

LIST

of the medicines recommended for the registration by the Center according to the meeting decision N 07-2/26 on July 31, 2026

N	Trade name	Common name of the active substance	Pharmaceutical form	Strength and packaging, presentation	All manufacturing sites involved in the medicinal product manufacturing process (name, location)	Country	Registration certificate holder (name, location)	Country	Legal status for supply	Conclusion number and date
1	Rinostop-Oticipharm	xylometazoline (xylometazoline hydrochloride)	spray nasal	0,5mg/ml; 15ml plastic vial	Pharmstandard-Leksredstva JSC, 305022, Kursk region, Kursk, Agregatnaya 2nd str., 1a/18	Russia	JSC "OTCPharm", Testovskaya street, room II, flr.12, h.10, off. 29, Moscow 123112	Russia	OTC	24348 31.07.2026
2	Testosteron Depo	testosterone (testosterone enantate)	solution for injection	250mg/ml; (5/1x5) ampoules 1ml	Galenika a.d. Beograd, Batajnicki drum b.b., 11080 Belgrad-Zemun- secondary packager, quality control (physicochemical), batch releaser, Panpharma GmbH, Bunsenstrasse 4, 22946, Trittau, Schleswig-Holstein, Germany- bulk manufacturer, primary packager, Faculty of Pharmacy, University of Belgrade, Vojvode Stepe 450, Belgrade, 11000, Serbia- quality control (microbiological)	Serbia	Galenika a.d. Beograd, Batajnicki drum b.b., 11080 Belgrade	Serbia	PoM	24349 31.07.2026
3	Rinomaximus	oxymetazoline (oxymetazoline hydrochloride)	spray nasal	0,25mg/ml; 15ml plastic vial with actuator applicator	Pharmstandard-Leksredstva JSC, Kursk region, Kursk, Agregatnaya 2nd str., 1a/18	Russia	JSC "OTCPharm", Testovskaya street, 10, flr.12, room II, off. 29, Moscow 123112	Russia	OTC	24350 31.07.2026
4	Rinomaximus	oxymetazoline (oxymetazoline hydrochloride)	spray nasal	0,5mg/ml; 15ml plastic vial with actuator applicator	Pharmstandard-Leksredstva JSC, Kursk region, Kursk, Agregatnaya 2nd str., 1a/18	Russia	JSC "OTCPharm", Testovskaya street, 10, flr.12, room II, off. 29, Moscow 123112	Russia	OTC	24351 31.07.2026
5	Biemexol	iohexol	solution for injection	350mg iodine/ml; glass vial 50ml	IDOL ILAC DOLUM SAN.ve TIC.A.S. Davutpasa Cad.CebeAli Bey Sok.No:20 Zeytinburnu / ISTANBUL/	Turkey	Biem ilac San. Ve Tic.A.S. Anittepe Mah.Turgut Reis Cad. No:21, Tandogan/Cankaya-Ankara/	Turkey	PoM	24352 31.07.2026
6	Biemexol	iohexol	solution for injection	350mg iodine/ml; glass vial 200ml	Mefer Ilac Sanayii A.S., Ramazanoglu Mah. Ensar Cad. No:20 Kurtkoy Pendik, Istanbul	Turkey	Biem ilac San. Ve Tic.A.S. Anittepe Mah.Turgut Reis Cad. No:21, Tandogan/Cankaya-Ankara/	Turkey	PoM	24353 31.07.2026

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2026

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1	Lomexin	fenticonazole (fenticonazole nitrate)	cream for vaginal and external use	20mg/g; 30g aluminium tube, 78g aluminium tube and dispenser	Recordati Industria Chimica e Farmaceutica S.p.A., Via Civitali, 1-20148 Milano	Italy	Recordati Ireland Ltd., Raheens East, Ringaskiddy, Co Cork	Ireland	PoM	24362 (019173) 31.07.2026
2	Lomexin	fenticonazole (fenticonazole nitrate)	cream for vaginal and external use	20mg/g; 30g aluminium tube, 78g aluminium tube and dispenser	Rekordati Ilach Sanayi ve Tıdzharet Anonim Shirketi, Cerkezkoy Organized Industrial Zone, Karagac, Ataturk Street No.36, Kapakli, Tekirdag	Turkey	Recordati Ireland Ltd., Raheens East, Ringaskiddy, Co Cork	Ireland	PoM	24363 (019173) 31.07.2026
3	IBUPIRIN	ibuprofen	tablets film-coated	200mg; (10/1x10) in blister, (20/2x10) in blister, (50/5x10) in blister	Danapha Pharmaceutical JSC, 253 Dung Si Thanh Khe str., Thanh Khe District, Danang city	Vietnam	"DOMINANTA-SERVIS" JSC, Komsomolskaya St. 1, building 49, room 1, apartment 223, Podolsk, Moscow region, 142100	Russia	OTC	24364 (010661) 31.07.2026
4	IBUPIRIN	Ibuprofen	tablets film-coated	400mg; (10/1x10) in blister, (20/2x10) in blister, (50/5x10) in blister	Danapha Pharmaceutical JSC, 253 Dung Si Thanh Khe str., Thanh Khe District, Danang city	Vietnam	"DOMINANTA-SERVIS" JSC, Komsomolskaya St. 1, building 49, apartment 1, office 223, Podolsk, Moscow region, 142100	Russia	OTC	24365 (010661) 31.07.2026
5	Milgamma	benfotiamine, pyridoxine (pyridoxine hydrochloride)	tablets coated	100mg+100mg; (15/1x15) in blister, (30/2x15) in blister, (60/4x15) in blister	Woerwag Pharma Production GmbH & Co. KG, Gewerbealle 1, 82343 Poeking- bulk manufacturer, packager, quality control (physicochemical), batch releaser, Labor LS SE & Co. KG, Mangelsfeld 4-6, Grossenbrach, Bad Bocklet, 97780, Germany- quality control (microbiological)	Germany	Woerwag Pharma GmbH & Co. KG, Flugfeld-Allee 24, 71034 Boeblingen	Germany	PoM	24366 (022940) 31.07.2026

6	Milgamma	benfotiamine, pyridoxine (pyridoxine hydrochloride)	tablets coated	100mg+100mg: (15/1x15) in blister, (30/2x15) in blister, (60/4x15) in blister	Woerwag Pharma Production GmbH & Co. KG, Gewerbeallee 1, 82343 Poeking- bulk manufacturer, packager, quality control (physicochemical), batch releaser, Labor für analytische und pharmazeutische Chemie Dr. Graner & Partner GmbH Lochhausener Str. 205 München, Germany- quality control (microbiological)	Germany	Woerwag Pharma GmbH & Co. KG, Flugfeld-Allee 24, 71034 Boeblingen	Germany	PoM	24367 (022940) 31.07.2026
7	Mildronat	meldonium (meldonium dihydrate)	capsules	250mg; (20/2x10) in blister, (40/4x10) in blister	Grindeks JSC, Krustpils street, 53, Riga, LV-1057	Latvia	Grindeks JSC, Krustpils street, 53, Riga, LV-1057	Latvia	OTC	24368 (004064) 31.07.2026
8	NovoRapid FlexPen	insulin aspart	solution for s/c or i/v injection	100U/ml; (5) pre-filled pens 3ml	Novo Nordisk A/S, Novo Alle 1, 2880 Bagsvaerd- bulk manufacturer, primary packager, quality control, batch releaser, Novo Nordisk A/S, Brennum Park, Hillerød, 3400, Denmark- secondary packager	Denmark	Novo Nordisk A/S, Novo Alle 1, 2880 Bagsvaerd	Denmark	PoM	24369 (020889) 31.07.2026
9	NovoRapid FlexPen	insulin aspart	solution for s/c or i/v injection	100U/ml; (5) pre-filled pens 3ml	Novo Nordisk LLC, Kaluga Region, Kaluga 2nd, Avtomobilniy proezd, bld. 1- secondary packager, batch releaser, Novo Nordisk A/S, Novo Alle 1, 2880 Bagsvaerd, Denmark- bulk manufacturer, primary packager, quality control	Russia	Novo Nordisk A/S, Novo Alle 1, 2880 Bagsvaerd	Denmark	PoM	24370 (020889) 31.07.2026
10	NovoRapid FlexPen	insulin aspart	solution for s/c or i/v injection	100U/ml; (5) pre-filled pens 3ml	Novo Nordisk A/S, Novo Alle 1, 2880 Bagsvaerd- batch releaser, Novo Nordisk Production SAS, 45 avenue d' Orleans, 28000, Chartres, France- bulk manufacturer, packager, quality control	Denmark	Novo Nordisk A/S, Novo Alle 1, 2880 Bagsvaerd	Denmark	PoM	24371 (020889) 31.07.2026
11	NovoRapid FlexPen	insulin aspart	solution for s/c or i/v injection	100U/ml; (5) pre-filled pens 3ml	Novo Nordisk LLC, Kaluga Region, Kaluga 2nd, Avtomobilniy proezd, bld. 1- secondary packager, batch releaser, Novo Nordisk Production SAS, 45 avenue d' Orleans, 28000, Chartres, France- bulk manufacturer, packager, quality control	Russia	Novo Nordisk A/S, Novo Alle 1, 2880 Bagsvaerd	Denmark	PoM	24372 (020889) 31.07.2026

