

LIST

of the medicines recommended for the registration by the Center according to the meeting decision N 04-2/26 on April 29, 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	Meldovens	meldonium (trimethylhydrazinium propionate dihydrate)	solution for injection	100mg/ml; (10/2x5) ampoules 5ml in blister	Velpharm LLC, Kurgan Region, Kurgan city, Prospekt Konstitutsii, Building 11, 640008	Russia	Vegapharm LLP, Unit 18, Norman road 53, Greenwich Centre Business park, SE10 9QF, London	United Kingdom	PoM	24056 29.04.2026

LIST

of the medicines recommended for registration under the EAEU procedure by the Center according to the meeting decision N 04-2/26 on April 29,
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	Omnitus	butamirate (butamirate citrate)	tablets modified-release film-coated	20mg; (10/1x10) in blister	Hemofarm A.D., 26300 Vrsac, Beogradski put bb	Serbia	Hemofarm A.D., 26300 Vrsac, Beogradski put bb	Serbia	OTC	24061 (021114) 29.04.2026
2	Omnitus	butamirate (butamirate citrate)	tablets modified-release film-coated	50mg; (10/1x10) in blister	Hemofarm A.D., 26300 Vrsac, Beogradski put bb	Serbia	Hemofarm A.D., 26300 Vrsac, Beogradski put bb	Serbia	OTC	24062 (021114) 29.04.2026
3	Enap-H	enalapril (enalapril maleate), hydrochlorothiazide	tablets	10mg+25mg; (20/2x10) in blister, (60/6x10) 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	24063 (024114) 29.04.2026
4	Enap-H	enalapril (enalapril maleate), hydrochlorothiazide	tablets	10mg+25mg; (20/2x10) in blister, (60/6x10) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto- bulk manufacturer, packager, batch releaser, National Laboratory of Health, Environment and Food (NLZOH), Dalmatinova 3, Novo mesto, 8000, Slovenia- quality control	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	24064 (024114) 29.04.2026
5	Enap-H	enalapril (enalapril maleate), hydrochlorothiazide	tablets	10mg+25mg; (20/2x10) in blister, (60/6x10) in blister	KRKA-RUS LLC, 50 Moskovskaya Str., Istra, Moscow Region, 143500- secondary packager, quality control, batch releaser, KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto, Slovenia- bulk manufacturer, primary packager	Russia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	240653 (024114) 29.04.2026

6	Enap-H	enalapril (enalapril maleate), hydrochlorothiazide	tablets	10mg+25mg; (20/2x10) in blister, (60/6x10) in blister	KRKA-RUS LLC, 50 Moskovskaya Str., Istra, Moscow Region, 143500- packager, quality control, batch releaser, KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto, Slovenia- bulk manufacturer	Russia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	24066 (024114) 29.04.2026
7	Enap-H	enalapril (enalapril maleate), hydrochlorothiazide	tablets	10mg+25mg; (20/2x10) in blister, (60/6x10) in blister	KRKA-RUS LLC, 50 Moskovskaya Str., Istra, Moscow Region, 143500	Russia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	24067 (024114) 29.04.2026
8	Enap-H	enalapril (enalapril maleate), hydrochlorothiazide	tablets	10mg+25mg; (20/2x10) in blister, (60/6x10) in blister	AO Vector-Medica, 630559, Novosibirsk Region, City District Industrial Community Koltsovo, rp Koltsovo, Reaserach and Production Zone, bld. 13- secondary packager, quality control, batch releaser, KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto, Slovenia- bulk manufacturer, primary packager	Russia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	24068 (024114) 29.04.2026
9	Metformin	metformin (metformin hydrochloride)	tablets film-coated	500mg; (30/3x10) in blister	Open joint stock company "Borisovskiy zavod medicinskih preparatov", 64A, No4, ul. Chapaeva, Borisov, Minsk region	Republic of Belarus	Open joint stock company "Borisovskiy zavod medicinskih preparatov", 64, ul. Chapaeva, Borisov, Minsk region	Republic of Belarus	PoM	24069 (089125) 29.04.2026
10	Metformin	metformin (metformin hydrochloride)	tablets film-coated	850mg; (30/3x10) in blister	Open joint stock company "Borisovskiy zavod medicinskih preparatov", 64A, No4, ul. Chapaeva, Borisov, Minsk region	Republic of Belarus	Open joint stock company "Borisovskiy zavod medicinskih preparatov", 64, ul. Chapaeva, Borisov, Minsk region	Republic of Belarus	PoM	24070 (089125) 29.04.2026
11	Metformin	metformin (metformin hydrochloride)	tablets film-coated	1000mg; (30/3x10) in blister	Open joint stock company "Borisovskiy zavod medicinskih preparatov", 64A, No4, ul. Chapaeva, Borisov, Minsk region	Republic of Belarus	Open joint stock company "Borisovskiy zavod medicinskih preparatov", 64, ul. Chapaeva, Borisov, Minsk region	Republic of Belarus	PoM	24071 (089125) 29.04.2026
12	Bepanthen Plus	dexpanthenol, chlorhexidine (chlorhexidine dihydrochloride)	cream for external use	50mg/g+5mg/g; 3,5g aluminium tube, 30g aluminium tube, 100g aluminium tube	GP Grenzach Produktions GmbH, Emil-Barell-Strasse 7, 79639 Grenzach-Wyhlen	Germany	Bayer Consumer Care AG, Peter Merian-Strasse 84, 4052 Basel	Switzerland	OTC	24072 (089125) 29.04.2026

13	Sybrava	inclisiran	solution for subcutaneous injection	189mg/ml; pre-filled syringe 1,5ml	Novartis Pharmaceutical Manufacturing GmbH, Biochemiestrasse 10, Langkampfen, 6336- batch releaser, Corden Pharma S.p.A., Reparto UP3, Via G. Galilei, 17, Caponago (MB), 20867, Italy- bulk manufacturer, primary packager, quality control, Corden Pharma S.p.A., viale dell'Industria, 3, Caponago (MB), 20867, Italy- secondary packager	Austria	Novartis Overseas Investments AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	24073 (000494) 29.04.2026
14	Sybrava	inclisiran	solution for subcutaneous injection	189mg/ml; pre-filled syringe 1,5ml	Novartis Pharmaceutical Manufacturing GmbH, Biochemiestrasse 10, Langkampfen, 6336	Austria	Novartis Pharma AG, 35, Lichtstrasse, 4056 Basel	Switzerland	PoM	24074 (000494) 29.04.2026
15	Sorbifer Durules	ferrous sulphate, ascorbic acid	tablets prolonged-release coated	320mg+60mg; (30) in glass bottle, (50) in glass bottle, (100) in glass bottle	Egis Pharmaceuticals PLC, 9900, Kormend, Matyas Kiraly ut 65 (legal address- Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi ut 30-38, Hungary)	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi ut 30-38	Hungary	PoM	24075 (000191) 29.04.2026
16	Amprilan HD	ramipril, hydrochlorothiazide	tablets	5mg+25mg; (14/2x7/) in blister, (28/4x7/) in blister, (56/8x7/) in blister, (84/12x7/) in blister, (98/14x7/) in blister, (30/3x10) in blister, (60/6x10/) in blister, (90/9x10) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto- packager, quality control, batch releaser, KRKA d.d., Novo mesto, Novomeska cesta 22, Sentjernej 8310, Slovenia- bulk manufacturer	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Switzerland	PoM	24076 (005664) 29.04.2026
17	Otrivin	xylometazoline (xylometazoline hydrochloride)	drops nasal	0,5mg/ml; 10ml plastic bottle-dropper	Haleon CH SARM, Route de l' Etraz, Nyon, 1260	Switzerland	JSC Haleon Rus, Presnenskaya Naberezhnaya, 10, unit III, room 9, 6 floor, Moscow, 123112	Russia	OTC	24077 (016333) 29.04.2026
18	Fastum gel	ketoprofen	gel	25mg/g; aluminum tube 30g, aluminum tube 50g, aluminum tube 100g	A. Menarini Manufacturing Logistics and Services S.r.l., Via Sette Santi, 3 50131 Firenze	Italy	A. Menarini Industrie Farmaceutiche Riunite S.r.l., Via Sette Santi, 3 50131 Firenze	Italy	PoM	24078 (011601) 29.04.2026

