

LIST

of the medicines recommended for the registration by the Center according to the meeting decision N 7-2/20 on July 30, 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	Meloxicam	meloxicam	tablets	7,5mg; (20/2x10/) in blister	Open joint stock company "Borisovskiy zavod medicinskikh preparatov", 64, No3/2, ul. Chapaeva, Borisov, Minsk region	Belarus	Open joint stock company "Borisovskiy zavod medicinskikh preparatov", 64, ul. Chapaeva, Borisov, Minsk region	Belarus	R	19330 30.07.2020
2	Meloxicam	meloxicam	tablets	15mg; (20/2x10/) in blister	Open joint stock company "Borisovskiy zavod medicinskikh preparatov", 64, No3/2, ul. Chapaeva, Borisov, Minsk region	Belarus	Open joint stock company "Borisovskiy zavod medicinskikh preparatov", 64, ul. Chapaeva, Borisov, Minsk region	Belarus	R	19331 30.07.2020

3	Tivicay	dolutegravir (dolutegravir sodium)	tablets film-coated	50mg; (30) in plastic container	Glaxo Wellcome S.A., Avda Extremadura, 3, 09400 Aranda de Duero, Burgos- packager, batch releaser, Glaxo Operations UK Ltd, Priory street, Ware, SG 12 0DJ, UK- bulk manufacturer, quality control	Spain	ViiV Healthcare B.V. Huis ter Heideweg 62, Zeist, 3705 LZ	the Netherlands	R	19332 30.07.2020
4	Trimedat forte	trimebutine	tablets prolonged- release film-coated	300mg; (20/2x10) in blister	Valenta Pharm JSC, 141101, Moscow Region, Shchelkovo, Fabrichnaya St., 2	Russia	Valenta Pharm JSC, 141101, Moscow Region, Shchelkovo, Fabrichnaya St., 2	Russia	R	19333 30.07.2020
5	Bofen	ibuprofen	suspension oral	100mg/5ml; 100ml plastic bottle and measuring spoon	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	19334 30.07.2020
6	Oftaquix	levofloxacin (levofloxacin hemihydrate)	drops eye	5mg/ml; 5ml plastic bottle-dropper	Santen Oy, Kelloportinkatu 1, Tampere, 33100- batch releaser, NextPharma Oy, Niittyhaankatu 20, 33720 Tampere, Finland- bulk manufacturer, primary packager, quality control, Manufacturing Packaging Farmaca (MPF) B.V., Neptunus 12, HEERENVEEN, 8448 CN, the Netherlands- secondary packager	Finland	Santen Oy, Niittyhaankatu 20, 33720 Tampere	Finland	R	19335 30.07.2020

7	Dioxydine-Farmak	dioxidine	solution	10mg/ml; (10) ampoules 10ml, (10/2x5/) ampoules 10ml in blister	JSC "Farmak", 04080, Kiev, Kyrylivska str. 74	Ukraine	JSC "Farmak", 04080, Kiev, Kyrylivska str. 63	Ukraine	R	19336 30.07.2020
8	Oftan Dexamethason	dexamethasone (dexamethasone sodium phosphate)	drops eye	1mg/ml; 5ml plastic bottle-dropper	Santen Oy, Kelloportinkatu 1, Tampere, 33100- batch releaser, NextPharma Oy, Niittyhaankatu 20, 33720 Tampere, Finland- bulk manufacturer, primary packager, quality control, Manufacturing Packaging Farmaca (MPF) B.V., Neptunus 12, HEERENVEEN, 8448 CN, the Netherlands- secondary packager	Finland	Santen Oy, Niittyhaankatu 20, 33720 Tampere	Finland	R	19337 30.07.2020

LIST

of the medicines recommended for the registration (new indication) by the Center according to the meeting decision N 7-2/20 on July 30, 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	Maviret	glecaprevir, pibrentasvir	tablets film-coated	100mg+40mg; (84(4x21(7x3)) in blister	AbbVie Deutschland GmbH & Co. KG, Knolstrasse, 67061 Ludwigshafen - batch releaser, packager, quality control, Fournier Laboratories Ireland Limited, Anngrove, Carrigtwohill, Co. Cork, Ireland- bulk manufacturer	Germany	AbbVie Biopharmaceuticals GmbH, Neuhofstrasse 23, 6341 Baar	Switzerland	R	18744/1 30.07.2020

LIST

of the medicines recommended for the registration (new packaging) by the Center according to the meeting decision N 7-2/20 on July 30, 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	Aler-G	cetirizine (cetirizine dihydrochloride)	tablets film-coated	10mg; (10/1x10/) in blister, (20/2x10/) in blister	GM Pharmaceuticals Ltd, Phonichala 65, 0165 Tbilisi	Georgia	GM Pharmaceuticals Ltd, Phonichala 65, 0165 Tbilisi	Georgia	OTC	18093/1 30.07.2020