12	NovoRapid FlexPen	insulin aspart	solution for s/c or i/v injection	100U/ml; (5) pre-filled pens 3ml	Novo Nordisk A/S, Novo Alle 1, 2880 Bagsvaerd- batch releaser, NOVO NORDISK PRODUCAO FARMACEUTICA DO BRASIL LTDA., Avenida C, 1413, Distrito Industrial, Minas Gerais, Montes Claros, 39404-004, Brasil- bulk manufacturer, packager, quality control	Denmark	Novo Nordisk A/S, Novo Alle 1, 2880 Bagsvaerd	Denmark	PoM	24373 (020889) 31.07.2026
13	NovoRapid FlexPen	insulin aspart	solution for s/c or i/v injection	100U/ml; (5) pre-filled pens 3ml	Novo Nordisk LLC, Kaluga Region, Kaluga 2nd, Avtomobilniy proezd, bld. 1- secondary packager, batch releaser, NOVO NORDISK PRODUCAO FARMACEUTICA DO BRASIL LTDA., Avenida C, 1413, Distrito Industrial, Minas Gerais, Montes Claros, 39404-004, Brasil- bulk manufacturer, primary packager, quality control	Russia	Novo Nordisk A/S, Novo Alle 1, 2880 Bagsvaerd	Denmark	PoM	24374 (020889) 31.07.2026
14	NovoRapid FlexPen	insulin aspart	solution for s/c or i/v injection	100U/ml; (5) pre-filled pens 3ml	Novo Nordisk A/S, Novo Alle 1, 2880 Bagsvaerd- batch releaser, NOVO NORDISK PRODUCAO FARMACEUTICA DO BRASIL LTDA., Avenida C, 1413, Distrito Industrial, Minas Gerais, Montes Claros, 39404-004, Brasil- bulk manufacturer, primary packager, quality control, Novo Nordisk A/S, Hallas Alle, DK-4400 Kalundborg, Denmark- secondary packager	Denmark	Novo Nordisk A/S, Novo Alle 1, 2880 Bagsvaerd	Denmark	PoM	24375 (020889) 31.07.2026
15	NovoRapid FlexPen	insulin aspart	solution for s/c or i/v injection	100U/ml; (5) pre-filled pens 3ml	Novo Nordisk A/S, Novo Alle 1, 2880 Bagsvaerd- batch releaser, Novo Nordisk Production SAS, 45 avenue d' Orleans, 28000, Chartres, France- bulk manufacturer, primary packager, quality control, Novo Nordisk A/S, Brennum Park, Hillerod, 3400, Denmark- secondary packager	Denmark	Novo Nordisk A/S, Novo Alle 1, 2880 Bagsvaerd	Denmark	PoM	24376 (020889) 31.07.2026
16	NovoRapid FlexPen	insulin aspart	solution for s/c or i/v injection	100U/ml; (5) pre-filled pens 3ml	LLC Novo Nordisk, Kaluga Region, Kaluga 2nd, Avtomobilniy proezd, bld. 1	Russia	Novo Nordisk A/S, Novo Alle, DK-2880 Bagsvaerd	Denmark	PoM	24377 (020889) 31.07.2026

17	NovoMix 30 FlexPen	insulin aspart (recombinant)	suspension for injection	100U/ml; (5) pre-filled pens 3ml	Novo Nordisk A/S, Novo Alle 1, 2880 Bagsvaerd- bulk manufacturer, primary packager, quality control, batch releaser, Novo Nordisk A/S, Brennum Park, Hillerod, 3400, Denmark- secondary packager	Denmark	Novo Nordisk A/S, Novo Alle 1, 2880 Bagsvaerd	Denmark	PoM	24378 (020886) 31.07.2026
18	NovoMix 30 FlexPen	insulin aspart (recombinant)	suspension for injection	100U/ml; (5) pre-filled pens 3ml	Novo Nordisk LLC, Kaluga Region, Kaluga 2nd, Avtomobilniy proezd, bld. 1- secondary packager, batch releaser, Novo Nordisk A/S, Novo Alle 1, 2880 Bagsvaerd, Denmark- bulk manufacturer, primary packager, quality control	Russia	Novo Nordisk A/S, Novo Alle 1, 2880 Bagsvaerd	Denmark	PoM	24379 (020886) 31.07.2026
19	NovoMix 30 FlexPen	insulin aspart (recombinant)	suspension for injection	100U/ml; (5) pre-filled pens 3ml	Novo Nordisk A/S, Novo Alle 1, 2880 Bagsvaerd- batch releaser, Novo Nordisk Production SAS, 45 avenue d' Orleans, 28000, Chartres, France- bulk manufacturer, packager, quality control	Denmark	Novo Nordisk A/S, Novo Alle 1, 2880 Bagsvaerd	Denmark	PoM	24380 (020886) 31.07.2026
20	NovoMix 30 FlexPen	insulin aspart (recombinant)	suspension for injection	100U/ml; (5) pre-filled pens 3ml	Novo Nordisk LLC, Kaluga Region, Kaluga 2nd, Avtomobilniy proezd, bld. 1- secondary packager, batch releaser, Novo Nordisk Production SAS, 45 avenue d' Orleans, 28000, Chartres, France- bulk manufacturer, packager, quality control	Russia	Novo Nordisk A/S, Novo Alle 1, 2880 Bagsvaerd	Denmark	PoM	24381 (020886) 31.07.2026
21	NovoMix 30 FlexPen	insulin aspart (recombinant)	suspension for injection	100U/ml; (5) pre-filled pens 3ml	Novo Nordisk A/S, Novo Alle 1, 2880 Bagsvaerd- batch releaser, NOVO NORDISK PRODUCAO FARMACEUTICA DO BRASIL LTDA., Avenida C, 1413, Distrito Industrial, Minas Gerais, Montes Claros, 39404-004, Brasil- bulk manufacturer, packager, quality control	Denmark	Novo Nordisk A/S, Novo Alle 1, 2880 Bagsvaerd	Denmark	PoM	24382 (020886) 31.07.2026
22	NovoMix 30 FlexPen	insulin aspart (recombinant)	suspension for injection	100U/ml; (5) pre-filled pens 3ml	LLC Novo Nordisk, Kaluga Region, Kaluga 2nd, Avtomobilniy proezd, bld. 1- secondary packager, batch releaser, NOVO NORDISK PRODUCAO FARMACEUTICA DO BRASIL LTDA., Avenida C, 1413, Distrito Industrial, Minas Gerais, Montes Claros, 39404-004, Brasil- bulk manufacturer, packager, quality control	Russia	Novo Nordisk A/S, Novo Alle 1, 2880 Bagsvaerd	Denmark	PoM	24383 (020886) 31.07.2026

23	NovoMix 30 FlexPen	insulin aspart (recombinant)	suspension for injection	100U/ml; (5) pre-filled pens 3ml	Novo Nordisk A/S, Novo Alle 1, 2880 Bagsvaerd - batch releaser, NOVO NORDISK PRODUCAO FARMACEUTICA DO BRASIL LTDA., Avenida C, 1413, Distrito Industrial, Minas Gerais, Montes Claros, 39404-004, Brazil- bulk manufacturer, primary packager, quality control, Novo Nordisk A/S, Hallas Alle, DK-4400 Kalundborg, Denmark- secondary packager	Denmark	Novo Nordisk A/S, Novo Alle 1, 2880 Bagsvaerd	Denmark	PoM	24384 (020886) 31.07.2026
24	NovoMix 30 FlexPen	insulin aspart (recombinant)	suspension for injection	100U/ml; (5) pre-filled pens 3ml	Novo Nordisk A/S, Novo Alle 1, 2880 Bagsvaerd - batch releaser, Novo Nordisk Production SAS, 45 avenue d'Orleans, 28000, Chartres, France- bulk manufacturer, primary packager, quality control, Novo Nordisk A/S, Brennum Park, Hillerod, 3400, Denmark- secondary packager	Denmark	Novo Nordisk A/S, Novo Alle 1, 2880 Bagsvaerd	Denmark	PoM	24385 (020886) 31.07.2026
25	Spasmalgon	metamizole (metamizole sodium), pitofenone (pitofenone hydrochloride), fempiverinium bromide	solution for i/m injection	500mg/ml+2mg/ml+0,02mg/ml; (5/1x5/) ampoules 2ml in blister, (10/1x10) ampoules 2ml in blister	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia	Bulgaria	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia	Bulgaria	PoM	24386 (022037) 31.07.2026
26	Spasmalgon	metamizole (metamizole sodium), pitofenone (pitofenone hydrochloride), fempiverinium bromide	solution for i/m injection	500mg/ml+2mg/ml+0,02mg/ml; (5/1x5/) ampoules 5ml in blister, (10/1x10) ampoules 5ml in blister	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia	Bulgaria	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia	Bulgaria	PoM	24387 (022037) 31.07.2026
27	Codelac Broncho- Oticipharm Pro	ambroxol (ambroxol hydrochloride), sodium glycyrrhizinate (glycyrrhizinic acid trisodium), thermopsis extract, sodium hydrocarbonate	tablets	20mg+30mg+10mg+200mg; (10/1x10) in blister, (20/2x10) in blister	Pharmstandard-Leksredstva JSC, 305022, Kursk oblast, Kursk, Agregatnaya 2nd str., 1a/18	Russia	JSC "Oticipharm Pro", Kaliningrad region, Zelenogradsky m.d., ter. Industrial park Khrabrovo, Innovatorov 6 str., building 1, 238315	Russia	OTC	24388 (012952) 31.07.2026
28	Codelac Broncho- Oticipharm Pro	ambroxol (ambroxol hydrochloride), sodium glycyrrhizinate (glycyrrhizinic acid trisodium), thermopsis extract, sodium hydrocarbonate	tablets	20mg+30mg+10mg+200mg; (10/1x10) in blister, (20/2x10) in blister	JSC "Oticipharm Pro", Kaliningrad region, Zelenogradsky m.d., ter. Industrial park Khrabrovo, Innovatorov 6 str., building 1	Russia	JSC "Oticipharm Pro", Kaliningrad region, Zelenogradsky m.d., ter. Industrial park Khrabrovo, Innovatorov 6 str., building 1, 238315	Russia	OTC	24389 (012952) 31.07.2026