19	Cindol	zinc oxide	suspension for external use	12,5g/100g; 125g glass vial, 125g plastic container	Yaroslavl Pharmaceutical Factory CJSC, Yaroslavl Region, 150030, Yaroslavl, 1st Putevaya Street b.5	Russia	"DOMINANTA-SERVIS" JSC, Komsomolskaya St. 1, building 49, room 1, apartment 223, Podolsk, Moscow region, 142100	Russia	OTC	24079 (011501) 29.04.2026
20	Doxycycline	doxycycline (doxycycline hyclate)	capsules	100mg; (10/1x10') in blister, (20/2x10') in blister	Open joint stock company "Borisovskiy zavod medicinskih preparatov", 64, ul. Chapaeva, Borisov, 222518, Minsk region	Republic of Belarus	Open joint stock company "Borisovskiy zavod medicinskih preparatov", 64, ul. Chapaeva, Borisov, 222518, Minsk region	Republic of Belarus	PoM	24080 (018699) 29.04.2026
21	Jadenu	deferasirox	tablets film-coated	90mg; (30/3x10') in blister, (90/9x10') in blister	Novartis Pharma Produktions GmbH, Oeflinger Strasse 44, Wehr, 79664- packager, quality control (physicochemical), batch releaser, Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, 4332, Switzerland- bulk manufacturer, quality control (microbiological)	Germany	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	24081 (048324) 29.04.2026
22	Jadenu	deferasirox	tablets film-coated	180mg; (30/3x10') in blister, (90/9x10') in blister	Novartis Pharma Produktions GmbH, Oeflinger Strasse 44, Wehr, 79664- packager, quality control (physicochemical), batch releaser, Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, 4332, Switzerland- bulk manufacturer, quality control (microbiological)	Germany	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	24082 (048324) 29.04.2026
23	Jadenu	deferasirox	tablets film-coated	360mg; (30/3x10') in blister, (90/9x10') in blister	Novartis Pharma Produktions GmbH, Oeflinger Strasse 44, Wehr, 79664- packager, quality control (physicochemical), batch releaser, Novartis Pharma Stein AG, Schaffhauserstrasse, Stein, 4332, Switzerland- bulk manufacturer, quality control (microbiological)	Germany	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	24083 (048324) 29.04.2026
24	Jadenu	deferasirox	tablets film-coated	90mg; (30/3x10') in blister, (90/9x10') in blister	Sandoz S.R.L., str. Livezeni nr. 7A, 540472, Targu Mures	Romania	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	24084 (048324) 29.04.2026

25	Jadenu	deferasirox	tablets film-coated	180mg: (30/3x10/) in blister, (90/9x10/) in blister	Sandoz S.R.L., str. Livezeni nr. 7A, 540472, Targu Mures	Romania	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	24085 (048324) 29.04.2026
26	Jadenu	deferasirox	tablets film-coated	360mg: (30/3x10/) in blister, (90/9x10/) in blister	Sandoz S.R.L., str. Livezeni nr. 7A, 540472, Targu Mures	Romania	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	24086 (048324) 29.04.2026
27	Jadenu	deferasirox	tablets film-coated	180mg: (30/3x10/) in blister, (90/9x10/) in blister	Novartis Neva LLC, Doroga v Kamenku Road to Kamenka, Building 40, Block 3, Letter A- secondary packager, batch releaser, Novartis Pharma Stein AG, Schaffhauserstrasse, 4332, Stein, Switzerland- bulk manufacturer, quality control (microbiological), Novartis Pharma Produktions GmbH, Oeflinger Strasse 44, 79664 Wehr, Germany- primary packager, quality control (physicochemical)	Russia	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	24087 (048324) 29.04.2026
28	Jadenu	deferasirox	tablets film-coated	360mg: (30/3x10/) in blister, (90/9x10/) in blister	Novartis Neva LLC, Doroga v Kamenku Road to Kamenka, Building 40, Block 3, Letter A- secondary packager, batch releaser, Novartis Pharma Stein AG, Schaffhauserstrasse, 4332, Stein, Switzerland- bulk manufacturer, quality control (microbiological), Novartis Pharma Produktions GmbH, Oeflinger Strasse 44, 79664 Wehr, Germany- primary packager, quality control (physicochemical)	Russia	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	24088 (048324) 29.04.2026

