

LIST

of the medicines recommended for the registration by the Center according to the meeting decision N 4-3/20 on April 29, 2020

President \_\_\_\_\_ E. Amroyan

N	Trade name	International non-proprietary (generic) names or names of active substances	dosage form	dosage strength & output form (packaging)	Manufacturer	country	License holder	License holder country	Prescription status	Conclusion N & date
1	Adenoprosin	adenoprosin	suppositories rectal	150mg; (10/2x5/) in blister	Farmaprim SRL, Crinilor str., 5, Porumbeni, Criuleni dis., MD-4829- bulk manufacturer, packager, quality control (physicochemical), batch releaser, Centrul National de Sanatate Publica, MD-2028, mun. Chisinau, str. Gh.Asachi, 67-A, Moldova-quality control (microbiological)	Moldova	Biotechnos SRL, 20 Maria Cebotari street, Chisinau city	Moldova	R	19198 29.04.2020
2	Klacid SR	clarithromycin	tablets modified-release film-coated	500mg; (5/1x5/) in bliister, (14/2x7/) in blister	AbbVie S.r.l., S.R. 148 Pontina KM 52, SNC 04011 Campoverde di Aprilia (LT)	Italy	Abbott Laboratories GmbH, Freundallee 9A, 30173 Hannover	Germany	R	19199 29.04.2020
3	Calcium gluconate Tatpharm	calcium gluconate	tablets	500mg; (10/1x10/) strip	Tatchempharmpreparaty JSC, 420091 Republic of Tatarstan, Kazan, str. Belomorskaya 260	Russia	Tatchempharmpreparaty JSC, 420091 Republic of Tatarstan, Kazan, str. Belomorskaya 260	Russia	OTC	19200 29.04.2020

## LIST

of the medicines recommended for the registration under simplified procedure by the Center according to the meeting decision N 4-3/20 on April 29, 2020

President \_\_\_\_\_ E. Amroya

N	Trade name	International non-proprietary (generic) names or names of active substances	dosage form	dosage strength & output form (packaging)	Manufacturer	country	License holder	License holder country	Prescription status	Conclusion N & date
1	Sintuss	butamirate (butamirate citrate)	drops oral (solution)	5mg/ml; glass bottle-dropper 20ml	Vetprom AD, Otez Paissij str. 26, Radomir 2400 for	Bulgaria	Danhson-BG Co Ltd., Otez Paissij str. 26, Radomir 2400	Bulgaria	OTC	19201 29.04.2020
2	Desallergan	desloratadine	solution oral	0.5mg/ml; glass bottle 120ml	Vetprom AD, Otez Paissij str. 26, Radomir 2400	Bulgaria	Danhson-BG Co Ltd., Otez Paissij str. 26, Radomir 2400	Bulgaria	R	19202 29.04.2020
3	Midazolam Kalceks	midazolam	solution for injection/infusion	5mg/ml; (5) ampoules 1ml, (10) ampoules 1ml	Kalceks JSC, 71E Krustpils Street, Riga, LV-1057- batch releaser, HBM Pharma s.r.o., Sklabinska 30, 03680 Martin, Slovakia- bulk manufacturer, packager, quality control	Latvia	Kalceks JSC, 53 Krustpils Street, Riga, LV-1057	Latvia	R	19203 29.04.2020

4	Midazolam Kalceks	midazolam	solution for injection/infusion	5mg/ml; (5) ampoules 3ml, (10) ampoules 3ml	Kalceks JSC, 71E Krustpils Street, Riga, LV-1057- batch releaser, HBM Pharma s.r.o., Sklabinska 30, 03680 Martin, Slovakia- bulk manufacturer, packager, quality control	Latvia	Kalceks JSC, 53 Krustpils Street, Riga, LV-1057	Latvia	R	19204 29.04.2020
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of the medicines recommended for the re-registration by the Center according to the meeting decision N 4-3/20 on April 29, 2020

President \_\_\_\_\_ E. Amroyan

N	Trade name	International non-proprietary (generic) names or names of active substances	dosage form	dosage strength & output form (packaging)	Manufacturer	country	License holder	License holder country	Prescription status	Conclusion N & date
1	Lignospan 2% special	lidocaine (lidocaine hydrochloride), adrenaline (adrenaline tartrate)	solution for injection	20mg/ml+12,5mcg/ml; (50/5x10/) cartridges 1,8ml	Septodont, 58 rue du Pont de Creteil, 94100 Saint-Maur- des- Fosses	France	Septodont, 58 rue du Pont de Creteil, 94100 Saint- Maur- des- Fosses	France	R	19205 29.04.2020
2	Dificlir	fidaxomicin	tablets film-coated	200mg; (20/2x10/) in blister, (100/10x10/) in blister	Astellas Pharma Europe B.V., Hogemaat 2, 7942 JG Meppel- packager, quality control, batch releaser, Patheon Inc., 2100 Syntex Court, Mississauga, Ontario, L5N 7K9, Canada- bulk manufacturer	the Netherlands	Astellas Pharma Europe B.V., Sylviusweg 62, 2333 BE Leiden	the Netherlands	R	19206 29.04.2020
3	Lyrica	pregabalin	capsules hard	75mg; (14/1x14/) in blister, (56/4x14/) in blister	Pfizer Manufacturing Deutschland GmbH, Mooswaldallee 1, 79090 Frieberg	Germany	Pfizer H.C.P. Corporation, 235, East 42nd street New York 10017	USA	R	19207 29.04.2020