29	Naphthyzin S	oxymetazoline (oxymetazoline hydrochloride)	drops nasal	0,5mg/ml; 10ml glass vial	Arsanit Ltd, Ararat region, Masis, Masis-Ranchpar highway 7	Republic of Armenia	Arsanit Ltd, Ararat region, Masis, Masis-Ranchpar highway 7	Republic of Armenia	OTC	24354 (030396) 31.07.2026
30	Naphthyzin S	oxymetazoline (oxymetazoline hydrochloride)	drops nasal	1mg/ml; 10ml glass vial	Arsanit Ltd, Ararat region, Masis, Masis-Ranchpar highway 7	Republic of Armenia	Arsanit Ltd, Ararat region, Masis, Masis-Ranchpar highway 7	Republic of Armenia	OTC	24355 (030396) 31.07.2026
31	Salivin	sodium chloride	drops nasal	6,5mg/ml; 5ml plastic bottle-dropper, 10ml plastic bottle-dropper	Arsanit Ltd, Ararat region, Masis, Masis-Ranchpar highway 7	Republic of Armenia	Arsanit Ltd, Ararat region, Masis, Masis-Ranchpar highway 7	Republic of Armenia	OTC	24356 (040008) 31.07.2026
32	Salivin	sodium chloride	spray nasal	6,5mg/ml; 10ml plastic vial with pump dispenser, 15ml plastic vial with pump dispenser, 30ml plastic vial with pump dispenser	Arsanit Ltd, Ararat region, Masis, Masis-Ranchpar highway 7	Republic of Armenia	Arsanit Ltd, Ararat region, Masis, Masis-Ranchpar highway 7	Republic of Armenia	OTC	24357 (040010) 31.07.2026
33	AqVirubicin	epirubicin (epirubicin hydrochloride)	solution for injection	2mg/ml; glass vial 5ml	AqVida GmbH, Kaiser-Wilhelm-Str. 89, Hamburg, 20355- batch releaser, AqVida GmbH, Werkstrasse 21, Dassow 23942, Germany- bulk manufacturer, packager, quality control	Germany	Aversi-Rational Ltd, David Kobahidze str. 33, 0198 Tbilisi	Georgia	PoM	24358 (042906) 31.07.2026
34	AqVirubicin	epirubicin (epirubicin hydrochloride)	solution for injection	2mg/ml; glass vial 25ml	AqVida GmbH, Kaiser-Wilhelm-Str. 89, Hamburg, 20355- batch releaser, AqVida GmbH, Werkstrasse 21, Dassow 23942, Germany- bulk manufacturer, packager, quality control	Germany	Aversi-Rational Ltd, David Kobahidze str. 33, 0198 Tbilisi	Georgia	PoM	24359 (042906) 31.07.2026
35	Metronidazole Denta	metronidazole (metronidazole benzoate), chlorhexidine (chlorhexidine gluconate 20% solution)	gel for gums	10mg/g+0,5mg/g; aluminium tube 20g	Arpimed LLC, Kotayk Marz, 2204, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	Arpimed LLC, Kotayk Marz, 2204, Abovyan, 2nd Micro-District, 19 Building	Republic of Armenia	OTC	24360 (039836) 31.07.2026
36	Vurdon-Neo	diclofenac (diclofenac sodium)	tablets prolonged-release	100mg; (10/1x10) in blister	Help S.A., Pedini Ioanninon, Ioannina, 45500	Greece	Help S.A., 10 Valaoritou str., 14452 Metamorfofi	Greece	PoM	24361 (034480) 31.07.2026

LIST

of the medicines recommended for re-registration under the EAEU procedure by the Center according to the meeting decision N 07-2/26 on July 31,
2026

N	Trade name	Common name of the active substance	Pharmaceutical form	Strength and packaging, presentation	All manufacturing sites involved in the medicinal product manufacturing process (name, location)	Country	Registration certificate holder (name, location)	Country	Legal status for supply	Conclusion number and date
1	Sinupret extract	gentiane radix, primulae flos, rumicis herba, sambuci flos, verbenae herba	tablets coated	160mg; (20/2x10) in blister, (40/4x10) in blister	Bionorica SE, Kerschensteinerstrasse 11-15, 92318 Neumarkt in der Oberpfalz- packager, quality control, batch releaser, Rottendorf Pharma GmbH, Ostenfelder Strasse 51-61, 59320 Ennigerloh, Germany- bulk manufacturer	Germany	Bionorica SE, Kerschensteinerstrasse 11-15, 92318 Neumarkt in der Oberpfalz	Germany	OTC	24390 (047068) 31.07.2026
2	Sinupret extract	gentiane radix, primulae flos, rumicis herba, sambuci flos, verbenae herba	tablets coated	160mg; (20/2x10) in blister, (40/4x10) in blister	Bionorica SE, Kerschensteinerstrasse 11-15, 92318 Neumarkt in der Oberpfalz- packager, quality control, batch releaser, Wiewelhove GmbH, Domebrink 19, 49479 Ibbenburen, Germany- bulk manufacturer	Germany	Bionorica SE, Kerschensteinerstrasse 11-15, 92318 Neumarkt in der Oberpfalz	Germany	OTC	24391 (047068) 31.07.2026
3	Sinupret extract	gentiane radix, primulae flos, rumicis herba, sambuci flos, verbenae herba	tablets coated	160mg; (20/2x10) in blister, (40/4x10) in blister	Bionorica Pharmaceuticals LLC, 396333, Voronezh Region, Novousmanskoy Municipal District, Nikolskoye Rural Settlement, Maslovsky Industrial Park territory, 1st Parkovaya Street, Building 2, Russia- packager, quality control(physicochemical), batch releaser, "ICLS Biotechnology" LLC10A, 8th Liniya Street, Vidnoye, 142700, Leninsky Urban District, Moscow Region, Russia- quality control (microbiological), Wiewelhove GmbH, Domebrink 19, 49479 Ibbenburen, Germany- bulk manufacturer	Russia	Bionorica SE, Kerschensteinerstrasse 11-15, 92318 Neumarkt in der Oberpfalz	Germany	OTC	24392 (047068) 31.07.2026

4	Sinupret extract	gentiane radix, primulae flos, rumicis herba, sambuci flos, verbenae herba	tablets coated	160mg; (20/2x10') in blister, (40/4x10') in blister	Bionorica Pharmaceuticals LLC, Voronezh Region, Novousmansky Municipal District, Nikolskoye Rural Settlement, Maslovsky Industrial Park territory, 1st Parkovaya Street, Building 2, Russia- packager, quality control (physicochemical), batch releaser, "ICLS Biotechnology" LLC10A, 8th Liniya Street, Vidnoye, Leninsky Urban District, Moscow Region, Russia- quality control (microbiological), Rottendorf Pharma GmbH, Ostenfelder Strasse 51-61, 59320 Ennigerloh, Germany- bulk manufacturer	Russia	Bionorica SE, Kerschensteinerstrasse 11-15, 92318 Neumarkt in der Oberpfalz	Germany	OTC	24393 (047068) 31.07.2026
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LIST

of registered variations requiring reformulation of registration certificate under the EAEU procedure by the Center according to the meeting decision

N 07-2/26 on July 31, 2026

N	Trade name	Common name of the active substance	Pharmaceutical form	Strength and packaging, presentation	All manufacturing sites involved in the medicinal product manufacturing process (name, location)	Country	Registration certificate holder (name, location)	Country	Legal status for supply	Conclusion number and date
1	Miropriston	mifepristone	tablets	200mg; (1/1x1) in blister, (2/2x1) in blister, (3/3x1) in blister, (5/5x1) in blister, (2/1x2) in blister, (4/2x2) in blister, (6/3x2) in blister, (10/5x2) in blister, (3/1x3) in blister, (6/2x3) in blister, (9/3x3) in blister, (15/5x3) in blister	Obninsk Chemical Pharmaceutical Company JSC, Kaluga region, Ozninsk, str. Kiev highway, 3a/3- batch releaser, Ozninsk Chemical Pharmaceutical Company JSC, Kaluga region, Ozninsk, str. Kiev highway, 107, Russia- bulk manufacturer, packager, quality control (physicochemical), "FARMOBORONA" Research and Testing center LTD, 46A, Gagarin St., Korolyov, Moscow Region, Russia- quality control (microbiological)	Russia	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	PoM	JITI-N°003179-ITI-AM 31.07.2026
2	Miropriston	mifepristone	tablets	200mg; (1/1x1) in blister, (2/2x1) in blister, (3/3x1) in blister, (5/5x1) in blister, (2/1x2) in blister, (4/2x2) in blister, (6/3x2) in blister, (10/5x2) in blister, (3/1x3) in blister, (6/2x3) in blister, (9/3x3) in blister, (15/5x3) in blister	Ozninsk Chemical Pharmaceutical Company JSC, Kaluga region, Ozninsk, str. Kiev highway, 3b- packager, batch releaser, Ozninsk Chemical Pharmaceutical Company JSC, Kaluga region, Ozninsk, str. Kiev highway, 107, Russia- bulk manufacturer, quality control (physicochemical), "FARMOBORONA" Research and Testing center LTD, 46A, Gagarin St., Korolyov, Moscow Region, Russia- quality control (microbiological)	Russia	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	PoM	JITI-N°003179-ITI-AM 31.07.2026

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N	Trade name	Common name of the active substance	Pharmaceutical form	Strength and packaging, presentation	All manufacturing sites involved in the medicinal product manufacturing process (name, location)	Country	Registration certificate holder (name, location)	Country	Legal status for supply	Conclusion number and date
1	Menopur	menotropin	powder lyophilized for solution for i/m or s/c injection	75IU; (5) glass vials and (5) solvent in ampoules 1ml, (10) glass vials and (10) solvent in ampoules 1ml	Ferring GmbH, Wittland 11, 24109 Kiel- powder bulk manufacturer, powder primary packager, quality control, batch releaser, Ferring Pharmaceuticals (China) Co., Ltd., Hui Ling Lu (Ferring Road) 6, National Health Technology Park, 528437 Zhongshan City-Guangdong Province, China- solvent bulk manufacturer, primary packager, Ferring-Leciva, a.s. (areal spol. ECP, a.s.), Ke Skale 455, Vestec u Prahy, 25250, Czech Republic- secondary packager	Germany	Ferring GmbH, Wittland 11, 24109 Kiel	Germany	PoM	24347/31.07.2026