29	LOROTRICIN- ALIUM	benzalkonium chloride, benzocaine, tyrothricin	tablets to be sucked	1mg+1.5mg+ 0.5mg: (6/1x6) in blister, (10/1x10) in blister, (12/2x6) in blister, (12/1x12) in blister, (20/2x10) in blister, (24/2x12) in blister	ALIUM AO, build. 1, No: 2, Quarter A, Obolensk settlement, Serpukhov urban district, 142279, Moscow reg.- batch releaser, ALIUM AO, No: 2, Quarter A, Obolensk settlement, Serpukhov urban district, 142279, Moscow region, Russia- bulk manufacturer, packager, quality control	Russia	Binnopharm JSC, 3, building 1, Konstruktora Guskova str., Zelenograd, Moscow, 124460	Russia	OTC	24089 (007110) 29.04.2026
30	Magnerot	magnesium orotate (magnesium orotate dihydrate)	tablets	500mg; (20/2x10) in blister, (50/5x10) in blister, (20/1x20) in blister, (40/2x20) in blister, (60/3x20) in blister, (80/4x20) in blister, (100/5x20) in blister	Woerwag Pharma Production GmbH & Co. KG, Gewerbealle 1, 82343 Poecking- 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	OTC	24090 (000774) 29.04.2026
31	Magnerot	magnesium orotate (magnesium orotate dihydrate)	tablets	500mg; (20/2x10) in blister, (50/5x10) in blister, (20/1x20) in blister, (40/2x20) in blister, (60/3x20) in blister, (80/4x20) in blister, (100/5x20) in blister	PIQ-PHARMA LEK LLC, 308010, Belgorod region, Belgorodsky district, urban village Severny, Berezovaya St. 1/19- bulk manufacturer, packager, quality control (physicochemical), batch releaser, FARMOBORONA Test Center, Ltd., Moscow Region, Korolyov, Gagarin St., 46A, Russia- quality control (microbiological)	Russia	Woerwag Pharma GmbH & Co. KG, Flugfeld-Allee 24, 71034 Boeblingen	Germany	OTC	24091 (000774) 29.04.2026
32	Magnerot	magnesium orotate (magnesium orotate dihydrate)	tablets	500mg; (20/2x10) in blister, (50/5x10) in blister, (20/1x20) in blister, (40/2x20) in blister, (60/3x20) in blister, (80/4x20) in blister, (100/5x20) in blister	Worwag Pharma Operations Sp. z o.o., Ul. Gen. Mariana Langiewiczza 58, Konstanynow Lodzki, 95-050- bulk manufacturer, packager, quality control (physicochemical), batch releaser, MIKROLAB Sp. z o.o., Ul. Lubelska 5/7, 03-802 Warsaw, Poland- quality control (microbiological)	Poland	Woerwag Pharma GmbH & Co. KG, Flugfeld-Allee 24, 71034 Boeblingen	Germany	OTC	24092 (000774) 29.04.2026

33	Bicillin-5	benzathine benzylpenicillin, benzylpenicillin procaine	powder for suspension for i/m injection	1200000IU+300000IU; (1) vial 10ml, (10) vials 10ml	Sintez PJSC, Pr. Konstitutsii, building 7/32, Kurgan, Kurgan City Urban District, Kurgan region- quality control (physicochemical), batch releaser, "Sintez" PJSC, Pr. Konstitutsii, No. 7, building 6, Kurgan, Kurgan City Urban District, Kurgan region, Russia- bulk manufacturer, packager, "Sintez" PJSC, Pr. Konstitutsii, No.7, Kurgan, Kurgan City Urban District, Kurgan region, Russia- quality control (microbiological)	Russia	"Sintez" PJSC, Pr. Konstitutsii, No. 7, Kurgan, Kurgan region, 640008	Russia	PoM	24093 (004414) 29.04.2026
34	TheraFlu	paracetamol, pheniramine (pheniramine maleate), phenylephrine (phenylephrine hydrochloride), ascorbic acid	powder for oral solution with lemon flavour	325mg+20mg+10mg+50mg; (1) sachet 22,1g, (2), (3), (4), (5), (6), (7), (8), (9), (10), (11), (12), (13), (14), (15), (16), (17), (18), (19), (20), (21), (22), (23), (24), (25), (26), (27), (28), (29), (30), (31), (32), (33), (34), (35), (36), (37), (38), (39), (40), (41), (42), (43), (44), (45), (46), (47), (48), (49), (50) sachets 22,1g	Delpharm Orleans, 5 avenue de Concyr, Orleans Cedex 2, 45071	France	JSC "Haleon Rus", Presnenskaya Naberezhnaya, 10, unit III, room 9, 6 floor, Moscow, 123112	Russia	OTC	24094 (010521) 29.04.2026
35	Galvus	vildagliptin	tablets	50mg; (14/2x7) in blister, (28/4x7) in blister, (56/8x7) in blister, (84/12x7) in blister, (28/2x14) in blister, (56/4x14) in blister, (112/8x14) in blister, (168/12x14) in blister	Novartis Neva LLC, Road to Kamenka, Building 40, Block 3, Letter A	Russia	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	24095 (001710) 29.04.2026
36	Galvus	vildagliptin	tablets	50mg; (14/2x7) in blister, (28/4x7) in blister, (56/8x7) in blister, (84/12x7) in blister, (28/2x14) in blister, (56/4x14) in blister, (112/8x14) in blister, (168/12x14) in blister	Novartis Pharmaceutica, S.A., Gran Via de les Corts Catalanes 764, 08013 Barcelona - batch releaser, Siegfried Barbera S.L., Ronda de Santa Maria 158, 08210 Barbera del Valles, Barcelona, Spain- bulk manufacturer, packager, quality control	Spain	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	24096 (001710) 29.04.2026
37	Galvus	vildagliptin	tablets	50mg; (14/2x7) in blister, (28/4x7) in blister, (56/8x7) in blister, (84/12x7) in blister, (28/2x14) in blister, (56/4x14) in blister, (112/8x14) in blister, (168/12x14) in blister	Novartis Pharmaceuticals Manufacturing LLC, Verovskova Ulica 57, 1000, Ljubljana	Slovenia	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	PoM	24097 (001710) 29.04.2026

38	Ampicillin	ampicillin (ampicillin sodium)	powder for solution for injection	500mg; (40) glass vials	Kyivmedpreparat PJSC, 01032, Kyiv, Saksaganskogo street, 139	Ukraine	Kyivmedpreparat PJSC, 01032, Kyiv, Saksaganskogo street, 139	Ukraine	PoM	24059 (023816) 29.04.2026
39	Ampicillin	ampicillin (ampicillin sodium)	powder for solution for injection	1000mg; (40) glass vials	Kyivmedpreparat PJSC, 01032, Kyiv, Saksaganskogo street, 139	Ukraine	Kyivmedpreparat PJSC, 01032, Kyiv, Saksaganskogo street, 139	Ukraine	PoM	24060 (023816) 29.04.2026
40	Vitamin B complex	thiamine (thiamine hydrochloride), riboflavin (riboflavin sodium phosphate), pyridoxine (pyridoxine hydrochloride), nicotinamide	solution for injection	5mg/ml+1mg/ml+5mg/ml+50mg/ml; (10) ampoules 2ml	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia	Bulgaria	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia	Bulgaria	PoM	24058 (029197) 29.04.2026

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of registered variations under the EAEU procedure requiring registration and reformulation of registration certificate approved by the Center according to the meeting decision N 04-2/26 on April 29, 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	Nalgesin forte	naproxen (naproxen sodium)	tablets film-coated	550mg; (10/1x10) in blister, (20/2x10) in blister, (60/6x10) 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	JIT-N*000259-ITI-AM 29.04.2026
2	Nalgesin forte	naproxen (naproxen sodium)	tablets film-coated	550mg; (10/1x10) in blister, (20/2x10) in blister, (60/6x10) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto- packager, quality control, batch releaser, Unichem Laboratories Limited, Plots 15, 16, 17, 17A,18, Pilerne Industrial Estate, Pilerne, Bardez GoA, 403511, India- bulk manufacturer	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	JIT-N*000259-ITI-AM 29.04.2026
3	Nalgesin forte	naproxen (naproxen sodium)	tablets film-coated	550mg; (10/1x10) in blister, (20/2x10) in blister, (60/6x10) 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 30, 1000 Lyublyana, Slovenia- quality control (physicochemical)	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	JIT-N*000259-ITI-AM 29.04.2026
4	Nalgesin forte	naproxen (naproxen sodium)	tablets film-coated	550mg; (10/1x10) in blister, (20/2x10) in blister, (60/6x10) in blister	KRKA, d.d., Novo mesto, Smarjaska cesta 6, 8501 Novo mesto- packager, quality control (microbiological), batch releaser, Unichem Laboratories Limited, Plots 15, 16, 17, 17A,18, Pilerne Industrial Estate, Pilerne, Bardez GoA, 403511, India- bulk manufacturer, Labena, d.o.o, Teslova 30, 1000 Lyublyana, Slovenia- quality control (physicochemical)	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	JIT-N*000259-ITI-AM 29.04.2026