4	Lyrica	pregabalin	capsules hard	150mg; (14/1x14/) in blister, (56/4x14/) in blister	Pfizer Manufacturing Deutschland GmbH, Mooswaldallee 1, 79090 Frieberg	Germany	Pfizer H.C.P. Corporation, 235, East 42nd street New York 10017	USA	R	19208 29.04.2020
5	Lyrica	pregabalin	capsules hard	300mg; (14/1x14/) in blister, (56/4x14/) in blister	Pfizer Manufacturing Deutschland GmbH, Mooswaldallee 1, 79090 Frieberg	Germany	Pfizer H.C.P. Corporation, 235, East 42nd street New York 10017	USA	R	19209 29.04.2020
6	Stazex	clopidogrel (clopidogrel hydrosulfate)	tablets film-coated	75mg; (10/1x10/) in blister	GM Pharmaceuticals Ltd, Phonichala 65, 0165 Tbilisi	Georgia	GM Pharmaceuticals Ltd, Phonichala 65, 0165 Tbilisi	Georgia	R	19210 29.04.2020
7	Phosphogliv	phospholipids (lipoid S 80), sodium glycyrrhizinate (glycyrrhizinic acid trisodium)	capsules	65mg+35mg; (50/5x10/) in blister	Pharmstandard-Leksredstva OJSC, 305022, Kursk, Agregatnaya 2nd str., 1a/18	Russia	Pharmstandard-Leksredstva OJSC, 305022, Kursk, Agregatnaya 2nd str., 1a/18	Russia	OTC	19211 29.04.2020
8	Azitrox	azithromycin (azithromycin dihydrate)	capsules	250mg; (6/1x6/) in blister	Pharmstandard-Leksredstva OJSC, 305022, Kursk, Agregatnaya 2nd str., 1a/18	Russia	OTCPharm PJSC, 123317, Moscow, Testovskaya str., 10	Russia	R	19212 29.04.2020
9	Azitrox	azithromycin (azithromycin dihydrate)	capsules	500mg; (2/1x2/) in blister, (3/1x3/) in blister	Pharmstandard-Leksredstva OJSC, 305022, Kursk, Agregatnaya 2nd str., 1a/18	Russia	OTCPharm PJSC, 123317, Moscow, Testovskaya str., 10	Russia	R	19213 29.04.2020

10	Diazolin	mebhydrolin (mebhydrolin napadisylate)	dragee	100mg; (20/2x10/) in blister	Marbiopharm JSC, 424006, the Republic of Mari El, Yoshkar-Ola, st. Karl Marx 121	Russia	Marbiopharm JSC, 424006, the Republic of Mari El, Yoshkar-Ola, st. Karl Marx 121	Russia	OTC	19214 29.04.2020
11	Pancef	cefixime (cefixime trihydrate)	powder for oral suspension	100mg/5ml; powder 32g in glass bottle 60ml and measuring spoon 5ml	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje- quality control, batch releaser, Alkaloid AD Skopje, Blvd. Partizanski odredi 98A, 1000 Skopje, Republic of North Macedonia- bulk manufacturer, packager	Republic of North Macedonia	Alkaloid AD Skopje, Blvd. Aleksandar Makedonski 12, 1000 Skopje	Republic of North Macedonia	R	19215 29.04.2020
12	Neoton	phosphocreatine (phosphocreatine sodium)	powder for solution for infusion	1000mg; glass vial, solvent in glass vial 50ml, infusion system	Alfasigma S.p.A., Via Enrico Fermi, 1-65020, Alanno (Pescara)	Italy	Alfasigma S.p.A., Via Ragazzi del, 99, 5-40133 Bologna (BO)	Italy	R	19216 29.04.2020
13	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	R	19217 29.04.2020
14	Disflatyl	simethicone	drops oral	40mg/ml; glass bottle 30ml	Legacy Pharmaceuticals Switzerland GmbH, Ruhrbergstrasse 21, 4127 Birsfelden	Switzerland	MEDA Pharmaceuticals Switzerland GmbH, Hegnaustrasse 60, 8602 Wangen-Bruttisellen	Switzerland	OTC	19220 29.04.2020

15	Arginine-Liqvo	arginine (arginine hydrochloride)	concentrate for solution for infusion	210,7mg/ml; glass vial 20ml	Liqvor CJSC, 0089, Yerevan, str. Kochinyan, 7/9	Republic of Armenia	Liqvor CJSC, 0089, Yerevan, str. Kochinyan, 7/9	Republic of Armenia	R	19221 29.04.2020
16	Stopdiar	nifuroxazide	capsules	200mg; (12/1x12/) in blister	Gedeon Richter Polska 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 ut 19-21, 1103 Budapest	Hungary	R	19222 29.04.2020