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N	Trade name	Common name of the active substance	Pharmaceutical form	Strength and packaging, presentation	All manufacturing sites involved in the medicinal product manufacturing process (name, location)	Country	Registration certificate holder (name, location)	Country	Legal status for supply	Conclusion number and date
1	Nicorette	nicotine	spray	1mg/dose; (1) plastic container 13,2ml(150 dose) with pump dispenser; (2) plastic container 13,2ml(150 dose) with pump dispenser	McNeil AB Norrebroplatsen 2, Helsingborg, 25109- bulk manufacturer, primary packager, quality control, batch releaser McNeil AB Bunkagardsgatan 19, Helsingborg, 253 68, Sweden- secondary packager	Sweden	JINL LLC, 121614, Moscow, Krylatskaya intercity municipal district, Krylatskaya str., 17, bld. 3	Russia	OTC	23401/1/1 31.07.2026
2	Menopur	menotropin	powder lyophilized for solution for i/m or s/c injection	75IU; (5) glass vials and (5) solvent in ampoules 1ml, (10) glass vials and (10) solvent in ampoules 1ml	Ferring GmbH, Wittland 11, 24109 Kiel- powder bulk manufacturer, powder primary packager, quality control, batch releaser, Haupt Pharma Wulfing GmbH, Bethelner Landstrasse 18, Gronau/Leine 31028, Germany- solvent bulk manufacturer, primary packager, Ferring-Leciva, a.s.(areal spol. ECP, a.s.) , Ke Skale 455, Vestec u Prahy, 25250, Czech Republic- secondary packager	Germany	Ferring GmbH, Wittland 11, 24109 Kiel	Germany	PoM	21471/1/1 31.07.2026
3	Menopur	menotropin	powder lyophilized for solution for i/m or s/c injection	75IU; (5) glass vials and (5) solvent in ampoules 1ml, (10) glass vials and (10) solvent in ampoules 1ml	Ferring GmbH, Wittland 11, 24109 Kiel- powder bulk manufacturer, powder primary packager, quality control, batch releaser, Ferring Pharmaceuticals (China) Co., Ltd, Hui Ling Lu (Ferring Road) 6, National Health Technology Park, 528437 Zhongshan City-Guangdong Province, China- solvent bulk manufacturer, primary packager, Ferring-Leciva, a.s. (areal spol. ECP, a.s.), Ke Skale 455, Vestec u Prahy, 25250, Czech Republic- secondary packager	Germany	Ferring GmbH, Wittland 11, 24109 Kiel	Germany	PoM	22617/1/1 31.07.2026

4	Trio Vision	neomycin (neomycin sulfate), polymyxin B (polymyxin B sulfate), dexamethasone	drops eye (suspension)	3500IU/ml+6000IU/ml+1mg/ml; plastic vial 5ml	Balkanpharma-Razgrad AD, 68 Aprisko Vastanie Blvd, 7200 Razgrad	Bulgaria	Balkanpharma-Razgrad AD, 68 Aprisko Vastanie Blvd, 7200 Razgrad	Bulgaria	PoM	23299/1/1 31.07.2026
5	Fluifort	carbocisteine lysinate (carbocisteine lysinate monohydrate)	powder for oral solution	2700mg; (5) sachets 2,7g, (30) sachets 2,7g, (50) sachets 2,7g	Polipharm Co., Ltd., 109 Bangna-Trad Road, Bang Phli District, Samut Prakan 10540	the Netherlands	Eurodrug Laboratories B.V., Regulusweg 11, 2516AC The Hague	the Netherlands	OTC	21608/3/1 31.07.2026
6	CARDIO AST	acetylsalicylic acid	tablets	100mg; (60/6x10) in blister	Medinfar Manufacturing S.A, Parque Industrial Armando Martins Tavares, Rua Outeiro Da Armada No 5, Coimbra, Condeixa-A-Nova, 3150-194, Sebal	Portugal	Asteria LLC, 72/3 Nairi Zaryan, 0051 Yerevan	Republic of Armenia	OTC	23230/2/2 31.07.2026

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N	Trade name	Common name of the active substance	Pharmaceutical form	Strength and packaging, presentation	All manufacturing sites involved in the medicinal product manufacturing process (name, location)	Country	Registration certificate holder (name, location)	Country	Legal status for supply	Conclusion number and date
1	Coraxan 5mg	ivabradine	tablets film-coated	5mg; (56/4x14) in blister	Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy	France	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	ЛПТ-№000306-ITI-AM 31.07.2026
2	Coraxan 7,5mg	ivabradine	tablets film-coated	7,5mg; (56/4x14) in blister	Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy	France	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	ЛПТ-№000306-ITI-AM 31.07.2026
3	Coraxan 5mg	ivabradine	tablets film-coated	5mg; (56/4x14) in blister	SERVIER RUS Ltd, 108828, block 159, 2, build.1, Krasnopakhorskiy district, Moscow	Russia	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	ЛПТ-№000306-ITI-AM 31.07.2026
4	Coraxan 7,5mg	ivabradine	tablets film-coated	7,5mg; (56/4x14) in blister	SERVIER RUS Ltd, 108828, block 159, 2, build.1, Krasnopakhorskiy district, Moscow	Russia	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	ЛПТ-№000306-ITI-AM 31.07.2026
5	Coraxan 5mg	ivabradine	tablets film-coated	5mg; (56/4x14) in blister	SERVIER RUS Ltd, 108828, block 159, 2, build.1, Krasnopakhorskiy district, Moscow- packager, quality control, batch releaser, Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy, France- bulk manufacturer	Russia	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	ЛПТ-№000306-ITI-AM 31.07.2026
6	Coraxan 7,5mg	ivabradine	tablets film-coated	7,5mg; (56/4x14) in blister	SERVIER RUS Ltd, 108828, block 159, 2, build.1, Krasnopakhorskiy district, Moscow- packager, quality control, batch releaser, Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy, France- bulk manufacturer	Russia	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	ЛПТ-№000306-ITI-AM 31.07.2026

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1	Amoksiklav 156.25mg/5ml	amoxicillin (amoxicillin trihydrate), clavulanic acid (potassium clavulanate)	powder for oral suspension	125mg/5ml+31,25mg/5ml; 7.88g powder containing 100ml amber glass bottle and a 5ml dosing syringe	Sandoz GmbH, Biochemiestrasse 10, A-6250, Kundl	Austria	Lek Pharmaceuticals d.d. Verovskova Str. 57, 1526 Ljubljana	Slovenia	PoM	20896/2/1 31.07.2026
2	Amoksiklav 312,5mg/5ml	amoxicillin (amoxicillin trihydrate), clavulanic acid (potassium clavulanate)	powder for oral suspension	250mg/5ml+62,5mg/5ml; 15.8g powder containing 100ml amber glass bottle and a 5ml dosing syringe	Sandoz GmbH, Biochemiestrasse 10, A-6250, Kundl	Austria	Lek Pharmaceuticals d.d. Verovskova Str. 57, 1526 Ljubljana	Slovenia	PoM	20897/2/1 31.07.2026
3	Vitaprost	prostate extract	tablets gastro-resistant	20mg; (20/2x10) in blister, (60/6x10) in blister	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7, c.1- quality control, batch releaser, Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7, Russia- bulk manufacturer, packager	Russia	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	OTC	22935/1 31.07.2026
4	CalciD-Denk	calcium (calcium carbonate), colecalciferol	tablets effervescent	1000mg+22mcg(880IU); (20) in plastic container	Losan Pharma GmbH, Otto- Hahn-Strasse 13, 79395 Neuenburg- bulk manufacturer, packager, quality control (physicochemical), batch releaser, Labor LSSE & Co. KG, Mangelsfeld 4,5, 6, Bad Bocklet-Grossenbrach, Bayern, 97708, Germany- quality control (microbiological)	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen	Germany	PoM	20939/1 31.07.2026
5	Ferretab Acino	ferrous fumarate, folic acid	capsules hard	152,1mg+0,5mg; (30/3x10) in blister, (100/10x10) in blister	G.L. Pharma GmbH, Industriestrasse 1, A-8502 Lannach- bulk manufacturer, packager, quality control (physicochemical), batch releaser, Austrian Agency For Health And Food Safety, Beethovenstrass 6, Graz, 8010, Austria- quality control (microbiological)	Austria	Acino Pharma AG, Birsweg 2, 4253 Liesberg	Switzerland	PoM	21062/5/2 31.07.2026