LIST

of the medicines recommended for the re-registration by the Center according to the meeting decision N 7-2/20 on July 30, 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	Locoid	hydrocortisone (hydrocortisone 17-butyrate)	cream for topical use	1mg/g; aluminum tube 30g	Temmler Italia S.r.L., Via delle Industrie 2, 20061 Carugate (MI)	Italy	LEO Pharma A/S, Industriparken 55, DK-2750 Ballerup	Denmark	R	19338 30.07.2020
2	Locoid Lipocream	hydrocortisone (hydrocortisone 17-butyrate)	cream for topical use	1mg/g; aluminum tube 30g	Temmler Italia S.r.L., Via delle Industrie 2, 20061 Carugate (MI)	Italy	LEO Pharma A/S, Industriparken 55, DK-2750 Ballerup	Denmark	R	19339 30.07.2020
3	Suprastin	chloropyramine (chloropyramine hydrochloride)	tablets	25mg; (20/2x10/) in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	OTC	19340 30.07.2020
4	Atoris	atorvastatin (atorvastatin calcium)	tablets film-coated	40mg; (30/3x10/) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	R	19341 30.07.2020

5	Tenikam	tenoxicam	powder lyophilized for solution for injection	20mg; (1) glass vial and solvent in ampoule 2ml	GM Pharmaceuticals Ltd, 65, Qvemo Phonichala str., 0165 Tbilisi - secondary packager, quality control (physicochemical), batch releaser, Anfarm Hellas S.A., Sximatari Viotias, 32009, Greece- bulk manufacturer, primary packager, quality control (microbiological)	Georgia	GM Pharmaceuticals Ltd, 65, Qvemo Phonichala str., 0165 Tbilisi	Georgia	R	19342 30.07.2020
6	Cytarabine	cytarabine	powder lyophilized for solution for injection	100mg; (1) glass vial, (40) glass vials	Belmedpreparaty RUE, 220007, Minsk, Fabritsius St., 30- quality control, batch releaser, Belmedpreparaty RUE, 220007, Minsk, Fabritsius St., 30, N2, Belarus- bulk manufacturer, packager	Belarus	Belmedpreparaty RUE, 220007, Minsk, Fabritsius St., 30	Belarus	R	19343 30.07.2020
7	Norcolut	norethisterone	tablets	5mg; (20/2x10/) in blister	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	Gedeon Richter PLC, Gyomroi ut 19-21, 1103 Budapest	Hungary	R	19344 30.07.2020
8	Jeanine	ethinylestradiol, dienogest	tablets coated	0.03mg+2mg; (21/1x21/) in blister	Bayer Weimar GmbH & Co. KG, Dobereinerstrasse 20, 99427 Weimar	Germany	Bayer AG, Kaiser-Wilhelm-Allee 1, 51373 Leverkusen	Germany	R	19345 30.07.2020
9	BC DentaHex Solution	chlorhexidine (chlorhexidine gluconate)	solution for external use	20mg/ml; (1) glass vial 100ml	Bio-Chem Ltd., 0046, Erevan, Manandyan str. 33, 1/1	Republic of Armenia	Bio-Chem Ltd., 0046, Erevan, Manandyan str. 33, 1/1	Republic of Armenia	OTC	19346 30.07.2020

10	Azibiot	azithromycin (azithromycin dihydrate)	tablets film-coated	500mg; (3/1x3/) 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	19347 30.07.2020
11	Lorista HD	losartan (losartan potassium), hydrochlorothiazide	tablets film-coated	100mg+25mg; (28/2x14) in blister	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	KRKA d.d., Novo mesto, Smarjeska cesta 6, 8501 Novo Mesto	Slovenia	R	19348 30.07.2020
12	Credanil 25/250	levodopa, carbidopa	tablets	250mg+25mg; (50/5x10/) in blister	Remedica Ltd, Aharnon street, Limassol Industrial Estate, 3056 Limassol	Cyprus	Remedica Ltd, Aharnon street, Limassol Industrial Estate, 3056 Limassol	Cyprus	R	19349 30.07.2020
13	Suprastin	chloropyramine (chloropyramine hydrochloride)	solution for injection	20mg/ml; (5/1x5/) ampoules 1ml in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi st. 30-38	Hungary	R	19350 30.07.2020
14	Vessel Due F	sulodexide	capsules	250LSU; (50/2x25/) in blister	Alfasigma S.p.A., Via Enrico Fermi, 1-65020, Alanno (Pescara)-packager, quality control, batch releaser, Catalent Italy S.p.A., Via Nettunense Km. 20, 100 - 04011 Aprilia (LT), Italy-bulk manufacturer	Italy	Alfasigma S.p.A., Via Ragazzi del, 99, 5-40133 Bologna (BO)	Italy	R	19351 30.07.2020