LIST

of variations requiring reformulation of registration certificate approved by the Center according to the meeting decision N 4-3/20 on April 29, 2020

President \_\_\_\_\_ E. Amroyan

N	Trade name	International non-proprietary (generic) names or names of active substances	dosage form	dosage strength & output form (packaging)	Manufacturer	country	License holder	License holder country	Prescription status	Conclusion N & date
1	Convulex	valproic acid	syrup	50mg/ml; glass bottle 100ml and measuring syringe	G.L. Pharma GmbH, Schlossplatz 1, 8502 Lannach-batch releaser, G.L. Pharma GmbH, Arnethgasse 3, 1160 Vienna, Austria -bulk manufacturer, packager	Austria	BAUSCH Health LLC, Shabolovka st. 31, building 5, 115162, Moscow	Russia	R	14449/1/1 29.04.2020
2	Convulex	valproic acid	solution oral	300mg/ml; glass bottle 100ml and measuring syringe	G.L. Pharma GmbH, Schlossplatz 1, 8502 Lannach-batch releaser, G.L. Pharma GmbH, Arnethgasse 3, 1160 Vienna, Austria -bulk manufacturer, packager	Austria	BAUSCH Health LLC, Shabolovka st. 31, building 5, 115162, Moscow	Russia	R	14448/1/1 29.04.2020
3	Enciale Forte	essential phospholipids	capsules	300mg; (30/3x10/) in blister, (50/5x10/) in blister	Minskintercaps U.V., 26/3, Inzhenernaya str., 220075, Minsk	Belarus	Minskintercaps U.V., 26, Inzhenernaya str., 220075, Minsk	Belarus	OTC	17493/1/1 29.04.2020



LIST

of the variations not requiring reformulation of registration certificate approved by the Center according to the meeting decision N 4-3/20 on April 29, 2020

President \_\_\_\_\_ E. Amroyan

N	Trade name	International non-proprietary (generic) names or names of active substances	dosage form	dosage strength & output form (packaging)	Manufacturer	country	License holder	License holder country	Prescription status	Conclusion N & date
1	Herceptin	trastuzumab	powder for concentrate for solution for infusion	440mg; (1) glass vial and solvent in vial 20ml	F. Hoffmann-La Roche AG Wurmisweg, Kaiseraugst, 4303- secondary packager, quality control, batch releaser, Genentech Inc., DNA Way 1, South San Francisco, CA 94080, USA- bulk manufacturer, primary packager, F. Hoffmann-La Roche AG, Wurmisweg, Kaiseraugst, 4303, Switzerland-solvent manufacturer	Switzerland	F. Hoffmann-La Roche Ltd., Grenzacherstrasse, 124, CH-4070, Basel	Switzerland	R	18964/1 29.04.2020
2	Advagraf	tacrolimus	capsules prolonged-release	3mg; (50/5x10/) in blister	Astellas Ireland Co. Ltd., Killorglin, County Kerry	Ireland	Astellas Pharma Europe B. V., Sylviusweg 62, 2333 BE Leiden	The Netherlands	R	17388/3 29.04.2020
3	Normodipine	amlodipine (amlodipine besilate)	tablets	5mg; (30/3x10/), in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	R	14919/1 29.04.2020

4	Normodipine	amlodipine (amlodipine besilate)	tablets	10mg; (30/3x10/), in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	R	14920/1 29.04.2020
5	Advagraf	tacrolimus	capsules prolonged-release	0,5mg; (50/5x10/) in blister	Astellas Ireland Co. Ltd., Killorglin, County Kerry	Ireland	Astellas Pharma Europe B. V., Sylviusweg 62, 2333 BE Leiden	the Netherlands	R	19027/2 29.04.2020
6	Advagraf	tacrolimus	capsules prolonged-release	1mg; (50/5x10/) in blister	Astellas Ireland Co. Ltd., Killorglin, County Kerry	Ireland	Astellas Pharma Europe B. V., Sylviusweg 62, 2333 BE Leiden	the Netherlands	R	19028/2 29.04.2020
7	Advagraf	tacrolimus	capsules prolonged-release	5mg; (50/5x10/) in blister	Astellas Ireland Co. Ltd., Killorglin, County Kerry	Ireland	Astellas Pharma Europe B. V., Sylviusweg 62, 2333 BE Leiden	the Netherlands	R	19029/2 29.04.2020
8	Upsarin Upsa with vitamin C	acetylsalicylic acid, ascorbic acid	tablets effervescent	330mg+200mg; (10) in plastic container	UPSA SAS, 979, Avenue des Pyrenees, 47520 Le Passage, France	France	UPSA SAS, 3, rue Joseph Monier-92500 Rueil-Malmaison	France	OTC	14912/2 29.04.2020
9	Enalapril	enalapril (enalapril maleate)	tablets	5mg; (20/2x10/) in blister	Hemofarm LLC, 249030, Obninsk, Kaluga Region, 62 Kievskoye highway	Russia	Nizhpharm JSC, 603950, Nizhny Novgorod, GSP-459, Salganskaya st., 7	Russia	R	16823/2 29.04.2020

