

LIST

of the medicines recommended for the registration by the Center according to the meeting decision N 09-1/25 on September 16, 2025

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	Tiosinekt	thioctic acid (thioctic acid meglumine)	solution for injection	12mg/ml; (1) glass vial 50ml	SC Balkan Pharmaceuticals SRL, Industriala street 7/A, MD-2091 Singera	Moldova	SPEY MEDICAL LTD, Lynton House 7-12 Tavistock Square, London, WC1H 9LT	UK	PoM	23448 16.09.2025
2	BP Anest with Adrenaline 1:100000	articaine (articaine hydrochloride), adrenaline (adrenaline tartrate)	solution for injection	40mg/ml+0,01mg/ml; (60/4x15/) cartridges 1,7ml, in blister	SC Balkan Pharmaceuticals SRL, Industriala street 7/A, MD-2091, Singera	Moldova	SC Balkan Pharmaceuticals SRL, Industriala street 7/A, MD-2091, Singera	Moldova	PoM	23449 16.09.2025
3	Relief Advance	benzocaine	suppositories rectal	206mg; (10/2x5/)	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7, apt. 1- quality control (physicochemical), batch releaser, Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7, Russia- bulk manufacturer, packager, Farmoborona Test Center, Ltd., 141074, Korolyov, Moscow Region, Gagarin St., 46A, Russia- quality control (microbiological)	Russia	JSC BAYER, 3rd Rybinskaya st., 18, build. 2, 107113 Moscow	Russia	OTC	23450 16.09.2025
4	Enclex	enoxaparin (enoxaparin sodium)	solution for injection	40mg/0,4ml; (10) pre-filled syringe 0,4ml	Biological E. Limited, Plot No.4, Survey No.542/P, Biotech Park, Phase-II, Kolthur Village, Shamirpet Mandal, Medchal, Telangana 500 078	India	Cipla Limited, Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai, Maharashtra - 400013	India	PoM	23451 16.09.2025
5	Enclex	enoxaparin (enoxaparin sodium)	solution for injection	60mg/0,6ml; (10) pre-filled syringe 0,6ml	Biological E. Limited, Plot No.4, Survey No.542/P, Biotech Park, Phase-II, Kolthur Village, Shamirpet Mandal, Medchal, Telangana 500 078	India	Cipla Limited, Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai, Maharashtra - 400013	India	PoM	23452 16.09.2025

6	Enclex	enoxaparin (enoxaparin sodium)	solution for injection	80mg/0,8ml; (10) pre-filled syringe 0,8ml	Biological E. Limited, Plot No.4, Survey No.542/P, Biotech Park, Phase-II, Kolthur Village, Shamirpet Mandal, Medchal, Telangana 500 078	India	Cipla Limited, Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai, Maharashtra - 400013	India	PoM	23453 16.09.2025
7	AMBER	ambroxol (ambroxol hydrochloride)	tablets film-coated	30mg; (20/2x10) in blister, (100/10x10) in blister	A LAB PHARMACEUTICALS LLC, Kochinyan 13/16, Yerevan- packager, quality control, batch releaser, RELAX BIOTECH PVT. LTD, 862/1, G.I.D.C., MAKARPURA, BARODA- 390010, India- bulk manufacturer	Republic of Armenia	A LAB PHARMACEUTICALS LLC, Kochinyan 13/16, Yerevan	Republic of Armenia	OTC	23454 16.09.2025
8	Artheek SP	articaine (articaine hydrochloride), epinephrine (adrenaline)	solution for injection	40mg/ml+10mcg/ml; (50) cartridges 1,8ml	New Stetic S.A. Carrera 53, No 50-09, GUARNE, ANTIOQUIA	Colombia	New Stetic S.A. Carrera 53, No 50-09, GUARNE, ANTIOQUIA	Colombia	PoM	23455 16.09.2025
9	Metoclopramide	metoclopramide (metoclopramide hydrochloride)	solution for i/v and i/m injection	5mg/ml; (5/1x5) ampoules 2ml in blister, (10/2x5) ampoules 2ml in blister	Moscow Endocrine Plant FSUE, 25, bld 1, Novokhokhlovskaya st., Moscow, 109052- quality control, batch releaser, "Moscow Endocrine Plant FSUE", 25, bld 2, Novokhokhlovskaya st., Moscow, 109052, Russia- bulk manufacturer, packager	Russia	"Moscow Endocrine Plant FSUE", 25, bld 1, Novokhokhlovskaya st., Moscow, 109052	Russia	PoM	23456 16.09.2025
10	DECALERTO	rivaroxaban	tablets film-coated	2,5mg; (10/1x10) in blister	Ibn Al Haytham Pharma Industries Co., Al Mansura, Aleppo	Syria	Ibn Al Haytham Pharma Industries Co., Al Mansura, Aleppo	Syria	PoM	23458 16.09.2025
11	DECALERTO	rivaroxaban	tablets film-coated	10mg; (10/1x10) in blister	Ibn Al Haytham Pharma Industries Co., Al Mansura, Aleppo	Syria	Ibn Al Haytham Pharma Industries Co., Al Mansura, Aleppo	Syria	PoM	23459 16.09.2025
12	DECALERTO	rivaroxaban	tablets film-coated	15mg; (10/1x10) in blister	Ibn Al Haytham Pharma Industries Co., Al Mansura, Aleppo	Syria	Ibn Al Haytham Pharma Industries Co., Al Mansura, Aleppo	Syria	PoM	23460 16.09.2025
13	DECALERTO	rivaroxaban	tablets film-coated	20mg; (10/1x10) in blister	Ibn Al Haytham Pharma Industries Co., Al Mansura, Aleppo	Syria	Ibn Al Haytham Pharma Industries Co., Al Mansura, Aleppo	Syria	PoM	23461 16.09.2025

14	Dentocain Simple	mepivacaine (mepivacaine hydrochloride)	solution for injection	30mg/ml; (50/5x10) glass cartridges 1,8ml, (50/5x10) plastic cartridges 1,8ml	LABORATORIOS ZEYCO, S.A. DE C.V., Camino a Santa Ana Tepetitlan No. 2230-C Col. Santa Ana Tepetitlan C.P. 45230, Zapopan, Jalisco	Mexico	LABORATORIOS ZEYCO, S.A. DE C.V., Camino a Santa Ana Tepetitlan No. 2230-C Col. Santa Ana Tepetitlan C.P. 45230, Zapopan, Jalisco	Mexico	PoM	23462 16.09.2025
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LIST

of the medicines recommended for registration under the EAEU procedure by the Center according to the meeting decision N 09-1/25 on September 16, 2025