6	Wobenzym	pancreatin, trypsin, chymotrypsin, bromelain, papain, amylase, lipase, nutoside trihydrate	tablets gastro-resistant	300 prot.UA+360FIP-U+300FIP-U+225FIP-U+90FIP-U+50FIP-U+34FIP-U+50mg (40/2x20) and (200/10x20) in blister, (800) in plastic container	Mucos Emulsionsgesellschaft mbH, Miraustrasse 17, D-13509 Berlin	Germany	Mucos Pharma GmbH & Co. KG, Miraustrasse 17, D-13509 Berlin	Germany	OTC	21258/6.31.07.2026
7	Deep Heat	methyl salicylate, menthol (racemic), eucalyptus oil, turpentine oil	cream for external use	128mg/g+59,1mg/g+19,7mg/g+14,7mg/g; 15g aluminium tube, 67g aluminium tube	The Mentholatum Company Limited, 1 Redwood Avenue, Peel Park Campus, East Kilbride, G74 5PE, Scotland	UK	The Mentholatum Company Limited, 1 Redwood Avenue, Peel Park Campus, East Kilbride, G74 5PE, Scotland	UK	OTC	22331/2.31.07.2026
8	Deep Relief	ibuprofen, levomenthol (menthol)	gel for external use	50mg/g+30mg/g; 15g aluminum tube, 50g aluminum tube, 100g aluminum tube	The Mentholatum Company Limited, 1 Redwood Avenue, Peel Park Campus, East Kilbride, G74 5PE, Scotland	UK	The Mentholatum Company Limited, 1 Redwood Avenue, Peel Park Campus, East Kilbride, G74 5PE, Scotland	UK	OTC	23310/2.31.07.2026
9	Elidel	pimecrolimus	cream for external use	10mg/g; aluminium tube 15g	MEDA Manufacturing, Avenue JF Kennedy, 33700 Merignac	France	MEDA Pharma GmbH & Co. KG, Benzstrasse 1, 61352 Bad Homburg	Germany	PoM	23022/1.31.07.2026
10	Thioctacid 600 T	thioctic acid (alfa-lipoic acid)	solution for injection	25mg/ml; (5) ampoules 24ml	MEDA Pharma GmbH & Co. KG, Benzstrasse 1, 61352 Bad Homburg- batch releaser, Siegfried Hameln GmbH, Langes Feld 13, Hameln, Niedersachsen, 31789, Germany- bulk manufacturer, packager, quality control	Germany	MEDA Pharma GmbH & Co. KG, Benzstrasse 1, 61352 Bad Homburg	Germany	PoM	21205/3.31.07.2026
11	Thioctacid 600 HR	alfa-lipoic acid	tablets film-coated	600mg; (30) in glass container, (100) in glass container	Rottapharm Ltd., Damastown Industrial Park, Mulhuddart, Dublin 15	Ireland	MEDA Pharma GmbH & Co. KG, Benzstrasse 1, 61352 Bad Homburg	Germany	PoM	20469/2.31.07.2026
12	Persen Night	valeriana officinalis extract, melissa officinalis extract, mentha piperita extract	capsules	87,5mg+17,5mg+17,5mg; (20/2x10) in blister	ADIPHARM EAD, 130 Simeonovsko shose Blvd., Sofia 1700	Bulgaria	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia	Bulgaria	OTC	22201/3.2.31.07.2026

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1	Milgamma	thiamine (thiamine hydrochloride), pyridoxine (pyridoxine hydrochloride), cyanocobalamin, lidocaine (lidocaine hydrochloride)	solution for i/m injection	100mg/2ml+100mg/2ml+1mg/2ml+20mg/2ml; (5/1x5) ampoules 2ml in tray, (10/2x5) ampoules 2ml in tray, (25/5x5) ampoules 2ml in tray	Solupharm Pharmazeutische Erzeugnisse GmbH, Industriestr. 3, 34212, Melsungen- bulk manufacturer, packager, quality control (physicochemical), batch releaser, Labor LSSE & Co. KG, Mangelsfeld 4, 5, 6, 3 Bad Bocklet- Grossenbrach, D- 97708, Germany- quality control (microbiological)	Germany	Woerwag Pharma GmbH & Co. KG, Flugfeld-Allee 24, 71034 Boeblingen	Germany	PoM	JITI-N°001507-ITI-AM 31.07.2026
2	Brilinta	ticagrelor	tablets film-coated	90mg; (14/1x14) in blister, (56/4x14) in blister, (168/12x14) in blister	AstraZeneca AB Gartunavagen, Sodertalje, 152 57	Sweden	AstraZeneca AB, Sodertalje, SE-15185	Sweden	PoM	JITI-N°006368-ITI-AM 31.07.2026
3	Brilinta	ticagrelor	tablets film-coated	90mg; (14/1x14) in blister, (56/4x14) in blister, (168/12x14) in blister	AstraZeneca Industries LLC, 249020, Kaluga Region, Borovsky District, Dobrino village, 1st Vostochny proezd, estate 8	Russia	AstraZeneca AB, Sodertalje, SE-15185	Sweden	PoM	JITI-N°006368-ITI-AM 31.07.2026
4	Brilinta	ticagrelor	tablets film-coated	90mg; (14/1x14) in blister, (56/4x14) in blister, (168/12x14) in blister	AstraZeneca Industries LLC, 249020, Kaluga Region, Borovsky District, Dobrino village, 1st Vostochny proezd, estate 8- secondary packager, batch releaser, AstraZeneca AB Gartunavagen, Sodertalje, 152 57, Sweden- bulk manufacturer, primary packager, quality control	Russia	AstraZeneca AB, Sodertalje, SE-15185	Sweden	PoM	JITI-N°006368-ITI-AM 31.07.2026
5	Moxiral	moxifloxacin (moxifloxacin hydrochloride)	tablets film-coated	400mg; (5/1x5) in blister, (7/1x7) in blister, (10/2x5) in blister	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	PoM	JITI-N°000191-ITI-AM 31.07.2026

6	Actilyse	alteplase	powder lyophilized for solution for infusion with solvent	50mg; glass vial and glass vial with solvent 50ml	Boehringer Ingelheim Pharma GmbH & Co. KG, Birkendorfer str. 65, 88397 Biberach a.d.R.	Germany	Boehringer Ingelheim International GmbH, Binger Strasse 173, 55216 Ingelheim am Rhein	Germany	PoM	JITI-N°004755-ITI-AM 31.07.2026
7	Forxiga	dapagliflozin	tablets film-coated	5mg; (14/1x14) in blister, (28/2x14) in blister, (30/3x10) in blister	AstraZeneca UK Limited, Silk Road Business Park, Macclesfield, Cheshire SK10 2NA- packager, quality control, batch releaser, AstraZeneca Pharmaceuticals LP, 4601 Highway 62 East, Mount Vernon, Indiana, 47620, USA- bulk manufacturer	UK	AstraZeneca UK Limited, 1 Francis Crick Avenue, Cambridge Biomedical Campus, Cambridge	United Kingdom	PoM	JITI-N°005264-ITI-AM 31.07.2026
8	Forxiga	dapagliflozin	tablets film-coated	10mg; (14/1x14) in blister, (28/2x14) in blister, (30/3x10) in blister	AstraZeneca UK Limited, Silk Road Business Park, Macclesfield, Cheshire SK10 2NA- packager, quality control, batch releaser, AstraZeneca Pharmaceuticals LP, 4601 Highway 62 East, Mount Vernon, Indiana, 47620, USA- bulk manufacturer	UK	AstraZeneca UK Limited, 1 Francis Crick Avenue, Cambridge Biomedical Campus, Cambridge	United Kingdom	PoM	JITI-N°005264-ITI-AM 31.07.2026
9	Forxiga	dapagliflozin	tablets film-coated	10mg; (30/3x10) in blister, (90/9x10) in blister	AstraZeneca Industries LLC, 249020, Kaluga Region, Borovsky District, Dobrino village, 1st Vostochny proezd, estate 8- secondary packager, quality control, batch releaser, AstraZeneca Pharmaceuticals LP, 4601 Highway 62 East, Mount Vernon, Indiana, 47620, USA- bulk manufacturer, AstraZeneca UK Limited, Silk Road Business Park, Macclesfield, Cheshire SK10 2NA- primary packager	Russia	AstraZeneca UK Limited, 1 Francis Crick Avenue, Cambridge Biomedical Campus, Cambridge	United Kingdom	PoM	JITI-N°005264-ITI-AM 31.07.2026
10	Forxiga	dapagliflozin	tablets film-coated	10mg; (30/3x10) in blister, (90/9x10) in blister	AstraZeneca Industries LLC, 249020, Kaluga Region, Borovsky District, Dobrino village, 1st Vostochny proezd, estate 8	Russia	AstraZeneca UK Limited, 1 Francis Crick Avenue, Cambridge Biomedical Campus, Cambridge	United Kingdom	PoM	JITI-N°005264-ITI-AM 31.07.2026
11	Forxiga	dapagliflozin	tablets film-coated	10mg; (14/1x14) in blister, (28/2x14) in blister	Nobel Almaty Pharmaceutical Factory, 050008, Almaty city, Almaty district, 162E Shevchenko Street- secondary packager, quality control, batch releaser, AstraZeneca Pharmaceuticals LP, 4601 Highway 62 East, Mount Vernon, Indiana, 47620- bulk manufacturer, AstraZeneca UK Limited, Silk Road Business Park, Macclesfield, Cheshire SK10 2NA- primary packager	Kazakhstan	AstraZeneca UK Limited, 1 Francis Crick Avenue, Cambridge Biomedical Campus, Cambridge	United Kingdom	PoM	JITI-N°005264-ITI-AM 31.07.2026