10	Enalapril	enalapril (enalapril maleate)	tablets	10mg; (20/2x10/) in blister	Hemofarm LLC, 249030, Obninsk, Kaluga Region, 62 Kievskoye highway	Russia	Nizhpharm JSC, 603950, Nizhny Novgorod, GSP-459, Salganskaya st., 7	Russia	R	16822/2 29.04.2020
11	Enalapril	enalapril (enalapril maleate)	tablets	20mg; (20/2x10/) in blister	Hemofarm LLC, 249030, Obninsk, Kaluga Region, 62 Kievskoye highway	Russia	Nizhpharm JSC, 603950, Nizhny Novgorod, GSP-459, Salganskaya st., 7	Russia	R	16821/2 29.04.2020
12	Co-Diroton	lisinopril (lisinopril dihydrate), hydrochlorothiazide	tablets	10mg+12,5mg; (10/1x10/) in blister, (30/3x10/) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest-batch releaser, Gedeon Richter Poland Sp.z o.o., ul.Graniczna 35,Grodzisk Mazowiecki, 05-825, Poland-bulk manufacturer, packager, quality control	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	R	18970/1 29.04.2020
13	Co-Diroton	lisinopril (lisinopril dihydrate), hydrochlorothiazide	tablets	20mg+12,5mg; (10/1x10/) in blister, (30/3x10/) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest-batch releaser, Gedeon Richter Poland Sp.z o.o., ul.Graniczna 35,Grodzisk Mazowiecki, 05-825, Poland-bulk manufacturer, packager, quality control	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	R	18969/1 29.04.2020

14	Cytarabine	cytarabine	powder lyophilized for solution for injection	100mg; (1) glass vial	Belmedpreparaty RUE, 220007, Minsk, Fabritsius St., 30	Belarus	Belmedpreparaty RUE, 220007, Minsk, Fabritsius St., 30	Belarus	R	15290/1 29.04.2020
15	Lignospan special	lidocaine (lidocaine hydrochloride), adrenaline (adrenaline tartrate)	solution for injection	20mg/ml+12,5mcg/ml ; (50/5x10/) cartridges 1,8ml	Septodont, 58 rue du Pont de Creteil, 94100 Saint-Maur- des- Fosses	France	Septodont, 58 rue du Pont de Creteil, 94100 Saint- Maur- des- Fosses	France	R	14177/1 29.04.2020
16	Mertenil	rosuvastatin (rosuvastatin calcium)	tablets film-coated	5mg; (30/3x10/) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	R	15905/2 29.04.2020
17	Mertenil	rosuvastatin (rosuvastatin calcium)	tablets film-coated	10mg; (30/3x10/) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	R	15904/2 29.04.2020
18	Mertenil	rosuvastatin (rosuvastatin calcium)	tablets film-coated	20mg; (30/3x10/) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	R	15903/2 29.04.2020

19	Metronidazole-Asteria	metronidazole	tablets	500mg; (30/3x10/) and (100/10x10/), in blister	Hankook Korus Pharm Co., Ltd, 30, Gangjeo-ro, Jecheon-si, Chungcheongbuk-do	Korea South	GL Corporation, Woori Venture Tower #201, 70, Seonyu-ro, Yeongdeungpo-ku, Seoul	South Korea	R	14424/3 29.04.2020
20	ACC Long	acetylcysteine	tablets effervescent	600mg; (10) in plastic container	Salutas Pharma GmbH, Otto-von-Guericke-Alle-1, 39179 Barleben-batch releaser, Hermes Arzneimittel GmbH, Hans-Urmiler Ring 52, 82515 Wolfratshausen, Germany-bulk manufacturer, packager, quality control	Germany	Sandoz Pharmaceuticals d.d. Verevskova 57, Ljubljana	Slovenia	OTC	18925/1 29.04.2020
21	Vitaprost Forte	samprost (dry extract of calf prostate)	suppositories rectal	100mg; (10/2x5/) in blister	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	Nizhpharm JSC, 603950, Nizhny Novgorod, Salganskaya st., 7	Russia	OTC	17128/1 29.04.2020
22	Arifam 1.5mg/5mg	indapamide, amlodipine (amlodipine besilate)	tablets modified-release	1,5mg+5mg; (30/2x15/) in blister	Les Laboratoires Servier Industrie, 905, route de Saran, 45520 Gidy	France	Les Laboratoires Servier, 50, rue Carnot 92284 Suresnes cedex	France	R	18548/1 29.04.2020
23	Arifam 1.5mg/10mg	indapamide, amlodipine (amlodipine besilate)	tablets modified-release	1,5mg+10mg; (30/2x15/) in blister	Les Laboratoires Servier Industrie, 905, route de Saran, 45520 Gidy	France	Les Laboratoires Servier, 50, rue Carnot 92284 Suresnes cedex	France	R	18549/1 29.04.2020