5	Nalgesin forte	naproxen (naproxen sodium)	tablets film-coated	550mg; (10/1x10) in blister, (20/2x10) in blister, (60/6x10) 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°000259-TTI-AM 29.04.2026
6	Nalgesin forte	naproxen (naproxen sodium)	tablets film-coated	550mg; (10/1x10) in blister, (20/2x10) in blister, (60/6x10) in blister	KRKA, d.d., Novo mesto, Smarjaska 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 30, 1000 Lyublyana, Slovenia- quality control (physicochemical)	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	JITI-N°000259-TTI-AM 29.04.2026

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of the medicines recommended for re-registration under the EAEU procedure by the Center according to the meeting decision N 04-2/26 on April 29,
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	Verapamil Alkaloid	verapamil (verapamil hydrochloride)	tablets coated	40mg; (30/2x15) 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	24098 (034614) 29.04.2026
2	Verapamil Alkaloid	verapamil (verapamil hydrochloride)	tablets coated	80mg; (30/2x15) 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	24099 (034614) 29.04.2026

LIST

of the medicines with extended of the registration certificate term by the Center according to the meeting decision N 04-2/26 on April 29, 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	Menovazine	menthol racemic, procaine (procaine hydrochloride), benzocaine	solution for external use	25mg/ml+10mg/ml+10mg/ml; glass vial 30ml	ESCO-PHARM LLC, Nor-Norq V block, Mikoyan 13, Yerevan 0079	Republic of Armenia	ESCO-PHARM LLC, Nor-Norq V block, Mikoyan 13, Yerevan 0079	Republic of Armenia	OTC	24100 29.04.2026
2	Duphaston	dydrogesterone	tablets film-coated	10mg; (20/1x20) in blister	ABBOTT Biologicals B.V., Veerweg 12, 8121 AA Olst	the Netherlands	ABBOTT Healthcare Products B.V., C.J. van Houtenlaan 36, NL-1381 CP Weesp	the Netherlands	PoM	24101 29.04.2026
3	Mexil	ethylmethylhydroxypyridine succinate	solution for i/v and i/m injection	50mg/ml; (10/2x5) ampoules 2ml in blister	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	PoM	24102 29.04.2026

LIST

of variations requiring reformulation of registration certificate approved by the Center according to the meeting decision N 04-2/26 on April 29, 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	Temozolamide Capsules	temozolamide	capsules hard gelatin	5mg; (5) in plastic container	Amneal Pharmaceuticals of New York LLC, Horseblock Road 50, Brookhaven, 11719, New York	USA	Amneal Pharmaceuticals LLC, Horseblock Road 50, Brookhaven, 11719, New York	USA	PoM	22854/1/1 29.04.2026
2	Temozolamide Capsules	temozolamide	capsules hard gelatin	20mg; (5) in plastic container	Amneal Pharmaceuticals of New York LLC, Horseblock Road 50, Brookhaven, 11719, New York	USA	Amneal Pharmaceuticals LLC, Horseblock Road 50, Brookhaven, 11719, New York	USA	PoM	22855/1/1 29.04.2026
3	Temozolamide Capsules	temozolamide	capsules hard gelatin	100mg; (5) in plastic container	Amneal Pharmaceuticals of New York LLC, Horseblock Road 50, Brookhaven, 11719, New York	USA	Amneal Pharmaceuticals LLC, Horseblock Road 50, Brookhaven, 11719, New York	USA	PoM	22856/1/1 29.04.2026
4	Temozolamide Capsules	temozolamide	capsules hard gelatin	140mg; (5) in plastic container	Amneal Pharmaceuticals of New York LLC, Horseblock Road 50, Brookhaven, 11719, New York	USA	Amneal Pharmaceuticals LLC, Horseblock Road 50, Brookhaven, 11719, New York	USA	PoM	22857/1/1 29.04.2026
5	Temozolamide Capsules	temozolamide	capsules hard gelatin	180mg; (5) in plastic container	Amneal Pharmaceuticals of New York LLC, Horseblock Road 50, Brookhaven, 11719, New York	USA	Amneal Pharmaceuticals LLC, Horseblock Road 50, Brookhaven, 11719, New York	USA	PoM	22858/1/1 29.04.2026
6	Temozolamide Capsules	temozolamide	capsules hard gelatin	250mg; (5) in plastic container	Amneal Pharmaceuticals of New York LLC, Horseblock Road 50, Brookhaven, 11719, New York	USA	Amneal Pharmaceuticals LLC, Horseblock Road 50, Brookhaven, 11719, New York	USA	PoM	22859/1/1 29.04.2026
7	Paracetamol for children-Pharmstandard	paracetamol	suspension oral with strawberry flavour	120mg/5ml; 100ml glass bottle and measuring spoon or measuring syringe	Pharmstandard-Leksredstva JSC, Kursk region, Kursk, Agregatnaya 2nd str., 1a/18	Russia	Pharmstandard-Leksredstva JSC, Kursk region, Kursk, Agregatnaya 2nd str., 1a/18	Russia	OTC	21446/1/1 29.04.2026

8	Cardiomagnyl	acetylsalicylic acid, magnesium hydroxide	tablets film-coated	75mg+15,2mg; (30) in glass vial, (100) in glass vial	Takeda Pharmaceuticals LLC, 150030, Yaroslavl city, 9 Tekhnoparkovaya street-quality control, batch releaser, Takeda Pharmaceuticals LLC, 150030, Yaroslavl city, 9 Tekhnoparkovaya street, 2 bld., Russia- bulk manufacturer, packager	Russia	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	OTC	22157/1/1 29.04.2026
9	Cardiomagnyl	acetylsalicylic acid, magnesium hydroxide	tablets film-coated	150mg+30,39mg; (30) in glass container, (100) in glass container	Takeda Pharmaceuticals LLC, 150030, Yaroslavl city, 9 Tekhnoparkovaya street-quality control, batch releaser, Takeda Pharmaceuticals LLC, 150030, Yaroslavl city, 9 Tekhnoparkovaya street, 2 bld., Russia- bulk manufacturer, packager	Russia	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	OTC	22158/1/1 29.04.2026
10	Diocor CH	sacubitril, valsartan	tablets film-coated	24,3mg+25,7mg; (28/2x14) in blister	ELPEN Pharmaceutical Co. Inc., Marathonos Avenue 95, Pikermi, 19009	Greece	Acino AG, Leopoldstrasse 115, 80804 Munich	Germany	PoM	23257/1/1 29.04.2026
11	Semglee	insulin glargine	solution for s/c injection	100U/ml; (5) pre-filled pens 3ml	Biocon Snd. Bhd., No.1, Jalan Bioteknologi 1, Kawasan Perindustrian SiLC, 79200, Iskandar Puteri, Johor	Malaysia	Biocon Snd. Bhd., No.1, Jalan Bioteknologi 1, Kawasan Perindustrian SiLC, 79200, Iskandar Puteri, Johor	Malaysia	PoM	23073/1/1 29.04.2026