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	Roxatenz-amlo	perindopril (perindopril tert-butylamine), amlodipine, rosuvastatin (rosuvastatin calcium)	tablets film-coated	4mg+5mg+10mg; (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	23412 (000628) 16.09.2025
2	Roxatenz-amlo	perindopril (perindopril tert-butylamine), amlodipine, rosuvastatin (rosuvastatin calcium)	tablets film-coated	8mg+5mg+10mg; (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	23413 (000628) 16.09.2025
3	Roxatenz-amlo	perindopril (perindopril tert-butylamine), amlodipine, rosuvastatin (rosuvastatin calcium)	tablets film-coated	8mg+5mg+20mg; (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	23414 (000628) 16.09.2025
4	Roxatenz-amlo	perindopril (perindopril tert-butylamine), amlodipine, rosuvastatin (rosuvastatin calcium)	tablets film-coated	8mg+10mg+20mg; (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	23415 (000628) 16.09.2025
5	Bromhexine	bromhexine (bromhexine hydrochloride)	tablets	8mg; (50/5x10) in blister	Open joint stock company "Borisovskiy zavod medicinskih preparatov", 24, Stroiteley str., Borisov, Minsk region	Republic of Belarus	Open joint stock company "Borisovskiy zavod medicinskih preparatov" 64, Chapayev str., Borisov 222518, Minsk region	Republic of Belarus	OTC	23416 (007746) 16.09.2025

6	Retinalamin	cattle eye retina polypeptides	powder lyophilized for solution for i/m and parabolbar injection	5mg; (10/2x5/) glass vials 5ml in blister	GEROPHARM Ltd., Moscow region, Serpukhov city district, Obolensk settlement, "Kvartal A" area, lane 82, bldg. 4- quality control (microbiological), batch releaser, "GEROPHARM" Ltd., Moscow region, Serpukhov city district, Obolensk settlement, "Kvartal A" area, bldg. 5, Russia- bulk manufacturer, packager, quality control (physicochemical)	Russia	"GEROPHARM" Ltd, 9 Zvenigorodskaya st., 191119 Saint Petersburg	Russia	PoM	23417 (001175) 16.09.2025
7	Retinalamin	cattle eye retina polypeptides	powder lyophilized for solution for i/m and parabolbar injection	5mg; (10/2x5/) glass vials 5ml in blister	GEROPHARM Ltd., Moscow region, Serpukhov city district, Obolensk settlement, "Kvartal A" area, lane 82, bldg. 4- quality control (microbiological), batch releaser, "GEROPHARM" Ltd., Moscow region, Serpukhov city district, Obolensk settlement, "Kvartal A" area, bldg. 5, Russia- bulk manufacturer, packager, quality control (physicochemical)	Russia	"GEROPHARM" Ltd, 9 Zvenigorodskaya st., 191119 Saint Petersburg	Russia	PoM	23418 (001175) 16.09.2025
8	Retinalamin	cattle eye retina polypeptides	powder lyophilized for solution for i/m and parabolbar injection	5mg; (10/2x5/) glass vials 5ml in blister	GEROPHARM Ltd., Moscow region, Serpukhov city district, Obolensk settlement, "Kvartal A" area, lane 82, bldg. 4- quality control (microbiological), batch releaser, "GEROPHARM" Ltd., Moscow region, Serpukhov city district, Obolensk settlement, "Kvartal A" area, bldg. 5, Russia- bulk manufacturer, packager, quality control (physicochemical)	Russia	"GEROPHARM" Ltd, 9 Zvenigorodskaya st., 191119 Saint Petersburg	Russia	PoM	23419 (001175) 16.09.2025
9	Retinalamin	cattle eye retina polypeptides	powder lyophilized for solution for i/m and parabolbar injection	5mg; (10/2x5/) glass vials 5ml in blister	GEROPHARM Ltd., Moscow region, Serpukhov city district, Obolensk settlement, "Kvartal A" area, lane 82, bldg. 4- quality control (microbiological), batch releaser, "GEROPHARM" Ltd., Moscow region, Serpukhov city district, Obolensk settlement, "Kvartal A" area, bldg. 5, Russia- bulk manufacturer, packager, quality control (physicochemical)	Russia	"GEROPHARM" Ltd, 9 Zvenigorodskaya st., 191119 Saint Petersburg	Russia	PoM	23420 (001175) 16.09.2025
10	Dopegyt	methyl dopa (methyl dopa sesquihydrate)	tablets	250mg; (50) in glass container	Egis Pharmaceuticals PLC, 9900, Kormend, Matyas Kiraly u. 65	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	23421 (003183) 16.09.2025

11	Egolanza	olanzapine (olanzapine dihydrochloride trihydrate)	tablets film-coated	5mg; (28/4x7/) in blister, (56/8x7/) in blister	Egis Pharmaceuticals PLC, 9900, Kormend, Matyas Kiraly u. 65	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	23422 (001402) 16.09.2025
12	Egolanza	olanzapine (olanzapine dihydrochloride trihydrate)	tablets film-coated	10mg; (28/4x7/) in blister, (56/8x7/) in blister	Egis Pharmaceuticals PLC, 9900, Kormend, Matyas Kiraly u. 65	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	23423 (001402) 16.09.2025
13	Egolanza	olanzapine (olanzapine dihydrochloride trihydrate)	tablets film-coated	15mg; (28/4x7/) in blister, (56/8x7/) in blister	Egis Pharmaceuticals PLC, 9900, Kormend, Matyas Kiraly u. 65	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	23424 (001402) 16.09.2025
14	Egolanza	olanzapine (olanzapine dihydrochloride trihydrate)	tablets film-coated	20mg; (28/4x7/) in blister, (56/8x7/) in blister	Egis Pharmaceuticals PLC, 9900, Kormend, Matyas Kiraly u. 65	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	PoM	23425 (001402) 16.09.2025
15	Celebrex	celecoxib	capsules	100mg; (10/1x10/) in blister, (20/2x10/) in blister, (30/3x10/) in blister, (40/4x10/) in blister, (50/5x10/) in blister, (100/10x10/) in blister	Pfizer Manufacturing Deutschland GmbH, Mooswaldallee 1, 79090 Frieburg Im Breisgau - packager, quality control, batch releaser, Pfizer Pharmaceuticals LLC, 1.9 km Road 689, Vega Baja, Puerto Rico 00693, USA- bulk manufacturer	Germany	VIATRIS SPECIALTY LLC, 3711 Collins Ferry Road, Morgantown, WV 26505	USA	PoM	23426 (012746) 16.09.2025
16	Celebrex	celecoxib	capsules	200mg; (10/1x10/) in blister, (20/2x10/) in blister, (30/3x10/) in blister, (40/4x10/) in blister, (50/5x10/) in blister, (100/10x10/) in blister	Pfizer Manufacturing Deutschland GmbH, Mooswaldallee 1, 79090 Frieburg Im Breisgau - packager, quality control, batch releaser, Pfizer Pharmaceuticals LLC, 1.9 km Road 689, Vega Baja, Puerto Rico 00693, USA- bulk manufacturer	Germany	VIATRIS SPECIALTY LLC, 3711 Collins Ferry Road, Morgantown, WV 26505	USA	PoM	23427 (012746) 16.09.2025
17	Captopril	captopril	tablets	25mg; (40/4x10/) in blister	Open joint stock company "Borisovskiy zavod medicinskih preparatov", 64A, 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	23428 (014733) 16.09.2025
18	Detragel	heparin sodium, essential phospholipids, escin	gel for external use	100IU+10mg+10mg; 40g aluminium tube; 80g aluminium tube	Bosnalijek d.d., Jukiceva 53, 71000 Sarajevo	Bosnia And Herzegovina	Servier JSC, 125196, Lesnaya str., 7, floor 7/8/9, Moscow	Russia	OTC	23429 (003902) 16.09.2025
19	Lyrica	pregabalin	capsules	25mg; (14/1x14/) in blister, (56/4x14/) in blister, (84/4x21/) in blister, (100/10x10/) in blister	Pfizer Manufacturing Deutschland GmbH, Mooswaldallee 1, 79090 Frieburg Im Breisgau	Germany	VIATRIS SPECIALTY LLC, 3711 Collins Ferry Road, Morgantown, WV 26505	USA	PoM	23430 (009083) 16.09.2025