24	Lipertance	atorvastatin (atorvastatin calcium trihydrate), perindopril arginine, amlodipine (amlodipine besilate)	tablets film-coated	10mg+5mg+5mg; (30) in plastic container, (100) in plastic container	Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy	France	Les Laboratoires Servier, 50,rue Carnot, 92284 Suresnes cedex	France	R	15824/2 29.04.2020
25	Lipertance	atorvastatin (atorvastatin calcium trihydrate), perindopril arginine, amlodipine (amlodipine besilate)	tablets film-coated	20mg+5mg+5mg; (30) in plastic container, (100) in plastic container	Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy	France	Les Laboratoires Servier, 50,rue Carnot, 92284 Suresnes cedex	France	R	15825/2 29.04.2020
26	Lipertance	atorvastatin (atorvastatin calcium trihydrate), perindopril arginine, amlodipine (amlodipine besilate)	tablets film-coated	20mg+10mg+5mg; (30) in plastic container, (100) in plastic container	Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy	France	Les Laboratoires Servier, 50,rue Carnot, 92284 Suresnes cedex	France	R	15826/2 29.04.2020
27	Lipertance	atorvastatin (atorvastatin calcium trihydrate), perindopril arginine, amlodipine (amlodipine besilate)	tablets film-coated	20mg+10mg+10mg; (30) in plastic container, (100) in plastic container	Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy	France	Les Laboratoires Servier, 50,rue Carnot, 92284 Suresnes cedex	France	R	15827/2 29.04.2020
28	Lipertance	atorvastatin (atorvastatin calcium trihydrate), perindopril arginine, amlodipine (amlodipine besilate)	tablets film-coated	40mg+10mg+10mg; (30) in plastic container, (100) in plastic container	Les Laboratoires Servier Industrie 905, route de Saran, 45520 Gidy	France	Les Laboratoires Servier, 50,rue Carnot, 92284 Suresnes cedex	France	R	15828/2 29.04.2020

29	Clopi-Denk 75	clopidogrel (clopidogrel besylate)	tablets film-coated	75mg; (30/3x10/) in blister	Artesan Pharma GmbH & Co. KG, Wendlandstrasse 1, 29439 Luechow	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Muenchen	Germany	R	19149/1 29.04.2020
30	CoLosar-Denk 50/12,5	losartan (losartan potassium), hydrochlorothiazide	tablets film-coated	50mg+12,5mg; (28/2x14/) in blister	Denk Pharma GmbH & Co. KG, Goellstr. 1, 84529 Tittmoning	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Munchen	Germany	R	16076/2 29.04.2020
31	Dermazin	silver sulfadiazine	cream	10mg/g; 50g aluminium tube	Salutas Pharma GmbH, Lange Goehren 3, 39171 Osterweddingen	Germany	Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	R	14950/1 29.04.2020
32	Colchicine Opocalcium	colchicine	tablets	1mg; (20/1x20/) in blister	S.C Zentiva S.A, Theodor Pallady Blvd nr. 50, sector 3, Bucuresti, cod 032266	Romania	Laboratoires MAYOLY SPINDLER, 6 avenue de l' Europe, 78400 Chatou	France	R	16129/2 29.04.2020
33	Groprinosin	inosine pranobex	tablets	500mg; (20/2x10/) in blister, (50/5x10/) in blister	Gedeon Richter Polska Sp. z o.o. 5, ks. J. Poniatowskiego Str., 05-825 Grodzisk Mazowiecki	Poland	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	R	14943/2 29.04.2020

34	EsCial Forte	essential phospholipids, thiamine mononitrate, riboflavin, pyridoxine hydrochloride, nicotinamide, tocopherol acetate, cyanocobalamin	capsules	300mg+6mg+6mg+6mg+30mg+6mg+6mcg; (30/3x10/) blisters	Nabros Pharma Pvt. Ltd.	India	Nabros Pharma Pvt. Ltd.	India	R	11409/2/1 29.04.2020
35	ACC 200mg Hot Drink	acetylcysteine	powder for oral solution	200mg; (20) sachets 3g	Salutas Pharma GmbH, Otto-von-Guericke-Alle-1, 39179 Barleben- batch releaser, Lindopharm GmbH, Neustrasse 82, D-40721 Hilden, Germany- bulk manufacturer, packager, quality control (physicochemical), IMQ- Institut fur mikrobiologische Qualitatssicherung GmbH, Benninghofer Weg 2, Mettmann, 40822, Germany- quality control (microbiological)	Germany	Sandoz Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	OTC	19052/1 29.04.2020
36	ACC Extra	acetylcysteine	tablets effervescent	600mg; (10/5x2/) in aluminium laminated sachets, (20/10x2/) in aluminium laminated sachets	Salutas Pharma GmbH, Otto-von-Guericke-Alle-1, 39179 Barleben-batch releaser, Hermes Arzneimittel GmbH, Hans-Urmiler Ring 52, Wolfratshausen, Germany- bulk manufacturer, packager	Germany	Sandoz Pharmaceuticals d.d., Verovskova Str. 57, 1000 Ljubljana	Slovenia	OTC	18240/1 29.04.2020