LIST

of variations under the EAEU procedure requiring reformulation of registration certificate approved by the Center according to the meeting decision N
N 04-2/26 on April 29, 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	Halidor	bencyclane (bencyclane fumarate)	tablets	100mg; (50) in glass container	Egis Pharmaceuticals PLC, 9900, Kormend, Matyas kiraly st. 65	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	ЛПТ-№000118-ІТІ-АМ 29.04.2025

LIST

of variations not requiring reformulation of registration certificate approved by the Center according to the meeting decision N 04-2/26 on April 29,
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	Lamisil	terbinafine (terbinafine hydrochloride)	cream	10mg/g; 15g aluminium tube, 15g laminated tube	GSK Consumer Healthcare SARL, Route de l' Etraz, 1260 Nyon	Switzerland	GSK Consumer Healthcare SARL, Route de l' Etraz, 1260 Nyon	Switzerland	OTC	20942/2 29.04.2026
2	Duphaston	dydrogesterone	tablets film-coated	10mg; (20/1x20) in blister	ABBOTT Biologicals B.V., Veerweg 12, 8121 AA Olst	the Netherlands	ABBOTT Healthcare Products B.V., C.J. van Houtenlaan 36, NL-1381 CP Weesp	the Netherlands	PoM	19642/3 29.04.2026
3	Lorista H 100	losartan (losartan potassium), hydrochlorothiazide	tablets film-coated	100mg+12,5mg; (28/2x14) 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	21333/2 29.04.2026
4	Letrozole Denk 2.5	letrozole	tablets film-coated	2,5mg; (30/3x10) in blister	Haupt Pharma Muenster GmbH, Schleebueggenkamp 15, 48159 Muenster- bulk manufacturer, packager, quality control (physicochemical), batch releaser, Umweltlabor ACB GmbH, Albrecht-Thaer-Strasse 14, 48147 Muenster, Germany- quality control (microbiological)	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen	Germany	PoM	19943/2 29.04.2026
5	Diocor CH	sacubitril, valsartan	tablets film-coated	48,6mg+51,4mg; (28/4x7) in blister	ELPEN Pharmaceutical Co. Inc., Marathonos Avenue 95, Pikermi, 19009	Greece	Acino AG, Leopoldstrasse 115, 80804 Munich	S Germany	PoM	23258/1 29.04.2026
6	Diocor CH	sacubitril, valsartan	tablets film-coated	97,2mg+102,8mg; (28/4x7) in blister, 56(8x7) in blister	ELPEN Pharmaceutical Co. Inc., Marathonos Avenue 95, Pikermi, 19009	Greece	Acino AG, Leopoldstrasse 115, 80804 Munich	Germany	PoM	23259/1 29.04.2026

7	Oxaliplatin Ebewe concentrate for infusion 5 mg/ml	oxaliplatin	concentrate for solution for infusion	5mg/ml; 10ml glass vial	Fareva Unterach GmbH, Mondseestrasse 11, A-4866 Unterach am Attersee- bulk manufacturer, packager, quality control (physicochemical), batch releaser, Labor LS SE & Co. KG, Mangelsfeld 4, 5, 6, Bad Bocklet-Grossenbrach, Bayern, 97708, Germany- quality control (microbiological)	Austria	EBEWE Pharma Ges. m.b.H. Nfg. KG, Mondseestrasse 11, A-4866 Unterach am Attersee	Austria	PoM	22403/1 29.04.2026
8	Oxaliplatin Ebewe concentrate for infusion 5mg/ml	oxaliplatin	concentrate for solution for infusion	5mg/ml; 20ml glass vial	Fareva Unterach GmbH, Mondseestrasse 11, A-4866 Unterach am Attersee- batch releaser, bulk manufacturer, packager, quality control (physicochemical), Labor LS SE & Co. KG, Mangelsfeld 4, 5, 6, Bad Bocklet-Grossenbrach, Bayern, 97708, Germany- quality control (microbiological, sterility)	Austria	EBEWE Pharma Ges. m.b.H. Nfg. KG, Mondseestrasse 11, A-4866 Unterach am Attersee	Austria	PoM	22404/1 29.04.2026
9	Nakom	levodopa, carbidopa	tablets	250mg+25mg; (100/10x10) in blister	Lek Pharmaceuticals d.d., Verovskova Ulica 57, 1526, Ljubljana - quality control (microbiological), batch releaser, Novartis Pharmaceutical Manufacturing LLC, Verovskova Ulica 57, 1000, Ljubljana, Slovenia- bulk manufacturer, packager, quality control (physicochemical)	Slovenia	Lek Pharmaceuticals d.d., Verovskova Ulica 57, Ljubljana	Slovenia	PoM	21954/2/1 29.04.2026
10	Roxera Plus	rosuvastatin (rosuvastatin calcium), ezetimibe	tablets film-coated	40mg+10mg; (30/3x10) in blister, (90/9x10) 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	22374/1 29.04.2026
11	Roxera Plus	rosuvastatin (rosuvastatin calcium), ezetimibe	tablets film-coated	10mg+10mg; (30/3x10) in blister, (60/6x10) in blister, (90/9x10) 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	23181/1 29.04.2026
12	Roxera Plus	rosuvastatin (rosuvastatin calcium), ezetimibe	tablets film-coated	20mg+10mg; (30/3x10) in blister, (60/6x10) in blister, (90/9x10) 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	23182/1 29.04.2026
13	AFOBAZOL RETARD- Oticipharm Pro	fabomotizole (fabomotizole dihydrochloride)	tablets prolonged-release	30mg; (20/1x20) 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	20993/2/1 29.04.2026