12	HERTICAD	trastuzumab	powder lyophilized for concentrate for solution for infusion	150mg: glass vial	BIOCAD JSC, 5 Promyshlennaya ul., bld. 2, Petrovo-Dalnee, Krasnogorsk Urban District, Moscow Region, 143422- quality control, batch releaser, BIOCAD JSC, 5 Promyshlennaya ul., bld. 1, Petrovo-Dalnee, Krasnogorsk Urban District, Moscow Region, 143422, Russia- bulk manufacturer, packager	Russia	BIOCAD JSC, Intracity Municipality the Settlement of Strelna, ul. Svyazi, d. 38, str. 1, pomesch. 89, Saint Petersburg, 198515	Russia	PoM	JITI-N°005524-ITI-AM 31.07.2026
13	HERTICAD	trastuzumab	powder lyophilized for concentrate for solution for infusion	440mg: glass vial and glass vial with 20ml solvent	BIOCAD JSC, 5 Promyshlennaya ul., bld. 2, Petrovo-Dalnee, Krasnogorsk Urban District, Moscow Region, 143422- quality control, batch releaser, BIOCAD JSC, 5 Promyshlennaya ul., bld. 1, Petrovo-Dalnee, Krasnogorsk Urban District, Moscow Region, 143422, Russia- bulk manufacturer, packager	Russia	BIOCAD JSC, Intracity Municipality the Settlement of Strelna, ul. Svyazi, d. 38, str. 1, pomesch. 89, Saint Petersburg, 198515	Russia	PoM	JITI-N°005524-ITI-AM 31.07.2026
14	HERTICAD	trastuzumab	powder lyophilized for concentrate for solution for infusion	150mg: glass vial	BIOCAD JSC, Intracity Municipality the Settlement of Strelna, ul. Svyazi, d. 38, str. 1, Saint Petersburg, 198515	Russia	BIOCAD JSC, Intracity Municipality the Settlement of Strelna, ul. Svyazi, d. 38, str. 1, pomesch. 89, Saint Petersburg, 198515	Russia	PoM	JITI-N°005524-ITI-AM 31.07.2026
15	HERTICAD	trastuzumab	powder lyophilized for concentrate for solution for infusion	440mg: glass vial and glass vial with 20ml solvent	BIOCAD JSC, Intracity Municipality the Settlement of Strelna, ul. Svyazi, d. 38, str. 1, Saint Petersburg, 198515	Russia	BIOCAD JSC, Intracity Municipality the Settlement of Strelna, ul. Svyazi, d. 38, str. 1, pomesch. 89, Saint Petersburg, 198515	Russia	PoM	JITI-N°005524-ITI-AM 31.07.2026
16	HERTICAD	trastuzumab	powder lyophilized for concentrate for solution for infusion	150mg: glass vial	PK-137 LLC, bld. 2, 5557th proezd, Zelenograd, Intracity territory of the Silino municipal district, Moscow, 124460	Russia	BIOCAD JSC, Intracity Municipality the Settlement of Strelna, ul. Svyazi, d. 38, str. 1, pomesch. 89, Saint Petersburg, 198515	Russia	PoM	JITI-N°005524-ITI-AM 31.07.2026
17	HERTICAD	trastuzumab	powder lyophilized for concentrate for solution for infusion	440mg: glass vial and glass vial with 20ml solvent	PK-137 LLC, bld. 2, 5557th proezd, Zelenograd, Intracity territory of the Silino municipal district, Moscow, 124460	Russia	BIOCAD JSC, Intracity Municipality the Settlement of Strelna, ul. Svyazi, d. 38, str. 1, pomesch. 89, Saint Petersburg, 198515	Russia	PoM	JITI-N°005524-ITI-AM 31.07.2026
18	HERTICAD	trastuzumab	powder lyophilized for concentrate for solution for infusion	150mg: glass vial	PK-137 LLC, bld. 2, 5557th proezd, Zelenograd, Intracity territory of the Silino municipal district, Moscow, 124460- secondary packager, quality control, batch releaser, BIOCAD JSC, Intracity Municipality the Settlement of Strelna, ul. Svyazi, d. 38, str. 1, Saint Petersburg, 198515, Russia- bulk manufacturer, primary packager	Russia	BIOCAD JSC, Intracity Municipality the Settlement of Strelna, ul. Svyazi, d. 38, str. 1, pomesch. 89, Saint Petersburg, 198515	Russia	PoM	JITI-N°005524-ITI-AM 31.07.2026

19	HERTICAD	trastuzumab	powder lyophilized for concentrate for solution for infusion	440mg; glass vial and glass vial with 20ml solvent	PK-137 LLC, bld. 2, 5557th proezd, Zelenograd, Intracity territory of the Silino municipal district, Moscow, 124460- secondary packager, quality control, batch releaser, BIOCAD JSC, Intracity Municipality the Settlement of Strelina, ul. Svyazi, d. 38, str. 1, Saint Petersburg, 198515, Russia- bulk manufacturer, primary packager	Russia	BIOCAD JSC, Intracity Municipality the Settlement of Strelina, ul. Svyazi, d. 38, str. 1, pomeshch. 89, Saint Petersburg, 198515	Russia	PoM	JITI-N°005524-ITI-AM 31.07.2026
20	HERTICAD	trastuzumab	powder lyophilized for concentrate for solution for infusion	150mg; glass vial	PK-137 LLC, bld. 2, 5557th proezd, Zelenograd, Intracity territory of the Silino municipal district, Moscow, 124460- secondary packager, quality control, batch releaser, BIOCAD JSC, 5 Promyshlennaya ul, bld. 1, Petrovo-Dalneye, Krasnogorsk Urban District, Moscow Region, 143422, Russia- bulk manufacturer, primary packager	Russia	BIOCAD JSC, Intracity Municipality the Settlement of Strelina, ul. Svyazi, d. 38, str. 1, pomeshch. 89, Saint Petersburg, 198515	Russia	PoM	JITI-N°005524-ITI-AM 31.07.2026
21	HERTICAD	trastuzumab	powder lyophilized for concentrate for solution for infusion	440mg; glass vial and glass vial with 20ml solvent	PK-137 LLC, bld. 2, 5557th proezd, Zelenograd, Intracity territory of the Silino municipal district, Moscow, 124460- secondary packager, quality control, batch releaser, BIOCAD JSC, 5 Promyshlennaya ul, bld. 1, Petrovo-Dalneye, Krasnogorsk Urban District, Moscow Region, 143422, Russia- bulk manufacturer, primary packager	Russia	BIOCAD JSC, Intracity Municipality the Settlement of Strelina, ul. Svyazi, d. 38, str. 1, pomeshch. 89, Saint Petersburg, 198515	Russia	PoM	JITI-N°005524-ITI-AM 31.07.2026
22	Prestilol 5mg/5mg	bisoprolol (bisoprolol fumarate), perindopril (perindopril arginine)	tablets film-coated	5mg+5mg; (30) in plastic container, (90/3x30) in plastic container	Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy	France	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	JITI-N°000569-ITI-AM 31.07.2026
23	Prestilol 5mg/10mg	bisoprolol (bisoprolol fumarate), perindopril (perindopril arginine)	tablets film-coated	5mg+10mg; (30) in plastic container, (90/3x30) in plastic container	Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy	France	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	JITI-N°000569-ITI-AM 31.07.2026
24	Prestilol 10mg/5mg	bisoprolol (bisoprolol fumarate), perindopril (perindopril arginine)	tablets film-coated	10mg+5mg; (30) in plastic container, (90/3x30) in plastic container	Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy	France	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	JITI-N°000569-ITI-AM 31.07.2026
25	Prestilol 10mg/10mg	bisoprolol (bisoprolol fumarate), perindopril (perindopril arginine)	tablets film-coated	10mg+10mg; (30) in plastic container, (90/3x30) in plastic container	Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy	France	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	JITI-N°000569-ITI-AM 31.07.2026

26	Prestilol 5mg/5mg	bisoprolol (bisoprolol fumarate), perindopril (perindopril arginine)	tablets film-coated	5mg+5mg: (30) in plastic container, (90/3x30) in plastic container	Servier (Ireland) Industries Ltd, Gorey Road, Arklow-Co. Wicklow, Y14 E284- batch releaser, packager, Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy, France- bulk manufacturer, quality control	Ireland	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	JITI-N°000569-ITI-AM 31.07.2026
27	Prestilol 5mg/10mg	bisoprolol (bisoprolol fumarate), perindopril (perindopril arginine)	tablets film-coated	5mg+10mg: (30) in plastic container, (90/3x30) in plastic container	Servier (Ireland) Industries Ltd, Gorey Road, Arklow-Co. Wicklow, Y14 E284- batch releaser, packager, Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy, France- bulk manufacturer, quality control	Ireland	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	JITI-N°000569-ITI-AM 31.07.2026
28	Prestilol 10mg/5mg	bisoprolol (bisoprolol fumarate), perindopril (perindopril arginine)	tablets film-coated	10mg+5mg: (30) in plastic container, (90/3x30) in plastic container	Servier (Ireland) Industries Ltd, Gorey Road, Arklow-Co. Wicklow, Y14 E284- batch releaser, packager, Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy, France- bulk manufacturer, quality control	Ireland	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	JITI-N°000569-ITI-AM 31.07.2026
29	Prestilol 10mg/10mg	bisoprolol (bisoprolol fumarate), perindopril (perindopril arginine)	tablets film-coated	10mg+10mg: (30) in plastic container, (90/3x30) in plastic container	Servier (Ireland) Industries Ltd, Gorey Road, Arklow-Co. Wicklow, Y14 E284- batch releaser, packager, Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy, France- bulk manufacturer, quality control	Ireland	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	JITI-N°000569-ITI-AM 31.07.2026
30	Glucophage	metformin (metformin hydrochloride)	tablets film-coated	500mg: (30/3x10) in blister, (30/2x15) in blister, (60/4x15) in blister, (60/3x20) in blister	Merck Sante s.a.s., 2 rue du Pressoir Vert, 45400 Semoy	France	Merck Sante s.a.s., 37 rue Saint Romain- 69379 Lyon	France	PoM	JITI-N°006054-ITI-AM 31.07.2026
31	Glucophage	metformin (metformin hydrochloride)	tablets film-coated	850mg: (30/2x15) in blister, (60/3x20) in blister, (60/4x15) in blister	Merck Sante s.a.s., 2 rue du Pressoir Vert, 45400 Semoy	France	Merck Sante s.a.s., 37 rue Saint Romain- 69379 Lyon	France	PoM	JITI-N°006054-ITI-AM 31.07.2026
32	Glucophage	metformin (metformin hydrochloride)	tablets film-coated	1000mg: (30/3x10) in blister, (30/2x15) in blister, (60/6x10) in blister, (60/4x15) in blister	Merck Sante s.a.s., 2 rue du Pressoir Vert, 45400 Semoy	France	Merck Sante s.a.s., 37 rue Saint Romain- 69379 Lyon	France	PoM	JITI-N°006054-ITI-AM 31.07.2026
33	Glucophage	metformin (metformin hydrochloride)	tablets film-coated	500mg: (30/3x10) in blister, (30/2x15) in blister, (60/4x15) in blister, (60/3x20) in blister	Merck S. L., Poligono Merck, Moliet-Del- Vales, 08100 Barcelona	Spain	Merck Sante s.a.s., 37 rue Saint Romain- 69379 Lyon	France	PoM	JITI-N°006054-ITI-AM 31.07.2026
34	Glucophage	metformin (metformin hydrochloride)	tablets film-coated	850mg: (30/2x15) in blister, (60/3x20) in blister, (60/4x15) in blister	Merck S. L., Poligono Merck, Moliet-Del- Vales, 08100 Barcelona	Spain	Merck Sante s.a.s., 37 rue Saint Romain- 69379 Lyon	France	PoM	JITI-N°006054-ITI-AM 31.07.2026
35	Glucophage	metformin (metformin hydrochloride)	tablets film-coated	1000mg: (30/3x10) in blister, (30/2x15) in blister, (60/6x10) in blister, (60/4x15) in blister	Merck S. L., Poligono Merck, Moliet-Del- Vales, 08100 Barcelona	Spain	Merck Sante s.a.s., 37 rue Saint Romain- 69379 Lyon	France	PoM	JITI-N°006054-ITI-AM 31.07.2026