20	Lyrica	pregabalin	capsules	50mg; (14/1x14) in blister, (56/4x14) in blister, (84/4x21) in blister, (100/10x10) in blister	Pfizer Manufacturing Deutschland GmbH, Mooswaldallee 1, 79090 Frieberg Im Breisgau	Germany	VIATRIS SPECIALTY LLC, 3711 Collins Ferry Road, Morgantown, WV 26505	USA	PoM	23431 (009083) 16.09.2025
21	Lyrica	pregabalin	capsules	75mg; (14/1x14) in blister, (56/4x14) in blister, (84/4x21) in blister, (100/10x10) in blister	Pfizer Manufacturing Deutschland GmbH, Mooswaldallee 1, 79090 Frieberg Im Breisgau	Germany	VIATRIS SPECIALTY LLC, 3711 Collins Ferry Road, Morgantown, WV 26505	USA	PoM	23432 (009083) 16.09.2025
22	Lyrica	pregabalin	capsules	100mg; (14/1x14) in blister, (56/4x14) in blister, (84/4x21) in blister, (100/10x10) in blister	Pfizer Manufacturing Deutschland GmbH, Mooswaldallee 1, 79090 Frieberg Im Breisgau	Germany	VIATRIS SPECIALTY LLC, 3711 Collins Ferry Road, Morgantown, WV 26505	USA	PoM	23433 (009083) 16.09.2025
23	Lyrica	pregabalin	capsules	150mg; (14/1x14) in blister, (56/4x14) in blister, (84/4x21) in blister, (100/10x10) in blister	Pfizer Manufacturing Deutschland GmbH, Mooswaldallee 1, 79090 Frieberg Im Breisgau	Germany	VIATRIS SPECIALTY LLC, 3711 Collins Ferry Road, Morgantown, WV 26505	USA	PoM	23434 (009083) 16.09.2025
24	Lyrica	pregabalin	capsules	200mg; (14/1x14) in blister, (56/4x14) in blister, (84/4x21) in blister, (100/10x10) in blister	Pfizer Manufacturing Deutschland GmbH, Mooswaldallee 1, 79090 Frieberg Im Breisgau	Germany	VIATRIS SPECIALTY LLC, 3711 Collins Ferry Road, Morgantown, WV 26505	USA	PoM	23435 (009083) 16.09.2025
25	Lyrica	pregabalin	capsules	300mg; (14/1x14) in blister, (56/4x14) in blister, (84/4x21) in blister, (100/10x10) in blister	Pfizer Manufacturing Deutschland GmbH, Mooswaldallee 1, 79090 Frieberg Im Breisgau	Germany	VIATRIS SPECIALTY LLC, 3711 Collins Ferry Road, Morgantown, WV 26505	USA	PoM	23436 (009083) 16.09.2025
26	VALIDOL	menthol solution in menthyl isovalerate	capsules	100mg; (15/1x15) in blister, (30/2x15) in blister	Minskintercaps U.V., 26/3, Inzhenernaya str., 220075, Minsk	Republic of Belarus	Minskintercaps U.V., 26, Inzhenernaya str., 220075, Minsk	Republic of Belarus	OTC	23437 (014772) 16.09.2025
27	Nolpaza	pantoprazole (pantoprazole sodium sesquihydrate)	tablets gastro-resistant	20mg; (28/2x14) in blister, (56/4x14) 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	23438 (009217) 16.09.2025
28	Nolpaza	pantoprazole (pantoprazole sodium sesquihydrate)	tablets gastro-resistant	20mg; (28/2x14) in blister, (56/4x14) 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	23439 (009217) 16.09.2025
29	Nolpaza	pantoprazole (pantoprazole sodium sesquihydrate)	tablets gastro-resistant	20mg; (28/2x14) in blister, (56/4x14) in blister	KRKA-RUS LLC, 50 Moskovskaya Str., Istra, Moscow Region, 143500- batch releaser, packager, quality control, 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	23440 (009217) 16.09.2025

30	Nolpaza	pantoprazole (pantoprazole sodium sesquihydrate)	tablets gastro-resistant	20mg; (28/2x14) in blister, (56/4x14) in blister	KRKA-RUS LLC, 50 Moskovskaya Str., Istra, Moscow Region, 143500- batch releaser, secondary packager, quality control, 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	23441 (009217) 16.09.2025
31	Nolpaza	pantoprazole (pantoprazole sodium sesquihydrate)	tablets gastro-resistant	40mg; (14/1x14) in blister, (28/2x14) in blister, (56/4x14) 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	23442 (009217) 16.09.2025
32	Nolpaza	pantoprazole (pantoprazole sodium sesquihydrate)	tablets gastro-resistant	40mg; (14/1x14) in blister, (28/2x14) in blister, (56/4x14) 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	23443 (009217) 16.09.2025
33	Nolpaza	pantoprazole (pantoprazole sodium sesquihydrate)	tablets gastro-resistant	40mg; (14/1x14) in blister, (28/2x14) in blister, (56/4x14) in blister	KRKA-RUS LLC, 50 Moskovskaya Str., Istra, Moscow Region, 143500- batch releaser, packager, quality control, 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	23444 (009217) 16.09.2025
34	Nolpaza	pantoprazole (pantoprazole sodium sesquihydrate)	tablets gastro-resistant	40mg; (14/1x14) in blister, (28/2x14) in blister, (56/4x14) in blister	KRKA-RUS LLC, 50 Moskovskaya Str., Istra, Moscow Region, 143500- batch releaser, secondary packager, quality control, 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	23445 (009217) 16.09.2025
35	Biseptol Medana	sulfamethoxazole, trimethoprim	suspension oral	200mg/5ml+40mg/5ml; 80ml glass bottle and measuring cup	Pharmaceutical Works POLPHARMA S.A. Medana Branch in Sieradz, 10 Wladyslawa Lokietka St. 98-200 Sieradz- batch releaser, Pharmaceutical Works POLPHARMA S.A. Medana Branch in Sieradz, 57 Polskiej Organizacji Wojskowej st. 98-200 Sieradz, Poland- bulk manufacturer, packager, quality control	Poland	Pharmaceutical Works Polpharma S.A., 19 Pelplinska Str., 83-200 Starogard Gdanski	Poland	PoM	23446 (009083) 16.09.2025
36	Depantol	dexpanthenol, chlorhexidine (chlorhexidine bigluconate)	suppositories vaginal	100mg+16mg; (5/1x5/), (10/2x5/), (20/4x5/)	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	PoM	23447 (009924) 16.09.2025