14	AFOBAZOL RETARD- Oticipharm Pro	fabomotizole (fabomotizole dihydrochloride)	tablets prolonged- release	30mg; (20/1x20) in blister	JSC "Oticipharm Pro", Kaliningrad region, Zelenogradsky m.d., ter. Industrial park Khrabrovo, Innovatorov 6 str., building 1, 238315	Russia	JSC "Oticipharm Pro", Kaliningrad region, Zelenogradsky m.d., ter. Industrial park Khrabrovo, Innovatorov 6 str., building 1, 238315	Russia	OTC	23471/1 29.04.2026
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LIST

of the variations under the EAEU procedure not requiring reformulation of registration certificate approved by the Center according to the meeting
decision N 04-2/26 on April 29, 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	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	Solpharm Pharmazeutische Erzeugnisse GmbH, Industriestr. 3, 34212, Melsungen- bulk manufacturer, packager, quality control (physicochemical), batch releaser, Labor LS SE & 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	JIИ-Nº001507-ITI-AM 29.04.2026
2	Cefecon D	paracetamol	suppositories rectal	50mg; (10/2x5)	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	JIИ-Nº002376-ITI-AM 29.04.2026
3	Cefecon D	paracetamol	suppositories rectal	100mg; (10/2x5)	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	JIИ-Nº002376-ITI-AM 29.04.2026

4	Cefecon D	paracetamol	suppositories rectal	250mg; (10/2x5)	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	ЖП-№002376-ИП-AM 29.04.2026
5	Mydocalm Long	tolperisone (tolperisone hydrochloride)	tablets film-coated prolonged release	450mg; (10/1x10) in blister, (30/3x10) in blister, (bag) 10,5-18,5 kg x 1(box)	Gedeon Richter Polska Sp. z o.o., ul. Ks. J. Poniatowskiego 5, Grodzisk Mazowiecki, 05-825- quality control, batch releaser, Gedeon Richter Polska Sp.z o.o., ul.Graniczna 35, Grodzisk Mazowiecki, 05-825, Poland- bulk manufacturer, packager	Poland	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	ЖП-№000314-ИП-AM 29.04.2026
6	Mydocalm Long	tolperisone (tolperisone hydrochloride)	tablets film-coated prolonged release	450mg; (10/1x10) in blister, (30/3x10) in blister, (bag) 10,5-18,5 kg x 1(box)	GEDEON RICHTER JSC- RUS, Lesnaya St. 40., Shuvoye, Moscow region, Yegoriyevsky district, 140342- batch releaser, Gedeon Richter Polska Sp.z o.o., ul.Graniczna 35, Grodzisk Mazowiecki, 05-825, Poland- bulk manufacturer, GEDEON RICHTER JSC- RUS, Lesnaya St. 43/5., Shuvoye, Moscow region, Yegoriyevsky district, 140342, Russia- packager, GEDEON RICHTER JSC- RUS, Lesnaya St. 40., build.1, Shuvoye, Moscow region, Yegoriyevsky district, 140342, Russia- quality control (physicochemical), GEDEON RICHTER JSC- RUS, Lesnaya St. 40., build.2, Shuvoye, Moscow region, Yegoriyevsky district, 140342, Russia- quality control (microbiological)	Russia	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	ЖП-№000314-ИП-AM 29.04.2026

7	Mydocalm Long	tolperisone (tolperisone hydrochloride)	tablets film-coated prolonged release	450mg; (10/1x10) in blister, (30/3x10) in blister, (bag) 10,5-18,5 kg x 1 (box)	GEDEON RICHTER JSC- RUS, Lesnaya St. 40., Shuvoye, Moscow region, Yegoriyevsky district, 140342- bulk manufacturer, batch releaser, GEDEON RICHTER JSC- RUS, Lesnaya St. 43/5., Shuvoye, Moscow region, Yegoriyevsky district, 140342, Russia- packager, GEDEON RICHTER JSC- RUS, Lesnaya St. 40., build.1, Shuvoye, Moscow region, Yegoriyevsky district, 140342, Russia- quality control (physicochemical), GEDEON RICHTER JSC- RUS, Lesnaya St. 40., build.2, Shuvoye, Moscow region, Yegoriyevsky district, 140342, Russia- quality control (microbiological)	Russia	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	JИП-№000314-ИТИ-AM 29.04.2026
8	Valsacor	valsartan	tablets film-coated	80mg; (28/4x7) 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	JИП-№001189-ИТИ-AM 29.04.2026
9	Valsacor	valsartan	tablets film-coated	80mg; (28/4x7) in blister	KRKA-RUS LLC, 50 Moskovskaya Str., Istra, Moscow Region, 143500	Russia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	JИП-№001189-ИТИ-AM 29.04.2026
10	Valsacor	valsartan	tablets film-coated	80mg; (28/4x7) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto- bulk manufacturer, packager, batch releaser, Chemilab d.o.o, Brnciceva ulica 31, 1231 Ljubljana Crnuce, Slovenia- quality control	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	JИП-№001189-ИТИ-AM 29.04.2026
11	Valsacor	valsartan	tablets film-coated	80mg; (28/4x7) in blister	KRKA-RUS LLC, 50 Moskovskaya Str., Istra, Moscow Region, 143500- bulk manufacturer, packager, batch releaser, Chemilab d.o.o, Brnciceva ulica 31, 1231 Ljubljana Crnuce, Slovenia- quality control	Russia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	JИП-№001189-ИТИ-AM 29.04.2026
12	Valsacor	valsartan	tablets film-coated	160mg; (28/4x7) 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	JИП-№001189-ИТИ-AM 29.04.2026
13	Valsacor	valsartan	tablets film-coated	160mg; (28/4x7) in blister	KRKA-RUS LLC, 50 Moskovskaya Str., Istra, Moscow Region, 143500	Russia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	JИП-№001189-ИТИ-AM 29.04.2026

14	Valsacor	valsartan	tablets film-coated	160mg; (28/4x7) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto- bulk manufacturer, packager, batch releaser, Chemilab d.o.o, Brnciceva ulica 31, 1231 Ljubljana Crnuce, Slovenia- quality control	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	JITI-N°001189-ITI-AM 29.04.2026
15	Valsacor	valsartan	tablets film-coated	160mg; (28/4x7) in blister	KRKA-RUS LLC, 50 Moskovskaya Str., Istra, Moscow Region, 143500- bulk manufacturer, packager, batch releaser, Chemilab d.o.o, Brnciceva ulica 31, 1231 Ljubljana Crnuce, Slovenia- quality control	Russia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	PoM	JITI-N°001189-ITI-AM 29.04.2026
16	Trichopol Polpharma	metronidazole	tablets	250mg; (20/2x10) in blister	Pharmaceutical Works Polpharma S.A., 19 Pelplinska Str., 83-200 Starogard Gdanski	Poland	Pharmaceutical Works Polpharma S.A., 19 Pelplinska Str., 83-200 Starogard Gdanski	Poland	PoM	JITI-N°001260-ITI-AM 29.04.2026
17	Zafirla	dienogest	tablets	2mg; (28/2x14) in blister, (84/6x14) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	JITI-N°000003-ITI-AM 29.04.2026
18	Sulid	nimesulide	granules for oral suspension	100mg; (30) sachets 2g	AVVA RUS JSC, Kirov region, Kirov city, Luganskaya Str. 53A	Russia	TOO "AVVA Kazakhstan", 050008, city Almaty, Almaly region, Abaya avenue, 109B, room 501	Republic of Kazakhstan	PoM	JITI-N°004593-ITI-AM 29.04.2026
19	Preductal MR	trimetazidine (trimetazidine dihydrochloride)	tablets film-coated modified-release	35mg; (60/2x30) in blister	Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy	France	Les Laboratoires Servier, 50, rue Camot, 92284 Suresnes cedex	France	PoM	JITI-N°000386-ITI-AM 29.04.2026
20	Preductal MR	trimetazidine (trimetazidine dihydrochloride)	tablets film-coated modified-release	35mg; (60/2x30) in blister	SERVIER RUS Ltd, 108828, block 158, possession 2, build.1, settlement Krasnopakhorskoye, Moscow	Russia	Les Laboratoires Servier, 50, rue Camot, 92284 Suresnes cedex	France	PoM	JITI-N°000386-ITI-AM 29.04.2026
21	Hemomycin	azithromycin (azithromycin dihydrate)	tablets film-coated	500mg; (3/1x3) in blister	Hemofarm A.D., 26300, Vrsac, Beogradskii put bb- packager, quality control (microbiological), batch releaser, Hemofarm d.o.o., Novakovici bb, Banja Luka 78000, Bosnia and Herzegovina- bulk manufacturer, quality control (physicochemical)	Serbia	Hemofarm A.D., 26300, Vrsac, Beogradskii put bb	Serbia	PoM	JITI-N°005237-ITI-AM 29.04.2026