37	ACC 600 Hot Drink	acetylcysteine	powder for oral solution	600mg; (6) sachets 3g	Salutas Pharma GmbH, Otto-von-Guericke-Alle-1, 39179 Barleben-batch releaser, Lindopharm GmbH, Neustrasse 82, D-40721 Hilden, Germany-bulk manufacturer, packager	Germany	Sandoz Pharmaceuticals d.d., Verovskova Str. 57, 1000 Ljubljana	Slovenia	OTC	17516/2 29.04.2020
38	ACC ACTIVE 600mg oral powder	acetylcysteine	powder oral	600mg; (10) and (20) sachets 3g	Salutas Pharma GmbH, Otto-von-Guericke-Alle-1, 39179 Barleben-batch releaser, Hermes Pharma Ges.m.b.H, Allgau 36, 9400 Wolfsberg, Austria-bulk manufacturer, packager	Germany	Sandoz Pharmaceuticals d.d. Verevskova 57, SI-1526 Ljubljana	Slovenia	OTC	17680/2 29.04.2020
39	ACC 100	acetylcysteine	tablets effervescent	100mg; (20) in plastic container	Salutas Pharma GmbH, Otto-von-Guericke-Alle-1, 39179 Barleben-batch releaser, Hermes Pharma Ges.m.b.H, Allgau 36, 9400 Wolfsberg, Austria-bulk manufacturer, packager, quality control	Germany	Sandoz Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	OTC	18715/1 29.04.2020
40	Nurofen for children	ibuprofen	suspension oral with strawberry flavour	20mg/ml; 100ml and 150ml plastic bottle and measuring syringe	Reckitt Benckiser HealthCare (UK) Limited, Dansom Lane, Hull, East Yorkshire, HU8 7DS	UK	Reckitt Benckiser Healthcare International Ltd, Thane Road, Nottingham, NG90 2DB	UK	OTC	15476/1 29.04.2020

41	Nurofen for children	ibuprofen	suspension oral with orange flavour	20mg/ml; 100ml and 150ml plastic bottle and measuring syringe	Reckitt Benckiser HealthCare (UK) Limited, Dansom Lane, Hull, East Yorkshire, HU8 7DS	UK	Reckitt Benckiser Healthcare International Ltd, Thane Road, Nottingham, NG90 2DB	UK	OTC	15477/1 29.04.2020
42	Simvastatin 20mg film-coated tablets	simvastatin	tablets film-coated	20mg; (30/3x10/) in blister	Lek S.A.,16 Podlipie Str., 95-010 Strykow- batch releaser, packager, Sandoz Grup Saglik Ueruenleri Ilaclari San. ve A.S., Gebze Organized Industrial Region Ihsan Dede, Cadde No. 900 Sokak, TR-41480, Gebze-Kocaeli, Turkey- bulk manufacturer	Poland	Sandoz Pharmaceuticals d.d., Verovskova Str. 57, 1000 Ljubljana	Slovenia	R	16465/1 29.04.2020
43	Simvastatin 40mg film-coated tablets	simvastatin	tablets film-coated	40mg; (100/10x10/) in blister	Lek S.A.,16 Podlipie Str., 95-010 Strykow- batch releaser, packager, Sandoz Grup Saglik Ueruenleri Ilaclari San. ve A.S., Gebze Organized Industrial Region Ihsan Dede, Cadde No. 900 Sokak, TR-41480, Gebze-Kocaeli, Turkey- bulk manufacturer	Poland	Sandoz Pharmaceuticals d.d., Verovskova Str. 57, 1000 Ljubljana	Slovenia	R	16466/1 29.04.2020

44	Janumet	sitagliptin (sitagliptin phosphate monohydrate), metformin (metformin hydrochloride)	tablets film-coated	50mg+850mg; (56/4x14/) in blister	Merck Sharp & Dohme B.V., Waarderweg 39, 2031 BN Haarlem-batch releaser, packager, Aesica Queenborough Limited, Queenborough Kent ME 11 5EL, UK-bulk manufacturer	the Netherlands	Merck Sharp & Dohme Corp., One Merck Drive, Whitehouse Station, New Jersey, 08889	USA	R	15580/2 29.04.2020
45	Janumet	sitagliptin (sitagliptin phosphate monohydrate), metformin (metformin hydrochloride)	tablets film-coated	50mg+1000mg; (56/4x14/) in blister	Merck Sharp & Dohme B.V., Waarderweg 39, 2031 BN Haarlem-batch releaser, packager, Aesica Queenborough Limited, Queenborough Kent ME 11 5EL, UK-bulk manufacturer	the Netherlands	Merck Sharp & Dohme Corp., One Merck Drive, Whitehouse Station, New Jersey, 08889	USA	R	15581/2 29.04.2020
46	Janumet	sitagliptin (sitagliptin phosphate monohydrate), metformin (metformin hydrochloride)	tablets film-coated	50mg+1000mg; (56/4x14/) in blister	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem-batch releaser, packager, Patheon Puerto Rico, Inc., State Road 670 Km. 2,7 Manati, Puerto Rico, 00674, USA-bulk manufacturer	the Netherlands	Merck Sharp & Dohme Corp., One Merck Drive, Whitehouse Station, New Jersey, 08889	USA	R	17069/2 29.04.2020
47	Janumet	sitagliptin (sitagliptin phosphate monohydrate), metformin (metformin hydrochloride)	tablets film-coated	50mg+500mg; (56/4x14/) in blister	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem-batch releaser, packager, Patheon Puerto Rico, Inc., State Road 670 Km. 2,7 Manati, Puerto Rico, 00674, USA-bulk manufacturer	the Netherlands	Merck Sharp & Dohme Corp., One Merck Drive, Whitehouse Station, New Jersey, 08889	USA	R	17070/2 29.04.2020