37	Nuroton Zero	ibuprofen	suspension oral	100mg/5ml; 100ml plastic bottle and measuring syringe 5ml	Pharmtechnology LLC, Korzhenevskogo str., 22, 220024, Minsk	Republic of Armenia	Giga Farm LLC, Gogunca str.3/5, Gyumri	Republic of Armenia	OTC	23465 (028622) 16.09.2025
38	Nuroton	ibuprofen	suspension oral	100mg/5ml; 100ml plastic bottle and measuring syringe 5ml	Pharmtechnology LLC, Korzhenevskogo str., 22, 220024, Minsk	Republic of Armenia	Giga Farm LLC, Gogunca str.3/5, Gyumri	Republic of Armenia	OTC	23466 (028126) 16.09.2025

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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	Cratal	crataegus, leonurus, taurine	tablets	43mg+87mg+867mg; (20/2x10/) in blister	SIC "Borshchahivskiy Chemical-Pharmaceutical Plant" PJSC, 17, Mira St, Kyiv, 03134	Ukraine	SIC "Borshchahivskiy Chemical-Pharmaceutical Plant" PJSC, 17, Mira St, Kyiv, 03134	Ukraine	OTC	23397 16.09.2025
2	Numeta G13%E Preterm	alanine, arginine, aspartic acid, cysteine, glutamic acid, glycine, histidine, Isoleucine, leucine, lysine monohydrate, methionine, ornithine hydrochloride, phenylalanine, proline, serine, taurine, threonine, tryptophan, tyrosine, valine, potassium acetate, calcium chloride dehydrate, magnesium acetate tetrahydrate, sodium glycerophosphate hydrated, glucose monohydrate, refined olive oil + refined soya bean oil	emulsion for infusion	0,75g+0,78g+0,56g+0,18g+0,93g+0,37g+0,35g+0,62g+0,93g+1,15g+0,22g+0,30g+0,39g+0,28g+0,37g+0,06g+0,35g+0,19g+0,07g+0,71g+0,61g+0,55g+0,10g+0,98g+44g+7,5g; (10) bags 300ml	Baxter SA., Boulevard Rene Branquart 80, Lessines, 7860	Belgium	Baxter Healthcare Ltd, Caxton Way, Thetford, Norfolk, IP24 3SE	UK	PoM	23398 16.09.2025

3	Numeta G16%E	alanine, arginine, aspartic acid, cysteine, glutamic acid, glycine, histidine, Isoleucine, leucine, lysine monohydrate, methionine, ornithine hydrochloride, phenylalanine, proline, serine, taurine, threonine, tryptophan, tyrosine, valine, sodium chloride, potassium acetate, calcium chloride dehydrate, magnesium acetate tetrahydrate, sodium glycerophosphate hydrated, glucose monohydrate, refined olive oil + refined soya bean oil	emulsion for infusion	1,03g+1,08g+0,77g+0,24g+1,29g+0,51g+0,49g+0,86g+1,29g+1,59g+0,31g+0,41g+0,54g+0,39g+0,51g+0,08g+0,48g+0,26g+0,10g+0,98g+0,30g+1,12g+0,46g+0,33g+0,98g+85,25+15,5g (6) bags 500ml	Baxter SA., Boulevard Rene Branquart 80, Lessines, 7860	Belgium	Baxter Healthcare Ltd, Caxton Way, Thetford, Norfolk, IP24 3SE	UK	PoM	23399 16.09.2025
4	Nalgesin	naproxen (naproxen sodium)	tablets film-coated	220mg (10/1x10/) in blister, (30/3x10/) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto- bulk manufacturer, packager, quality control (microbiological), batch releaser, KRKA 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	23400 16.09.2025
5	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 Norrbroplatsen 2, Helsingborg, 25109	Sweden	Johnson & Johnson LLC, 121614, Moscow, Krylatskaya str., 17, building 2	Russia	OTC	23401 16.09.2025

LIST

of the medicines with extended of the registration certificate term by the Center according to the meeting decision N 09-1/25 on September 16, 2025

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	Xefocam Rapid	lornoxicam	tablets film-coated	8mg; (12/2x6) in blister	Takeda GmbH, Betriebsstatte Oranienburg, Lehnitzstrasse 70-98, 16515 Oranienburg	Russia	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	PoM	23403 16.09.2025
2	Cefichew	cefixime (cefixime trihydrate)	tablets chewable	400mg; (10/1x10) in blister	Maxim Pharmaceuticals Pvt. Ltd., Plot No. 11 & 12, Gat No. 1251-1261, Alandi-Markal Road, Markal Khed, Pune 412 105, Maharashtra State	India	SRS Pharmaceuticals Pvt. Ltd., 504, 5th Floor, Marathon Max Bldg. No 2, Mulund-Goregaon Link Road, L.B.S. Marg, Mulund, Mumbai 400 080	India	PoM	23404 16.09.2025
3	Ketoconazole	ketoconazole	shampoo	20mg/ml; plastic container 90ml	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	23405 16.09.2025
4	HEXALYSE	biclotymol, lysozyme (lysozyme hydrochloride), enoxolone	tablets orodispersible	5mg+5mg+5mg; (30/3x10) in blister	Laboratoires Bouchara-Recordati, Parc Mecatronic 03410 Saint Victo	France	Laboratoires Bouchara-Recordati, Immeuble le Wilson, 70 avenue du General de Gaulle, 92800 Puteaux	France	OTC	23406 16.09.2025
5	Ceftriaxone 1g powder for solution for injection or infusion	ceftriaxone (ceftriaxone sodium)	powder for solution for injection or infusion	1000mg; (10) glass vials	CP Pharmaceuticals Ltd., Ash Road North, Wrexham, LL13 9UF- batch releaser, Labesfal-Laboratorios Almiro, S.A, Zona Industrial do Lagedo, Santiago de Besteiros, 3465-157, Portugal- bulk manufacturer, packager, quality control	UK	Wockhardt UK Ltd., Ash Road North, Wrexham, LL13 9UF	UK	PoM	23407 16.09.2025