22	Hemomycin	azithromycin (azithromycin dihydrate)	tablets film-coated	500mg; (3/1x3) in blister	Hemofarm A.D., 26300, Vrsac, Beogradskii put bb- packager, quality control, batch releaser, Hemofarm d.o.o., Novakovici bb, Banja Luka 78000, Bosnia and Herzegovina- bulk manufacturer	Serbia	Hemofarm A.D., 26300, Vrsac, Beogradskii put bb	Serbia	PoM	JИП-N*005237-ITI-AM 29.04.2026
23	Hemomycin	azithromycin (azithromycin dihydrate)	tablets film-coated	500mg; (3/1x3) in blister	Hemofarm A.D., 26300 Vrsac, Beogradski put bb	Serbia	Hemofarm A.D., 26300 Vrsac, Beogradski put bb	Serbia	PoM	JИП-N*005237-ITI-AM 29.04.2026
24	Hemomycin	azithromycin (azithromycin dihydrate)	powder lyophilized for solution for infusion	500mg; glass vial	Hemofarm A.D., 26300 Vrsac, Beogradski put bb	Serbia	Hemofarm A.D., 26300 Vrsac, Beogradski put bb	Serbia	PoM	JИП-N*005345-ITI-AM 29.04.2026
25	Kogavant	ticagrelor	tablets film-coated	60mg; (56/4x14) in blister, (112/8x14) in blister, (168/12x14) in blister	GEDEON RICHTER-RUS JSC, Lesnaya St. 40, Shuvoye, Moscow region, Yegoriyevsky district- batch releaser, Gedeon Richter Poland Co Ltd., Poland, 35 Graniczna Str., 05-825 Grodzisk Mazowiecki, Poland- bulk manufacturer, GEDEON RICHTER-RUS JSC, Lesnaya St. 43/5., Shuvoye, Moscow region, Yegoriyevsky district, Russia- packager, GEDEON RICHTER-RUS JSC, Lesnaya St. 40 build.1, build.2, Shuvoye, Moscow region, Yegoriyevsky district, Russia- quality control	Russia	Gedeon Richter PLC, Gyomroi st. 19-21, 1103 Budapest	Hungary	PoM	JИП-N*004848-ITI-AM 29.04.2026
26	Kogavant	ticagrelor	tablets film-coated	60mg; (56/4x14) in blister, (112/8x14) in blister, (168/12x14) in blister	GEDEON RICHTER-RUS JSC, Lesnaya St. 40, Shuvoye, Moscow region, Yegoriyevsky district- bulk manufacturer, batch releaser, GEDEON RICHTER-RUS JSC, Lesnaya St. 43/5., Shuvoye, Moscow region, Yegoriyevsky district, Russia- packager, GEDEON RICHTER-RUS JSC, Lesnaya St. 40 build.1, build.2, Shuvoye, Moscow region, Yegoriyevsky district, Russia- quality control	Russia	Gedeon Richter PLC, Gyomroi st. 19-21, 1103 Budapest	Hungary	PoM	JИП-N*004848-ITI-AM 29.04.2026

27	Kogavant	ticagrelor	tablets film-coated	60mg; (56/4x14) in blister, (112/8x14) in blister, (168/12x14) in blister	Gedeon Richter Poland Sp. z o.o., ul. Ks. J. Poniatowskiego 5, Grodzisk Mazowiecki, 05-825- quality control, batch releaser, Gedeon Richter Poland Sp.z o.o., ul. Graniczna 35, Grodzisk Mazowiecki, 05-825, Poland- bulk manufacturer, packager	Poland	Gedeon Richter PLC, Gyomroi st. 19-21, 1103 Budapest	Hungary	PoM	JИП-N°004848-ITI-AM 29.04.2026
28	Kogavant	ticagrelor	tablets film-coated	90mg; (56/4x14) in blister, (112/8x14) in blister, (168/12x14) in blister	GEDEON RICHTER-RUS JSC, Lesnaya St. 40, Shuvoye, Moscow region, Yegoriyevsky district- batch releaser, Gedeon Richter Poland Co Ltd., Poland, 35 Graniczna Str., 05-825 Grodzisk Mazowiecki, Poland- bulk manufacturer, GEDEON RICHTER-RUS JSC, Lesnaya St. 43/5., Shuvoye, Moscow region, Yegoriyevsky district, Russia- packager, GEDEON RICHTER-RUS JSC, Lesnaya St. 40 build.1, build.2, Shuvoye, Moscow region, Yegoriyevsky district, Russia- quality control	Russia	Gedeon Richter PLC, Gyomroi st. 19-21, 1103 Budapest	Hungary	PoM	JИП-N°004848-ITI-AM 29.04.2026
29	Kogavant	ticagrelor	tablets film-coated	90mg; (56/4x14) in blister, (112/8x14) in blister, (168/12x14) in blister	GEDEON RICHTER-RUS JSC, Lesnaya St. 40, Shuvoye, Moscow region, Yegoriyevsky district- bulk manufacturer, batch releaser, GEDEON RICHTER-RUS JSC, Lesnaya St. 43/5., Shuvoye, Moscow region, Yegoriyevsky district, Russia- packager, GEDEON RICHTER-RUS JSC, Lesnaya St. 40 build.1, build.2, Shuvoye, Moscow region, Yegoriyevsky district, Russia- quality control	Russia	Gedeon Richter PLC, Gyomroi st. 19-21, 1103 Budapest	Hungary	PoM	JИП-N°004848-ITI-AM 29.04.2026
30	Kogavant	ticagrelor	tablets film-coated	90mg; (56/4x14) in blister, (112/8x14) in blister, (168/12x14) in blister	Gedeon Richter Poland Sp. z o.o., ul. Ks. J. Poniatowskiego 5, Grodzisk Mazowiecki, 05-825- quality control, batch releaser, Gedeon Richter Poland Sp.z o.o., ul. Graniczna 35, Grodzisk Mazowiecki, 05-825, Poland- bulk manufacturer, packager	Poland	Gedeon Richter PLC, Gyomroi st. 19-21, 1103 Budapest	Hungary	PoM	JИП-N°004848-ITI-AM 29.04.2026