48	Janumet	sitagliptin (sitagliptin phosphate monohydrate), metformin (metformin hydrochloride)	tablets film-coated	50mg+850mg; (56/4x14/) in blister	Merck Sharp & Dohme B.V. Waarderweg 39, 2031 BN Haarlem-batch releaser, packager, Patheon Puerto Rico, Inc., State Road 670 Km. 2,7 Manati, Puerto Rico, 00674, USA-bulk manufacturer	the Netherlands	Merck Sharp & Dohme Corp., One Merck Drive, Whitehouse Station, New Jersey, 08889	USA	R	17071/2 29.04.2020
49	Strepsils	dichlorobenzyl alcohol, amylmetacresol	lozenges sugar free, with strawberry flavour	1,2mg+0,6mg; (16/2x8/) in blister	Reckitt Benckiser Healthcare International Limited, Nottingham site, Thane Road, Nottingham, Nottinghamshire, NG90 2DB	UK	Reckitt Benckiser Healthcare International Limited, Nottingham site, Thane Road, Nottingham, Nottinghamshire, NG90 2DB	UK	OTC	14817/3 29.04.2020
50	Strepsils	dichlorobenzyl alcohol, amylmetacresol	lozenges sugar free, with lemon flavour	1,2mg+0,6mg; (16/2x8/) and (24/2x12/), in blister	Reckitt Benckiser Healthcare International Limited, Nottingham site, Thane Road, Nottingham, Nottinghamshire, NG90 2DB	UK	Reckitt Benckiser Healthcare International Limited, Nottingham site, Thane Road, Nottingham, Nottinghamshire, NG90 2DB	UK	OTC	15038/1 29.04.2020

51	Gazyva	obinutuzumab	concentrate for solution for infusion	1000mg/40ml; (1) glass vial 40ml	F. Hoffmann-La Roche Ltd. 4303 Kaiseraugst- batch releaser, secondary packager, Roche Diagnostics GmbH, Sandhofer Strasse 116, 68305 Mannheim, Germany- bulk manufacturer, primary packager	Switzerland	F. Hoffmann-La Roche Ltd., Grenzacherstrasse, 124, CH-4070, Basel	Switzerland	R	17026/1 29.04.2020
52	Dexamethason	dexamethasone	tablets	0,5mg; (10/1x10/) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto-bulk manufacturer, batch releaser, KRKA, d.d. Novo mesto, Novomeskacesta 22, Sentjernej 8310, Slovenia-packager	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	R	18556/1 29.04.2020
53	Integrilin	eptifibatide	solution for infusion	0,75mg/ml; (1) glass vial 100ml	Glaxo Operations UK Ltd., Harmire Road Barnard Castle Co Durham, DL12 8DT	UK	GlaxoSmithKline (Ireland) Limited, 12 Riverwalk, Citywest Business Campus, Dublin 24	Ireland	R	19043/2 29.04.2020
54	Integrilin	eptifibatide	solution for injection	2mg/ml; (1) glass vial 10ml	Glaxo Operations UK Ltd., Harmire Road Barnard Castle Co Durham, DL12 8DT	UK	GlaxoSmithKline (Ireland) Limited, 12 Riverwalk, Citywest Business Campus, Dublin 24	Ireland	R	19044/1 29.04.2020