6	Somazina	citicoline (citicoline sodium)	solution for injection	1000mg/4ml; (5) ampoules 4ml	Ferrer International, S.A., Joan Buscalla,1-9 08173 Sant Cugat del Valles, Barcelona	Spain	Ferrer International, S.A., Gran Via Carlos III, 94, 08028, Barcelona	Spain	PoM	23408 16.09.2025
7	Anti Gripp complex for children	pheniramine (pheniramine maleate), paracetamol, vitamin C	powder for oral solution with raspberry flavor	10mg+280mg+100mg; (10) sachets 8g	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	23409 16.09.2025
8	Anti Gripp complex with lemon flavor	pheniramine (pheniramine maleate), paracetamol, vitamin C	powder for oral solution with lemon flavor	25mg+500mg+200mg; (10) sachets 8g	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	23410 16.09.2025
9	Afobazol-Oticipharm Pro	fabomotizole (fabomotizole dihydrochloride)	tablets	10mg; (30/1x30/) in blister, (60/3x20/) in blister, (60/2x30/) in blister, (90/3x30/) in blister, (120/4x30/) 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	23411 16.09.2025

LIST

of the variations requiring registration approved by the Center according to the meeting decision N 09-1/25 on September 16, 2025

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	Afobazol-Oticipharm Pro	fabomotizole (fabomotizole dihydrochloride)	tablets	10mg; (30/1x30) in blister, (60/3x20) in blister, (60/2x30) in blister, (90/3x30) in blister, (120/4x30) 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	23468 16.09.2025
2	Azitrox-Oticipharm Pro	azithromycin (azithromycin dihydrate)	capsules	250mg; (6/1x6) in blister	JSC "Oticipharm Pro", Kaliningrad region, Zelenogradsky m.d., ter. Industrial park Khrabrovo, Innovatorov str., 6, building 1	Russia	JSC "Oticipharm Pro", Kaliningrad region, Zelenogradsky m.d., ter. Industrial park Khrabrovo, Innovatorov str., 6, building 1, 238315	Russia	PoM	23394 25.08.2025
3	Azitrox-Oticipharm Pro	azithromycin (azithromycin dihydrate)	capsules	500mg; (2/1x2) in blister, (3/1x3) in blister	JSC "Oticipharm Pro", Kaliningrad region, Zelenogradsky m.d., ter. Industrial park Khrabrovo, Innovatorov str., 6, building 1	Russia	JSC "Oticipharm Pro", Kaliningrad region, Zelenogradsky m.d., ter. Industrial park Khrabrovo, Innovatorov str., 6, building 1, 238315	Russia	PoM	23395 25.08.2025

LIST

of variations requiring reformulation of registration certificate approved by the Center according to the meeting decision N 09-1/25 on September 16, 2025

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	Ferrum LEK	iron (III) hydroxide with polymaltose complex	tablets chewable	100mg; (30/3x10') in blister	Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana- batch releaser, quality control (microbiological), Novartis Pharmaceuticals Manufacturing LLC, Verovskova Ulica 57, 1000, Ljubljana bulk manufacturer, packager, quality control (physicochemical)	Slovenia	Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	PoM	20950/2/1 16.09.2025
2	Ketoconazole	ketoconazole	shampoo	20mg/ml; plastic container 90ml	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	19294/2/2 16.09.2025
3	Paclitaxel 6mg/ml	paclitaxel	concentrate for solution for infusion	6mg/ml; 5ml glass vial	SEACROSS PHARMACEUTICALS LIMITED, BEAUMONT BUSINESS CENTRES, 6 SNOW HILL, LONDON, EC1A 2AY - batch releaser, Sichuan Huiyu Pharmaceuticals Co.,Ltd, Building 3, No.333, Hanyang Road, Shizhong District, Neijiang, Sichuan, China- bulk manufacturer, packager, quality control	UK	SEACROSS PHARMACEUTICALS LIMITED, BEAUMONT BUSINESS CENTRES, 6 SNOW HILL, LONDON, EC1A 2AY	UK	PoM	20768/1/1 16.09.2025
4	Paclitaxel 6mg/ml	paclitaxel	concentrate for solution for infusion	6mg/ml; 16,7ml glass vial	SEACROSS PHARMACEUTICALS LIMITED, BEAUMONT BUSINESS CENTRES, 6 SNOW HILL, LONDON, EC1A 2AY - batch releaser, Sichuan Huiyu Pharmaceuticals Co.,Ltd, Building 3, No.333, Hanyang Road, Shizhong District, Neijiang, Sichuan, China- bulk manufacturer, packager, quality control	UK	SEACROSS PHARMACEUTICALS LIMITED, BEAUMONT BUSINESS CENTRES, 6 SNOW HILL, LONDON, EC1A 2AY	UK	PoM	20769/1/1 16.09.2025

5	Paclitaxel 6mg/ml	paclitaxel	concentrate for solution for infusion	6mg/ml; 50ml glass vial	SEACROSS PHARMACEUTICALS LIMITED, BEAUMONT BUSINESS CENTRES, 6 SNOW HILL, LONDON, EC1A 2AY - batch releaser, Sichuan Huiyu Pharmaceuticals Co.,Ltd, Building 3, No.333, Hanyang Road, Shizhong District, Neijiang, Sichuan, China- bulk manufacturer, packager, quality control	UK	SEACROSS PHARMACEUTICALS LIMITED, BEAUMONT BUSINESS CENTRES, 6 SNOW HILL, LONDON, EC1A 2AY	UK	PoM	20770/1/1 16.09.2025
6	Oxaliplatin 5mg/ ml concentrate for solution for infusion	oxaliplatin	concentrate for solution for infusion	5mg/ml; 10ml glass vial	SEACROSS PHARMACEUTICALS LIMITED, BEAUMONT BUSINESS CENTRES, 6 SNOW HILL, LONDON, EC1A 2AY - batch releaser, Sichuan Huiyu Pharmaceuticals Co.,Ltd, Building 3, No.333, Hanyang Road, Shizhong District, Neijiang, Sichuan, China- bulk manufacturer, packager, quality control	UK	SEACROSS PHARMACEUTICALS LIMITED, BEAUMONT BUSINESS CENTRES, 6 SNOW HILL, LONDON, EC1A 2AY	UK	PoM	20771/1/1 16.09.2025
7	Oxaliplatin 5mg/ ml concentrate for solution for infusion	oxaliplatin	concentrate for solution for infusion	5mg/ml; 20ml glass vial	SEACROSS PHARMACEUTICALS LIMITED, BEAUMONT BUSINESS CENTRES, 6 SNOW HILL, LONDON, EC1A 2AY - batch releaser, Sichuan Huiyu Pharmaceuticals Co.,Ltd, Building 3, No.333, Hanyang Road, Shizhong District, Neijiang, Sichuan, China- bulk manufacturer, packager, quality control	UK	SEACROSS PHARMACEUTICALS LIMITED, BEAUMONT BUSINESS CENTRES, 6 SNOW HILL, LONDON, EC1A 2AY	UK	PoM	20772/1/1 16.09.2025

