	Comprimate de supt cu aplicator	Citrat de fentanil	YES Pharmaceuticals Development Services		2/15/2019	NL/H/4053/005/DC	APP emis
21	Fentanil YES Pharmaceuticals	1600 micrograme	Comprimate de supt cu aplicator	Citrat de fentanil	YES Pharmaceuticals Development Services		2/15/2019	NL/H/4053/006/DC	APP emis
22	Treosulfan Tillomed 5 g	5 g	Pulbere pentru solutie perfuzabila	Treosulfan	Laboratorios Tillomed Spain S.L.U., Spania	A - in baza art. 708 (1)	9/26/2018	UK/H/6644/001/E001	APP emis
23	Uniquet 50 mg	50 mg	Comprimate cu eliberare prelungita	Quetiapina sub forma de fumarat de quetiapina	Terapia S.A., Romania	R - art.738 (4) A - in baza art. 708 (1)	10/3/2017	NL/H/2562/001/R001	APP emis
24	Uniquet 200 mg	200 mg	Comprimate cu eliberare prelungita	Quetiapina sub forma de fumarat de quetiapina	Terapia S.A., Romania	R - art.738 (4) A - in baza art. 708 (1)	10/3/2017	NL/H/2562/002/R001	APP emis
25	Uniquet 300 mg	300 mg	Comprimate cu eliberare prelungita	Quetiapina sub forma de fumarat de quetiapina	Terapia S.A., Romania	R - art.738 (4) A - in baza art. 708 (1)	10/3/2017	NL/H/2562/003/R001	APP emis
26	Uniquet 400 mg	400 mg	Comprimate cu eliberare prelungita	Quetiapina sub forma de fumarat de quetiapina	Terapia S.A., Romania	R - art.738 (4) A - in baza art. 708 (1)	10/3/2017	NL/H/2562/004/R001	APP emis
27	Aminoplasmal 100 g/l	100 g/l	Solutie perfuzabila	Electroliti	B.Braun Melsungen AG, Germania	R - art.738 (4) A - in baza art. 709	8/17/2017	DE/H/0544/001/R002	APP emis
28	Paduden Rapid 200 mg	200 mg	Comprimate filmate	Ibuprofen	Terapia S.A., Romania	R - art.738 (4) A - in baza art. 708 (1)	10/8/2018	DE/H/5463/001/R001	APP emis
29	Clofarabina Vivanta 1 mg/ml	1 mg/ml	Concentrat pentru solutie perfuzabila	Clofarabina	Vivanta Generics s.r.o, Republica Ceha	A - in baza art. 708 (1)	2/25/2019	PT/H/2012/001/DC	App emis
30	Dasatinib Stada 20 mg	20 mg	Comprimate filmate	Dasatinib	Stada M&D SRL, Romania	A - in baza art. 708 (1)	2/25/2019	NL/H/4003/001/E001	App emis
31	Dasatinib Stada 50 mg	50 mg	Comprimate filmate	Dasatinib	Stada M&D SRL, Romania	A - in baza art. 708 (1)	2/25/2019	NL/H/4003/002/E001	App emis
32	Dasatinib Stada 100 mg	100 mg	Comprimate filmate	Dasatinib	Stada M&D SRL, Romania	A - in baza art. 708 (1)	2/25/2019	NL/H/4003/005/E001	App emis
33	Gnak 50 mg/ml	50 mg/ml	Solutie perfuzabila	Glucoză monohidrat, clorură de magneziu hexahidrat, clorură de potasiu, acetat de sodiu trihidrat, clorură de sodiu	Baxter Healthcare SRL, Romania	A - in baza art. 709	2/25/2019	SE/H/0921/001/E001	App emis
34	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	Amanat