31	Nalgesin	naproxen (naproxen sodium)	tablets film-coated	275mg; (10/1x10) in blister, (20/2x10) 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	OTC	JITI-N°000256-IITI-AM 29.04.2026
32	Nalgesin	naproxen (naproxen sodium)	tablets film-coated	275mg; (10/1x10) in blister, (20/2x10) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto- packager, quality control, batch releaser, Unichem Laboratories Limited, Plots 15, 16, 17, 17A,18, Pilerne Industrial Estate, Pilerne, Bardez GoA, 403511, India- bulk manufacturer	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	OTC	JITI-N°000256-IITI-AM 29.04.2026
33	Nalgesin	naproxen (naproxen sodium)	tablets film-coated	275mg; (10/1x10) in blister, (20/2x10) 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 30, 1000 Lyublyana, Slovenia- quality control (physicochemical)	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	OTC	JITI-N°000256-IITI-AM 29.04.2026
34	Nalgesin	naproxen (naproxen sodium)	tablets film-coated	275mg; (10/1x10) in blister, (20/2x10) in blister	KRKA, d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo mesto- packager, quality control (microbiological), batch releaser, Unichem Laboratories Limited, Plots 15-18, Pilerne Industrial Estate, Pilerne, Bardez GoA, India- bulk manufacturer, KRKA, tovarna zdravil, d.d., Novo mesto, Povhova ulica 5, 8501 Novo Mesto, Slovenia- quality control (physicochemical)	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	OTC	JITI-N°000256-IITI-AM 29.04.2026
35	MabThera	rituximab	concentrate for solution for infusion	10mg/ml; (2) glass vials 10ml	F. Hoffmann-La Roche Ltd., Wurmisweg, 4303 Kaiseraugst- secondary packager, batch releaser, Roche Diagnostics GmbH, Sandhofer strasse 116, 68305 Mannheim, Germany- bulk manufacturer, primary packager, quality control	Switzerland	F. Hoffmann-La Roche Ltd, Grenzacherstrasse 124, 4070 Basel	Switzerland	PoM	JITI-N°004365-IITI-AM 29.04.2026

36	MabThera	rituximab	concentrate for solution for infusion	10mg/ml; (2) glass vials 10ml	F. Hoffmann-La Roche Ltd, Wurmisweg, 4303 Kaiseraugst- secondary packager, quality control, batch releaser, Roche Diagnostics GmbH, Sandhofer strasse 116, 68305 Mannheim, Germany- bulk manufacturer, primary packager	Switzerland	F. Hoffmann-La Roche Ltd, Grenzacherstrasse 124, 4070 Basel	Switzerland	PoM	JITI-N°004365-ITI- AM 29.04.2026
37	MabThera	rituximab	concentrate for solution for infusion	10mg/ml; (2) glass vials 10ml	F. Hoffmann-La Roche Ltd, Wurmisweg, 4303 Kaiseraugst- secondary packager, quality control, batch releaser, Genentech Inc., 4625 NE Brookwood Parkway, Hillsboro, OR 97124, USA- bulk manufacturer, primary packager	Switzerland	F. Hoffmann-La Roche Ltd, Grenzacherstrasse 124, 4070 Basel	France	PoM	JITI-N°004365-ITI- AM 29.04.2026
38	MabThera	rituximab	concentrate for solution for infusion	10mg/ml; (2) glass vials 10ml	F. Hoffmann-La Roche Ltd, Wurmisweg, 4303 Kaiseraugst- secondary packager, batch releaser, Genentech Inc., 4625 NE Brookwood Parkway, Hillsboro, OR 97124, USA- bulk manufacturer, primary packager, Roche Diagnostics GmbH, Sandhofer strasse 116, 68305 Mannheim, Germany- quality control	Switzerland	F. Hoffmann-La Roche Ltd, Grenzacherstrasse 124, 4070 Basel	Switzerland	PoM	JITI-N°004365-ITI- AM 29.04.2026
39	MabThera	rituximab	concentrate for solution for infusion	10mg/ml; (1) glass vial 50ml	F. Hoffmann-La Roche Ltd, Wurmisweg, 4303 Kaiseraugst- secondary packager, batch releaser, Roche Diagnostics GmbH, Sandhofer strasse 116, 68305 Mannheim, Germany- bulk manufacturer, primary packager, quality control	Switzerland	F. Hoffmann-La Roche Ltd, Grenzacherstrasse 124, 4070 Basel	Switzerland	PoM	JITI-N°004365-ITI- AM 29.04.2026
40	MabThera	rituximab	concentrate for solution for infusion	10mg/ml; (1) glass vial 50ml	F. Hoffmann-La Roche Ltd, Wurmisweg, 4303 Kaiseraugst- secondary packager, quality control, batch releaser, Roche Diagnostics GmbH, Sandhofer strasse 116, 68305 Mannheim, Germany- bulk manufacturer, primary packager	Switzerland	F. Hoffmann-La Roche Ltd, Grenzacherstrasse 124, 4070 Basel	Switzerland	PoM	JITI-N°004365-ITI- AM 29.04.2026

41	MabThera	rituximab	concentrate for solution for infusion	10mg/ml; (1) glass vial 50ml	F. Hoffmann-La Roche Ltd, Wurmisweg, 4303 Kaiseraugst- secondary packager, batch releaser, Genentech Inc., 4625 NE Brookwood Parkway, Hillsboro, OR 97124, USA- bulk manufacturer, primary packager, Roche Diagnostics GmbH, Sandhofer strasse 116, 68305 Mannheim, Germany- quality control	Switzerland	F. Hoffmann-La Roche Ltd, Grenzacherstrasse 124, 4070 Basel	Switzerland	PoM	JИП-N°004365-ИП- AM 29.04.2026
42	MabThera	rituximab	concentrate for solution for infusion	10mg/ml; (1) glass vial 50ml	F. Hoffmann-La Roche Ltd, Wurmisweg, 4303 Kaiseraugst- secondary packager, quality control, batch releaser, Genentech Inc., 4625 NE Brookwood Parkway, Hillsboro, OR 97124, USA- bulk manufacturer, primary packager	Switzerland	F. Hoffmann-La Roche Ltd, Grenzacherstrasse 124, 4070 Basel	Switzerland	PoM	JИП-N°004365-ИП- AM 29.04.2026