LIST

of the variations under the EAEU procedure requiring reformulation of registration certificate approved by the Center according to the meeting
decision N 09-1/25 on September 16, 2025

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	Besponsa	inotuzumab ozogamicin	lyophilizate for concentrate for solution for infusion	1mg; glass vial 20ml	Pharmacia and Upjohn Company, 7000 Portage road, Kalamazoo, Michigan, 49001 - secondary packager, batch releaser, Wyeth pharmaceutical Division of Wyeth Holdings LLC, 401 North Middletown Road, Pearl River, New York 10965, USA- bulk manufacturer, primary packager, quality control	USA	Pfizer Inc., 66 Hudson Boulevard East, New York, New York 10001-2192	USA	PoM	ЛП-№000413-ИТ-АМ 16.09.2025
2	Tantum Verde	benzydamine (benzydamine hydrochloride)	solution for local use	150mg/100ml; 120ml glass bottle and measuring cup, 240ml glass bottle and measuring cup, 500ml plastic bottle and measuring cup	Aziende Chimiche Riunite Angelini Francesco A.C.R.A.F. S.p.A. Via Vecchia Del Pinocchio, 22, 60131 Ancona	Italy	Angelini Pharma S.p.A., Viale, Amelia 70, 00181, Rome,	Italy	OTC	ЛП-№000704-ИТ-АМ 16.09.2025
3	Vitaprost Forte	extract of prostate	suppositories rectal	20mg; (10/2x5/)	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7, s.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	ЛП-№000284-ИТ-АМ 16.09.2025
4	Vitaprost	prostate extract	suppositories rectal	10mg; (10/2x5/)	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	Nizhpharm JSC, 603105, Nizhny Novgorod, Salganskaya st., 7	Russia	OTC	ЛП-№000363-ИТ-АМ 16.09.2025

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	ЛПТ-№000314-ГТИ- AM 16.09.2025
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	ЛПТ-№000314-ГТИ- AM 16.09.2025

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	ЛПТ-№000314-ИТИ- AM 16.09.2025
8	Noliprel A Bi-forte	indapamide, perindopril arginine	tablets film-coated	2,5mg+10mg; (30) in plastic container	Servier (Ireland) Industries Ltd., Gorey Road, Arklow-Co. Wicklow, Y14 E284	Ireland	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	ЛПТ-№001806-ИТИ- AM 16.09.2025
9	Noliprel A Bi-forte	indapamide, perindopril arginine	tablets film-coated	2,5mg+10mg; (30) in plastic container, (90) in plastic container	SERVIER RUS Ltd, 108828, block 158, possession 2, build.1, settlement Krasnopakhorskoye, Moscow	Russia	Les Laboratoires Servier, 50, rue Carnot, 92284 Suresnes cedex	France	PoM	ЛПТ-№001806-ИТИ- AM 16.09.2025
10	Diroton	lisinopril (lisinopril dihydrate)	tablets	5mg; (14/1x14) in blister, (28/2x14) in blister, (56/4x14) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	ЛПТ-№002345-ИТИ- AM 16.09.2025

11	Diroton	lisinopril (lisinopril dihydrate)	tablets	5mg; (14/1x14) in blister, (28/2x14) in blister, (56/4x14) in blister	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	ЛПТ-№002345-ITI-AM 16.09.2025
12	Diroton	lisinopril (lisinopril dihydrate)	tablets	5mg; (14/1x14) in blister, (28/2x14) in blister, (56/4x14) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest- bulk manufacturer, primary packager, batch releaser, GEDEON RICHTER JSC - RUS, Lesnaya St. 43/5., Shuvoye, Moscow region, Yegoriyevsky district, 140342, Russia- secondary 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)	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	ЛПТ-№002345-ITI-AM 16.09.2025

13	Diroton	lisinopril (lisinopril dihydrate)	tablets	5mg; (14/1x14/) in blister, (28/2x14/) in blister, (56/4x14/) in blister	GEDEON RICHTER JSC- RUS, Lesnaya St. 40., Shuvoye, Moscow region, Yegoriyevsky district, 140342- batch releaser, Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest, Hungary- 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	ЛПТ-№002345-ИТИ-AM 16.09.2025
14	Diroton	lisinopril (lisinopril dihydrate)	tablets	10mg; (14/1x14/) in blister, (28/2x14/) in blister, (56/4x14/) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest- bulk manufacturer, primary packager, batch releaser, GEDEON RICHTER JSC - RUS, Lesnaya St. 43/5., Shuvoye, Moscow region, Yegoriyevsky district, 140342, Russia- secondary 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)	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	ЛПТ-№002345-ИТИ-AM 16.09.2025

15	Diroton	lisinopril (lisinopril dihydrate)	tablets	10mg; (14/1x14/) in blister, (28/2x14/) in blister, (56/4x14/) in blister	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	ЛПТ-№002345-ІТІ-AM 16.09.2025
16	Diroton	lisinopril (lisinopril dihydrate)	tablets	10mg; (14/1x14/) in blister, (28/2x14/) in blister, (56/4x14/) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest- bulk manufacturer, primary packager, batch releaser, GEDEON RICHTER JSC - RUS, Lesnaya St. 43/5., Shuvoye, Moscow region, Yegoriyevsky district, 140342, Russia- secondary 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)	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	ЛПТ-№002345-ІТІ-AM 16.09.2025

17	Diroton	lisinopril (lisinopril dihydrate)	tablets	10mg; (14/1x14/) in blister, (28/2x14/) in blister, (56/4x14/) in blister	GEDEON RICHTER JSC- RUS, Lesnaya St. 40., Shuvoye, Moscow region, Yegoriyevsky district, 140342- batch releaser, Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest, Hungary- 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	ЛПТ-№002345-ИТИ-AM 16.09.2025
18	Diroton	lisinopril (lisinopril dihydrate)	tablets	20mg; (14/1x14/) in blister, (28/2x14/) in blister, (56/4x14/) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	ЛПТ-№002345-ИТИ-AM 16.09.2025
19	Diroton	lisinopril (lisinopril dihydrate)	tablets	20mg; (14/1x14/) in blister, (28/2x14/) in blister, (56/4x14/) in blister	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	ЛПТ-№002345-ИТИ-AM 16.09.2025

20	Diroton	lisinopril (lisinopril dihydrate)	tablets	20mg; (14/1x14/) in blister, (28/2x14/) in blister, (56/4x14/) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest- bulk manufacturer, primary packager, batch releaser, GEDEON RICHTER JSC- RUS, Lesnaya St. 43/5., Shuvoye, Moscow region, Yegoriyevsky district, 140342, Russia- secondary 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)	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	ЛПТ-№002345-ITI-AM 16.09.2025
21	Diroton	lisinopril (lisinopril dihydrate)	tablets	20mg; (14/1x14/) in blister, (28/2x14/) in blister, (56/4x14/) in blister	GEDEON RICHTER JSC- RUS, Lesnaya St. 40., Shuvoye, Moscow region, Yegoriyevsky district, 140342- batch releaser, Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest, Hungary- 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	ЛПТ-№002345-ITI-AM 16.09.2025