55	Lotar	losartan (losartan potassium)	tablets film-coated	50mg; (30/3x10/) 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	R	17226/2/1 29.04.2020
56	Lotar	losartan (losartan potassium)	tablets film-coated	100mg; (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	R	17225/2/1 29.04.2020
57	Cordarone	amiodarone (amiodarone hydrochloride)	solution for i/v injection	50mg/ml; (6) ampoules 3ml	Sanofi Winthrop Industrie, 1, rue de la Vierge, Ambares et Lagrave, 33565 Carbon Blanc cedex	France	Sanofi-Aventis France, 1-13, boulevard Romain Rolland, 75014 Paris	France	R	17436/1 29.04.2020
58	Fevarin	fluvoxamine (fluvoxamine maleate)	tablets film-coated	50mg; (15/1x15/) in blister	Mylan Laboratories SAS, Route de Belleville, Lieudit Maillard, 01400 Chatillon sur Chalaronne	France	Abbott Healthcare Products B.V., C.J. van Houtenlaan 36, 1381 CP Weesp	the Netherlands	R	18477/2 29.04.2020
59	Fevarin	fluvoxamine (fluvoxamine maleate)	tablets film-coated	100mg; (15/1x15/) in blister	Mylan Laboratories SAS, Route de Belleville, Lieudit Maillard, 01400 Chatillon sur Chalaronne	France	Abbott Healthcare Products B.V., C.J. van Houtenlaan 36, 1381 CP Weesp	the Netherlands	R	18478/2 29.04.2020

60	Anastrozole Denk 1mg	anastrozole	tablets film- coated	1mg; (30/3x10/) in blister	Haupt Pharma Muenster GmbH, Schleebrueggenkamp 15, 48159 Muenster	Germany	Denk Pharma GmbH & Co. KG, Prinzregentenstr. 79, 81675 Munchen	Germany	R	18777/1 29.04.2020
61	Ketonal DUO	ketoprofen	capsules modified-release	150mg; (20/2x10/) in blister, (30/3x10/) in blister	Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	R	15235/1 29.04.2020
62	Augmentin	amoxicillin (amoxicillin trihydrate), clavulanic acid (potassium clavulanate)	tablets film- coated	500mg+125mg; (14/2x7/) in blister	SmithKline Beecham Limited, Clarendon road, Worthing, West Sussex, BN14 8QH	UK	Beecham Group PLC, 980 Great West Road, Brentford, Middlesex, TW8 9GS	UK	R	17633/2 29.04.2020
63	Augmentin	amoxicillin (amoxicillin trihydrate), clavulanic acid (potassium clavulanate)	tablets film- coated	875mg+125mg; (14/2x7/) in blister	SmithKline Beecham Limited, Clarendon road, Worthing, West Sussex, BN14 8QH	UK	Beecham Group PLC, 980 Great West Road, Brentford, Middlesex, TW8 9GS	UK	R	17634/2 29.04.2020

64	Berlithion 600 capsules	thioctic acid	capsules soft	600mg; (15/1x15/) in blister, (30/2x15/) in blister	Berlin-Chemie AG, Glienicker Weg 125, 12489 Berlin-batch releaser, Catalent Germany Eberbach GmbH, Gammelsbacherstrasse 2, D- 69412 Eberbach, Germany- bulk manufacturer, Catalent Germany Schorndorf GmbH, Steinbeisstrasse 1 und 2, 73614, Schorndorf, Germany-packager	Germany	Berlin-Chemie AG, Glienicker Weg 125, 12489 Berlin	Germany	R	15972/1 29.04.2020
65	Analgin GIGAfarm	metamizole (metamizole sodium)	tablets	500mg; (200) in blister	Arpimed LLC, Kotayk Marz, Abovyan, 2nd Micro- District, 19 Building	Republic of Armenia	Giga Farm LLC, Gogunc str.3/5, Gyumri	Republic of Armenia	OTC	13971/2 29.04.2020
66	Atoris	atorvastatin (atorvastatin calcium)	tablets film-coated	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	R	15618/1 29.04.2020
67	Atoris	atorvastatin (atorvastatin calcium)	tablets film-coated	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	R	15617/1 29.04.2020



68	Mydoptic	phenylephrine (phenylephrine hydrochloride)	drops eye	25mg/ml; (1) and (10) plastic vial-dropper 10ml	Liqvor CJSC, 0089, Yerevan, str. Kochinyan, 7/9	Republic of Armenia	Liqvor CJSC, 0089, Yerevan, str. Kochinyan, 7/9	Republic of Armenia	R	17612/1 29.04.2020
69	Aqvitabin	gemcitabine (gemcitabine hydrochloride)	powder lyophilized for solution for infusion	200mg; glass vial	AqVida GmbH, Kaiser- Wilhelm-Str. 89, Hamburg, 20355-batch releaser, Actavis Italy S.p.A., Via Pasteur, 10, 20014 Nerviano, Milan, Italy-bulk manufacturer, packager	Germany	Aversi-Rational Ltd, Chirnakhuli Str. 14, 0198 Tbilisi	Georgia	R	18386/1 29.04.2020
70	Aqvitabin	gemcitabine (gemcitabine hydrochloride)	powder lyophilized for solution for infusion	1000mg; glass vial	AqVida GmbH, Kaiser- Wilhelm-Str. 89, Hamburg, 20355-batch releaser, Actavis Italy S.p.A., Via Pasteur, 10, 20014 Nerviano, Milan, Italy-bulk manufacturer, packager	Germany	Aversi-Rational Ltd, Chirnakhuli Str. 14, 0198 Tbilisi	Georgia	R	18387/1 29.04.2020