36	Telmista	telmisartan	tablets	40mg; (30/3x10) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	JITI-N°000860-PT-AM 31.07.2026
37	Telmista	telmisartan	tablets	40mg; (30/3x10) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto- bulk manufacturer, packager, quality control (microbiological), batch releaser, National Laboratory of Health, Environment and Food (NLZOH), Dalmatinova ulica 3, Novo mesto, 8000, Slovenia- quality control (physicochemical)	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto	Slovenia	PoM	JITI-N°000860-PT-AM 31.07.2026
38	Telmista	telmisartan	tablets	40mg; (30/3x10) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto- packager, quality control (microbiological), batch releaser, Laurus Labs Limited, Unit-2, Plot No. 19, 20 And 21 Western Sector, APSEZ, Gurajapalem Village, Rambilli Mandal, Anakapalli District, Andhra-Pradesh- 531011, India- bulk manufacturer, Nacional Laboratory of Health, Environment and Food (NLZOH), Dalmatinova ulica 3, Novo mesto, 8000, Slovenia- quality control (physicochemical)	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto	Slovenia	PoM	JITI-N°000860-PT-AM 31.07.2026
39	Telmista	telmisartan	tablets	40mg; (30/3x10) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto- packager, quality control, batch releaser, Laurus Labs Limited, Unit-2, Plot No. 19, 20 And 21 Western Sector, APSEZ, Gurajapalem Village, Rambilli Mandal, Anakapalli District, Andhra-Pradesh- 531011, India- bulk manufacturer	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto	Slovenia	PoM	JITI-N°000860-PT-AM 31.07.2026
40	Telmista	telmisartan	tablets	40mg; (30/3x10) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto- quality control, batch releaser, Laurus Labs Limited, Unit-2, Plot No. 19, 20 And 21 Western Sector, APSEZ, Gurajapalem Village, Rambilli Mandal, Anakapalli District, Andhra-Pradesh- 531011, India- bulk manufacturer, packager	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto	Slovenia	PoM	JITI-N°000860-PT-AM 31.07.2026

41	Telmista	telmisartan	tablets	40mg; (30/3x10) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto- quality control (microbiological), batch releaser, Laurus Labs Limited, Unit-2, Plot No. 19, 20 And 21 Western Sector, APSEZ, Gurajapalem Village, Rambilli Mandal, Anakapalli District, Andhra-Pradesh- 531011, India- bulk manufacturer, packager, Nacional Laboratory of Health, Environment and Food (NLZOH), Dalmatinova ulica 3, Novo mesto, 8000, Slovenia- quality control (physicochemical)	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto	Slovenia	PoM	JITI-N°000860-PT-AM 31.07.2026
42	Telmista	telmisartan	tablets	40mg; (30/3x10) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto- bulk manufacturer, packager, quality control (microbiological), batch releaser, Chemilab d.o.o., Brnciceva ulica 31, 1231 Ljubljana Cmuce, Slovenia- quality control (physicochemical)	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto	Slovenia	PoM	JITI-N°000860-PT-AM 31.07.2026
43	Telmista	telmisartan	tablets	40mg; (30/3x10) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto- packager, quality control (microbiological), batch releaser, Laurus Labs Limited, Unit-2, Plot No. 19, 20 And 21 Western Sector, APSEZ, Gurajapalem Village, Rambilli Mandal, Anakapalli District, Andhra-Pradesh- 531011, India- bulk manufacturer, Chemilab d.o.o., Brnciceva ulica 31, 1231 Ljubljana Cmuce, Slovenia- quality control (physicochemical)	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto	Slovenia	PoM	JITI-N°000860-PT-AM 31.07.2026
44	Telmista	telmisartan	tablets	40mg; (30/3x10) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto- quality control (microbiological), batch releaser, Laurus Labs Limited, Unit-2, Plot No. 19, 20 And 21 Western Sector, APSEZ, Gurajapalem Village, Rambilli Mandal, Anakapalli District, Andhra-Pradesh- 531011, India- bulk manufacturer, packager, Chemilab d.o.o., Brnciceva ulica 31, 1231 Ljubljana Cmuce, Slovenia- quality control (physicochemical)	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto	Slovenia	PoM	JITI-N°000860-PT-AM 31.07.2026

45	Telmista	telmisartan	tablets	40mg; (30/3x10) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto- bulk manufacturer, packager, quality control (microbiological), batch releaser, Labena d.o.o., Teslova Ulica 30, 1000 Ljubljana, Slovenia- quality control (physicochemical)	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto	Slovenia	PoM	JITI-N°000860-PT-AM 31.07.2026
46	Telmista	telmisartan	tablets	40mg; (30/3x10) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto- packager, quality control (microbiological), batch releaser, Laurus Labs Limited, Unit-2, Plot No. 19, 20 And 21 Western Sector, APSEZ, Gurajapalem Village, Rambilli Mandal, Anakapalli District, Andhra- Pradesh- 531011, India- bulk manufacturer, Labena d.o.o., Teslova Ulica 30, 1000 Ljubljana, Slovenia- quality control (physicochemical)	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto	Slovenia	PoM	JITI-N°000860-PT-AM 31.07.2026
47	Telmista	telmisartan	tablets	80mg; (30/3x10) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	JITI-N°000860-PT-AM 31.07.2026
48	Telmista	telmisartan	tablets	80mg; (30/3x10) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto- bulk manufacturer, packager, quality control (microbiological), batch releaser, National Laboratory of Health, Environment and Food (NLZOH), Dalmatinova ulica 3, Novo mesto, 8000, Slovenia- quality control (physicochemical)	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto	Slovenia	PoM	JITI-N°000860-PT-AM 31.07.2026
49	Telmista	telmisartan	tablets	80mg; (30/3x10) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto- packager, quality control (microbiological), batch releaser, Laurus Labs Limited, Unit-2, Plot No. 19, 20 And 21 Western Sector, APSEZ, Gurajapalem Village, Rambilli Mandal, Anakapalli District, Andhra- Pradesh- 531011, India- bulk manufacturer, Nacional Laboratory of Health, Environment and Food (NLZOH), Dalmatinova ulica 3, Novo mesto, 8000, Slovenia- quality control (physicochemical)	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto	Slovenia	PoM	

50	Telmista	telmisartan	tablets	80mg; (30/3x10) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto- packager, quality control (microbiological), batch releaser, Laurus Labs Limited, Unit-2, Plot No. 19, 20 And 21 Western Sector, APSEZ, Gurajapalem Village, Rambilli Mandal, Anakapalli District, Andhra- Pradesh- 531011, India- bulk manufacturer, Nacional Laboratory of Health, Environment and Food (NLZOH), Dalmatinova ulica 3, Novo mesto, 8000, Slovenia- quality control (physicochemical)	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto	Slovenia	PoM	JITI-N°000860-PT-AM 31.07.2026
51	Telmista	telmisartan	tablets	80mg; (30/3x10) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto- packager, quality control, batch releaser, Laurus Labs Limited, Unit-2, Plot No. 19, 20 And 21 Western Sector, APSEZ, Gurajapalem Village, Rambilli Mandal, Anakapalli District, Andhra-Pradesh- 531011, India- bulk manufacturer	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto	Slovenia	PoM	JITI-N°000860-PT-AM 31.07.2026
52	Telmista	telmisartan	tablets	80mg; (30/3x10) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto- quality control, batch releaser, Laurus Labs Limited, Unit-2, Plot No. 19, 20 And 21 Western Sector, APSEZ, Gurajapalem Village, Rambilli Mandal, Anakapalli District, Andhra-Pradesh- 531011, India- bulk manufacturer, packager	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto	Slovenia	PoM	JITI-N°000860-PT-AM 31.07.2026
53	Telmista	telmisartan	tablets	80mg; (30/3x10) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto- quality control (microbiological), batch releaser, Laurus Labs Limited, Unit-2, Plot No. 19, 20 And 21 Western Sector, APSEZ, Gurajapalem Village, Rambilli Mandal, Anakapalli District, Andhra-Pradesh- 531011, India- bulk manufacturer, packager, Nacional Laboratory of Health, Environment and Food (NLZOH), Dalmatinova ulica 3, Novo mesto, 8000, Slovenia- quality control (physicochemical)	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto	Slovenia	PoM	JITI-N°000860-PT-AM 31.07.2026