LIST

of the variations not requiring reformulation of registration certificate approved by the Center according to the meeting decision N 09-1/25 on September 16, 2025

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	Diclofenac sodium	diclofenac (diclofenac sodium)	solution for i/m and i/v injection	25mg/ml; (5) ampoules 3ml, (5/1x5) ampoules 3ml in blister	Lekhim-Kharkiv PrJSC, 36, Severyna Pototskoho str., 61115, Kharkiv region, Kharkiv	Ukraine	Lekhim-Kharkiv PrJSC, 36, Severyna Pototskoho str., 61115, Kharkiv region, Kharkiv	Ukraine	PoM	20099/1 16.09.2025
2	Cefichew	cefixime (cefixime trihydrate)	tablets chewable	400mg; (10/1x10) in blister	Maxim Pharmaceuticals Pvt. Ltd., Plot No. 11 & 12, Gat No. 1251-1261, Alandi-Markal Road, Markal Khed, Pune 412 105, Maharashtra State	India	SRS Pharmaceuticals Pvt. Ltd., 504, 5th Floor, Marathon Max Bldg. No 2, Mulund-Goregaon Link Road, L.B.S. Marg, Mulund, Mumbai 400 080	India	PoM	19508/1 16.09.2025
3	Nalgesin	naproxen (naproxen sodium)	tablets film-coated	220mg (10/1x10) in blister, (30/3x10) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto- bulk manufacturer, packager, quality control (microbiological), batch releaser, KRKA 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	19477/2 16.09.2025

4	Acnamino MR 100mg Capsules	minocycline (minocycline hydrochloride)	capsules hard	100mg; (56/8x7/) in blister	Dexcel-Pharma Ltd., 7 Sopwith Way, Drayton Fields, Daventry, Northamptonshire, NN11 8PB- batch releaser, Dexcel Ltd., 1 Dexcel Street, Or-Akiva 3060000, Israel- bulk manufacturer, packager, quality control (physicochemical), The Institute for Food Microbiology and Consumer Goods Ltd., 9 HaShalom Road, Nesher, Israel- quality control (microbiological)	UK	Dexcel-Pharma Ltd., 7 Sopwith Way, Drayton Fields, Daventry, Northamptonshire, NN11 8PB	UK	PoM	21674/5 16.09.2025
5	Aspirin C	acetylsalicylic acid, ascorbic acid	tablets effervescent	400mg+240mg; (10/5x2/) in strip	Bayer Bitterfeld GmbH, Ortsteil Greppin Salegaster Chaussee 1, 06803 Bitterfeld-Wolfen	Germany	Bayer Consumer Care AG, Peter Merian-Strasse 84, 4052 Basel	Switzerland	OTC	19731/2 16.09.2025
6	Somazina	citicoline (citicoline sodium)	solution for injection	1000mg/4ml; (5) ampoules 4ml	Ferrer International, S.A., Joan Buscalla, 1-9 08173 Sant Cugat del Valles, Barcelona	Spain	Ferrer International, S.A., Gran Via Carlos III, 94, 08028, Barcelona	Spain	PoM	19328/2 16.09.2025
7	Afobazol-Oticipharm Pro	fabomotizole (fabomotizole dihydrochloride)	tablets	10mg; (30/1x30/) in blister, (60/3x20/) in blister, (60/2x30/) in blister, (90/3x30/) in blister, (120/4x30/) 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	19634/1 16.09.2025
8	Analgin-Pharmstandard	metamizole (metamizole sodium)	tablets	500mg; (10/1x10/) in blister	Pharmstandard-Leksredstva JSC, Kursk region, Kursk, Agregatnaya 2nd str., 1a/18	Russia	Pharmstandard-Leksredstva JSC, 305022, Kursk region, Kursk, Agregatnaya 2nd str., 1a/18	Russia	OTC	22436/1 16.09.2025
9	Glycerin	glycerol	solution for local use (enema)	900mg/g; plastic container 5ml, plastic container 10ml	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	22222/1 16.09.2025
10	Anti Gripp complex for children	pheniramine (pheniramine maleate), paracetamol, vitamin C	powder for oral solution with raspberry flavor	10mg+280mg+100mg; (10) sachets 8g	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	19415/3/1 16.09.2025

11	Anti Gripp complex with lemon flavor	pheniramine (pheniramine maleate), paracetamol, vitamin C	powder for oral solution with lemon flavor	25mg+500mg+200mg; (10) sachets 8g	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	19414/3/1 16.09.2025
12	Truedex	tobramycin (tobramycin sulfate), dexamethasone	drops eye (suspension)	3mg/ml+1mg/ml; plastic vial- dropper 5ml	Balkanpharma-Razgrad AD, 68 Aprilsko Vastanie Blvd, 7200 Razgrad	Bulgaria	Pharmatech CJSC, 111 Raffi str., Yerevan, 0064	Republic of Armenia	PoM	19920/1 16.09.2025

LIST

of the variations under the EAEU procedure not requiring reformulation of registration certificate approved by the Center according to the meeting decision N 09-1/25 on September 16, 2025

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	Sedistress	dry extract of passiflora, ethyl ester of alpha-bromisovaleric acid	tablets	300mg+10,2mg; (30/3x10) in blister, (60/6x10) in blister	Pharma Start LLC, Boulevard Vatslava Havela, 8, 03124, Kiev	Ukraine	Acino Ukraine LLC, Boulevard Vatslava Havela, 8, 03124, Kiev	Ukraine	OTC	ЛІТ-№004871-PT-AM 16.09.2025
2	Decaris	levamisole (levamisole hydrochloride)	tablets	50mg; (2/1x2) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest- batch releaser, Gedeon Richter Romania S.A., 99-105 Guza Voda str., Targu-Mures, Jud. Mures, 540306, Romania- bulk manufacturer, packager, quality control	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	ЛІТ-№002801-ITI-AM 16.09.2025
3	Decaris	levamisole (levamisole hydrochloride)	tablets	50mg; (2/1x2) in blister	Gedeon Richter Romania S.A., 99-105 Guza Voda str., Targu-Mures, Jud. Mures, 540306	Romania	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	ЛІТ-№002801-ITI-AM 16.09.2025
4	Decaris	levamisole (levamisole hydrochloride)	tablets	150mg; (1/1x1) in blister	Gedeon Richter Romania S.A., 99-105 Guza Voda str., Targu-Mures, Jud. Mures, 540306	Romania	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	ЛІТ-№002801-ITI-AM 16.09.2025
5	Decaris	levamisole (levamisole hydrochloride)	tablets	150mg; (1/1x1) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest- batch releaser, Gedeon Richter Romania S.A., 99-105 Guza Voda str., Targu-Mures, Jud. Mures, 540306, Romania- bulk manufacturer, packager, quality control	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	ЛІТ-№002801-ITI-AM 16.09.2025
6	Terbisil	terbinafine (terbinafine hydrochloride)	cream for external use	10mg/g; aluminium tube 15g	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	OTC	ЛІТ-№002081-ITI-AM 16.09.2025