54	Telmista	telmisartan	tablets	80mg; (30/3x10) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto- bulk manufacturer, packager, quality control (microbiological), batch releaser, Chemilab d.o.o., Brnciceva ulica 31, 1231 Ljubljana Crnuce, Slovenia- quality control (physicochemical)	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto	Slovenia	PoM	JITI-N°000860-PT-AM 31.07.2026
55	Telmista	telmisartan	tablets	80mg; (30/3x10) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto- packager, quality control (microbiological), batch releaser, Laurus Labs Limited, Unit-2, Plot No. 19, 20 And 21 Western Sector, APSEZ, Gurajapalem Village, Rambilli Mandal, Anakapalli District, Andhra- Pradesh- 531011, India- bulk manufacturer, Chemilab d.o.o., Brnciceva ulica 31, 1231 Ljubljana Crnuce, Slovenia- quality control (physicochemical)	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto	Slovenia	PoM	JITI-N°000860-PT-AM 31.07.2026
56	Telmista	telmisartan	tablets	80mg; (30/3x10) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto- quality control (microbiological), batch releaser, Laurus Labs Limited, Unit-2, Plot No. 19, 20 And 21 Western Sector, APSEZ, Gurajapalem Village, Rambilli Mandal, Anakapalli District, Andhra- Pradesh- 531011, India- bulk manufacturer, packager, Chemilab d.o.o., Brnciceva ulica 31, 1231 Ljubljana Crnuce, Slovenia- quality control (physicochemical)	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto	Slovenia	PoM	JITI-N°000860-PT-AM 31.07.2026
57	Telmista	telmisartan	tablets	80mg; (30/3x10) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto- bulk manufacturer, packager, quality control (microbiological), batch releaser, Labena d.o.o., Teslova Ulica 30, 1000 Ljubljana, Slovenia- quality control (physicochemical)	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto	Slovenia	PoM	JITI-N°000860-PT-AM 31.07.2026

58	Telmista	telmisartan	tablets	80mg; (30/3x10) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto- packager, quality control (microbiological), batch releaser, Laurus Labs Limited, Unit-2, Plot No. 19, 20 And 21 Western Sector, APSEZ, Gurajapalem Village, Rambilli Mandal, Anakapalli District, Andhra- Pradesh- 531011, India- bulk manufacturer, Labena d.o.o., Teslova Ulica 30, 1000 Ljubljana, Slovenia- quality control (physicochemical)	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto	Slovenia	PoM	JITI-N°000860-PT-AM 31.07.2026
59	Telmista	telmisartan	tablets	80mg; (30/3x10) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto- quality control (microbiological), batch releaser, Laurus Labs Limited, Unit-2, Plot No. 19, 20 And 21 Western Sector, APSEZ, Gurajapalem Village, Rambilli Mandal, Anakapalli District, Andhra- Pradesh- 531011, India- bulk manufacturer, packager, Labena d.o.o., Teslova Ulica 30, 1000 Ljubljana, Slovenia- quality control (physicochemical)	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto	Slovenia	PoM	JITI-N°000860-PT-AM 31.07.2026
60	FRAXIPARINE	nadroparin calcium	solution for s/c injection	2850IU AXa/0,3ml; (10/5x2) pre-filled glass syringes 0,3ml	Aspen Notre Dame de Bondeville, 1 rue de l' Abbaye, 76960 Notre Dame de Bondeville	France	Aspen Pharma Trading Limited, 3016 Lake Drive, Citywest Business Campus, Dublin 24	Ireland	PoM	JITI-N°009545-ITI-AM 31.07.2026
61	FRAXIPARINE	nadroparin calcium	solution for s/c injection	2850IU AXa/0,3ml; (10/5x2) pre-filled glass syringes 0,3ml	LLC Nanolek, 612079, Kirov region, Orichovsky municipal district, Levinskoye urban settlement, Biomedical complex NANOLEK territory	Russia	Aspen Pharma Trading Limited, 3016 Lake Drive, Citywest Business Campus, Dublin 24	Ireland	PoM	JITI-N°009545-ITI-AM 31.07.2026
62	FRAXIPARINE	nadroparin calcium	solution for s/c injection	3800IU AXa/0,4ml; (10/5x2) pre-filled glass syringes 0,4ml	Aspen Notre Dame de Bondeville, 1 rue de l' Abbaye, 76960 Notre Dame de Bondeville	France	Aspen Pharma Trading Limited, 3016 Lake Drive, Citywest Business Campus, Dublin 24	Ireland	PoM	JITI-N°009545-ITI-AM 31.07.2026
63	FRAXIPARINE	nadroparin calcium	solution for s/c injection	3800IU AXa/0,4ml; (10/5x2) pre-filled glass syringes 0,4ml	LLC Nanolek, 612079, Kirov region, Orichovsky municipal district, Levinskoye urban settlement, Biomedical complex NANOLEK territory	Russia	Aspen Pharma Trading Limited, 3016 Lake Drive, Citywest Business Campus, Dublin 24	Ireland	PoM	JITI-N°009545-ITI-AM 31.07.2026
64	FRAXIPARINE	nadroparin calcium	solution for s/c injection	5700IU AXa/0,6ml; (10/5x2) pre-filled glass syringes 0,6ml	Aspen Notre Dame de Bondeville, 1 rue de l' Abbaye, 76960 Notre Dame de Bondeville	France	Aspen Pharma Trading Limited, 3016 Lake Drive, Citywest Business Campus, Dublin 24	Ireland	PoM	JITI-N°009545-ITI-AM 31.07.2026

65	FRAXIPARINE	nadroparin calcium	solution for s/c injection	5700IU AXa/0,6ml; (10/5x2) pre-filled glass syringes 0,6ml	LLC Nanolek, 612079, Kirov region, Orichvsky municipal district, Levinskoye urban settlement, Biomedical complex NANOLEK territory	Russia	Aspen Pharma Trading Limited, 3016 Lake Drive, Citywest Business Campus, Dublin 24	Ireland	PoM	JITI-N°009545-ITI-AM 31.07.2026
66	FRAXIPARINE	nadroparin calcium	solution for s/c injection	7600IU AXa/0,8ml; (10/5x2) pre-filled glass syringes 0,8ml	Aspen Notre Dame de Bondeville, 1 rue de l' Abbaye, 76960 Notre Dame de Bondeville	France	Aspen Pharma Trading Limited, 3016 Lake Drive, Citywest Business Campus, Dublin 24	Ireland	PoM	JITI-N°009545-ITI-AM 31.07.2026
67	FRAXIPARINE	nadroparin calcium	solution for s/c injection	7600IU AXa/0,8ml; (10/5x2) pre-filled glass syringes 0,8ml	LLC Nanolek, 612079, Kirov region, Orichvsky municipal district, Levinskoye urban settlement, Biomedical complex NANOLEK territory	Russia	Aspen Pharma Trading Limited, 3016 Lake Drive, Citywest Business Campus, Dublin 24	Ireland	PoM	JITI-N°009545-ITI-AM 31.07.2026
68	Viagra	sildenafil (sildenafil citrate)	tablets film-coated	25mg; (1/1x1) in blister, (2/2x1) in blister, (3/3x1) in blister, (2/1x2) in blister, (4/2x2) in blister, (6/2x3) in blister, (4/1x4) in blister, (8/2x4) in blister, (12/3x4) in blister, (8/1x8) in blister, (16/2x8) in blister, (24/3x8) in blister, (12/1x12) in blister, (24/2x12) in blister, (36/3x12) in blister	Fareva Amboise, Zone Industrielle, 29 route des Industries, 37530 Poce-sur-Cisse	France	VIATRIS SPECIALTY LLC, 3711 Collins Ferry Road, Morgantown, WV 26505	USA	PoM	JITI-N°002020-ITI-AM 31.07.2026
69	Viagra	sildenafil (sildenafil citrate)	tablets film-coated	50mg; (1/1x1) in blister, (2/2x1) in blister, (3/3x1) in blister, (2/1x2) in blister, (4/2x2) in blister, (6/2x3) in blister, (4/1x4) in blister, (8/2x4) in blister, (12/3x4) in blister, (8/1x8) in blister, (16/2x8) in blister, (24/3x8) in blister, (12/1x12) in blister, (24/2x12) in blister, (36/3x12) in blister	Fareva Amboise, Zone Industrielle, 29 route des Industries, 37530 Poce-sur-Cisse	France	VIATRIS SPECIALTY LLC, 3711 Collins Ferry Road, Morgantown, WV 26505	USA	PoM	JITI-N°002020-ITI-AM 31.07.2026
70	Viagra	sildenafil (sildenafil citrate)	tablets film-coated	100mg; (1/1x1) in blister, (2/2x1) in blister, (3/3x1) in blister, (2/1x2) in blister, (4/2x2) in blister, (6/2x3) in blister, (4/1x4) in blister, (8/2x4) in blister, (12/3x4) in blister, (8/1x8) in blister, (16/2x8) in blister, (24/3x8) in blister, (12/1x12) in blister, (24/2x12) in blister, (36/3x12) in blister	Fareva Amboise, Zone Industrielle, 29 route des Industries, 37530 Poce-sur-Cisse	France	VIATRIS SPECIALTY LLC, 3711 Collins Ferry Road, Morgantown, WV 26505	USA	PoM	JITI-N°002020-ITI-AM 31.07.2026
71	Sinaflan	fluocinolone acetonide	ointment	0,25mg/g; 10g aluminium tube, 15g aluminium tube	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7, c.1- quality control, batch releaser, Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7, Russia- bulk manufacturer, packager	Russia	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	PoM	JITI-N°004588-ITI-AM 31.07.2026

72	Bospri	ofatumumab	solution for subcutaneous injection	20mg/0,4ml; glass pre-filled syringe 0,4ml in blister	Novartis Pharma Stein, Schaffhauserstrasse, Stein AG, 4332	Switzerland	Novartis Overseas Investments AG, Lichtstrasse 35 4056 Basel,	Switzerland	PoM	JITI-N°001332 ITI-AM 31.07.2026
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