7	Ekvator	lisinopril (lisinopril dihydrate), amlodipine (amlodipine besilate)	tablets	10mg+5mg; (10/1x10) in blister, (30/3x10') in blister, (60/6x10') in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	ЛПТ-№003869- ITI-AM 16.09.2025
8	Ekvator	lisinopril (lisinopril dihydrate), amlodipine (amlodipine besilate)	tablets	10mg+5mg; (10/1x10) in blister, (30/3x10') in blister, (60/6x10') in blister	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	ЛПТ-№003869- ITI-AM 16.09.2025
9	Ekvator	lisinopril (lisinopril dihydrate), amlodipine (amlodipine besilate)	tablets	20mg+10mg; (10/1x10') in blister, (30/3x10') in blister, (60/6x10') in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest- bulk manufacturer, packager, batch releaser, Gedeon Richter PLC, Quality Control Laboratory, Gyomroi ut 19-21, 1103 Budapest, Hungary- quality control (physicochemical), Gedeon Richter PLC, 2510 Dorog, Esztergomi st. 27, Hungary- quality control (microbiological)	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	PoM	ЛПТ-№003869- ITI-AM 16.09.2025
10	Ekvator	lisinopril (lisinopril dihydrate), amlodipine (amlodipine besilate)	tablets	20mg+10mg; (10/1x10') in blister, (30/3x10') in blister, (60/6x10') in blister	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	ЛПТ-№003869- ITI-AM 16.09.2025

11	Riquatron	rivaroxaban	tablets film-coated	2,5mg; (14/1x14/) in blister, (28/2x14/) in blister, (56/4x14/) in blister, (98/7x14/) in blister, (168/12x14/) in blister, (196/14x14/) in blister, (20/2x10/) in blister, (30/3x10/) in blister, (60/6x10/) in blister, (100/10x10/) in blister	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	ЛПТ-№003000-ITI-AM 16.09.2025
12	Riquatron	rivaroxaban	tablets film-coated	2,5mg; (14/1x14/) in blister, (28/2x14/) in blister, (56/4x14/) in blister, (98/7x14/) in blister, (168/12x14/) in blister, (196/14x14/) in blister, (20/2x10/) in blister, (30/3x10/) in blister, (60/6x10/) in blister, (100/10x10/) in blister	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	ЛПТ-№003000-ITI-AM 16.09.2025
13	Riquatron	rivaroxaban	tablets film-coated	2,5mg; (14/1x14/) in blister, (28/2x14/) in blister, (56/4x14/) in blister, (98/7x14/) in blister, (168/12x14/) in blister, (196/14x14/) in blister, (20/2x10/) in blister, (30/3x10/) in blister, (60/6x10/) in blister, (100/10x10/) in blister	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	ЛПТ-№003000-ITI-AM 16.09.2025

14	Riquatron	rivaroxaban	tablets film-coated	10mg; (5/1x5) in blister, (14/1x14) in blister, (28/2x14) in blister, (56/4x14) in blister, (98/7x14) in blister, (10/1x10) in blister, (30/3x10) in blister, (100/10x10) in blister	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	ЛПТ-№003000-ITI-AM 16.09.2025
15	Riquatron	rivaroxaban	tablets film-coated	10mg; (5/1x5) in blister, (14/1x14) in blister, (28/2x14) in blister, (56/4x14) in blister, (98/7x14) in blister, (10/1x10) in blister, (30/3x10) in blister, (100/10x10) in blister	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	ЛПТ-№003000-ITI-AM 16.09.2025
16	Riquatron	rivaroxaban	tablets film-coated	10mg; (5/1x5) in blister, (14/1x14) in blister, (28/2x14) in blister, (56/4x14) in blister, (98/7x14) in blister, (10/1x10) in blister, (30/3x10) in blister, (100/10x10) in blister	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	ЛПТ-№003000-ITI-AM 16.09.2025

17	Riquatron	rivaroxaban	tablets film-coated	15mg; (14/1x14/) in blister, (28/2x14/) in blister, (42/3x14/) in blister, (56/4x14/) in blister, (98/7x14/) in blister, (10/1x10/) in blister, (100/10x10/) in blister	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	ЛПТ-№003000-ITI-AM 16.09.2025
18	Riquatron	rivaroxaban	tablets film-coated	15mg; (14/1x14/) in blister, (28/2x14/) in blister, (42/3x14/) in blister, (56/4x14/) in blister, (98/7x14/) in blister, (10/1x10/) in blister, (100/10x10/) in blister	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	ЛПТ-№003000-ITI-AM 16.09.2025
19	Riquatron	rivaroxaban	tablets film-coated	15mg; (14/1x14/) in blister, (28/2x14/) in blister, (42/3x14/) in blister, (56/4x14/) in blister, (98/7x14/) in blister, (10/1x10/) in blister, (100/10x10/) in blister	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	ЛПТ-№003000-ITI-AM 16.09.2025

20	Riquatron	rivaroxaban	tablets film-coated	20mg; (14/1x14/) in blister, (28/2x14/) in blister, (56/4x14/) in blister, (98/7x14/) in blister, (10/1x10/) in blister, (100/10x10/) in blister	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	ЛІП-№003000-ITI-AM 16.09.2025
21	Riquatron	rivaroxaban	tablets film-coated	20mg; (14/1x14/) in blister, (28/2x14/) in blister, (56/4x14/) in blister, (98/7x14/) in blister, (10/1x10/) in blister, (100/10x10/) in blister	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	ЛІП-№003000-ITI-AM 16.09.2025
22	Riquatron	rivaroxaban	tablets film-coated	20mg; (14/1x14/) in blister, (28/2x14/) in blister, (56/4x14/) in blister, (98/7x14/) in blister, (10/1x10/) in blister, (100/10x10/) in blister	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	ЛІП-№003000-ITI-AM 16.09.2025
23	Bioson	dry extract of passiflora, doxylamine (doxylamine hydrogen succinate)	tablets film-coated	300mg+3,75mg; (10/1x10/) in blister, (30/3x10/) in blister	Pharma Start LLC, Boulevard Vatslava Havela, 8, 03124, Kiev	Ukraine	Acino Ukraine LLC, Boulevard Vatslava Havela, 8, 03124, Kiev	Ukraine	OTC	ЛІП-№007499-PT-AM 16.09.2025