15	Vessel Due F	sulodexide	solution for injection	300LSU/ml; (10/2x5/) ampoules 2ml in blister	Alfasigma S.p.A., Via Enrico Fermi, 1-65020, Alanno (Pescara) for	Italy	Alfasigma S.p.A., Via Ragazzi del, 99, 5-40133 Bologna (BO)	Italy	R	19352 30.07.2020
16	Vurdon	diclofenac (diclofenac sodium)	tablets gastro-resistant	50mg; (20/2x10/) in blister	Help S.A., Pedini Ioanninon, Ioannina, 45500	Greece	ARGO-PHARM LLC, 13/9 Sundukyan str., 0012 Yerevan	Republic of Armenia	R	19353 30.07.2020

LIST

of variations requiring reformulation of registration certificate approved by the Center according to the meeting decision N 7-2/20 on July 30, 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	Ibuprofen-Asteria Tab. 400mg	ibuprofen	tablets film-coated	400mg; (20/2x10/) in blister, (100/10x10/) in blister	Hankook Korus Pharm Co., Ltd, 30, Gangjeo-ro, Jecheon-Si, Chungcheongbuk-do	Korea South	Asteria LLC, 28 Tigran Mets str., office 24, 0018 Yerevan	Republic of Armenia	OTC	18788/1/1 30.07.2020
2	Levofloxacin-Asteria	levofloxacin	tablets film-coated	500mg; (10/1x10/) in blister and(100/10x10/) in blister	Hankook Korus Pharm Co., Ltd, 30, Gangjeo-ro, Jecheon-si, Chungcheongbuk-do	Korea South	Asteria LLC, 28 Tigran Mets str., office 24, 0018 Yerevan	Republic of Armenia	R	15254/3/1 30.07.2020
3	Niperten	bisoprolol (bisoprolol fumarate)	tablets film-coated	2,5mg; (30/2x15/) 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	16716/2/1 30.07.2020
4	Niperten	bisoprolol (bisoprolol fumarate)	tablets film-coated	5mg; (30/2x15/) 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	16714/2/1 30.07.2020

LIST

of the variations not requiring reformulation of registration certificate approved by the Center according to the meeting decision N 7-2/20 on July 30, 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	Euphylline	aminophylline	solution for i/v injection	24mg/ml; (10) ampoules 5ml, label banderol, (10) ampoules 5ml	Open joint stock company "Borisovskiy zavod medicinskih preparatov", 64, No11/1, No 14/1 ul. Chapaeva, Borisov, Minsk region	Belarus	Open joint stock company "Borisovskiy zavod medicinskih preparatov", 64, ul. Chapaeva, Borisov, Minsk region	Belarus	R	18495/1 30.07.2020
2	Atoris	atorvastatin (atorvastatin calcium)	tablets film-coated	40mg; (30/3x10/) blisters	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	14652/2 30.07.2020
3	Amoksiklav powder for solution for injection 500mg/100mg	amoxicillin (amoxicillin sodium), clavulanic acid (potassium clavulanate)	powder for solution for injection	500mg+100mg; (5) glass vial	Sandoz GmbH, Biochemiestrasse 10, A-6250 Kundl	Austria	Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	R	16075/1 30.07.2020

4	Amoksiklav powder for solution for injection 1000mg /200mg	amoxicillin (amoxicillin sodium), clavulanic acid (potassium clavulanate)	powder for solution for injection	1000mg+200mg; (5) glass vial	Sandoz GmbH, Biochemiestrasse 10, A-6250 Kundl	Austria	Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	R	16074/1 30.07.2020
5	Cevikap	ascorbic acid	drops oral	100mg/ml; glass bottle-dropper 10ml, glass bottle-dropper 30ml	Medana Pharma JSC, 98-200 Sieradz, W. Lokietka 10 - batch releaser, Medana Pharma JSC, str. Polskiej Organizacji Wojskowej 57, 98-200 Sieradz, Poland-bulk manufacturer, packager	Poland	Medana Pharma JSC, 98-200 Sieradz, W. Lokietka 10	Poland	OTC	15528/1 30.07.2020
6	Indovasin	indometacin, troxerutin	gel for external use	30mg/g+20mg/g; 45g aluminium tube	Balkanpharma-Troyan AD, Krayrechna Str. N1, 5600, Troyan	Bulgaria	Balkanpharma-Troyan AD, (ACTAVIS GROUP) Krayrechna Str. N1, 5600, Troyan	Bulgaria	OTC	16834/2 30.07.2020
7	Troxevasin 2%	troxerutin	gel for external use	20mg/g; 40g aluminium or plastic tube	Balkanpharma-Troyan AD, Krayrechna Str. N1, 5600, Troyan	Bulgaria	Balkanpharma-Troyan AD, (ACTAVIS GROUP) Krayrechna Str. N1, 5600, Troyan	Bulgaria	OTC	16580/2 30.07.2020

8	Spitomin	bupirone	tablets	5mg; (60/6x10/), in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120 - batch releaser, packager, Egis Pharmaceuticals PLC, 9900, Kormend, Matyas Kiraly u. 65, Hungary- bulk manufacturer	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi ut 30- 38	Hungary	R	15377/1 30.07.2020
9	Spitomin	bupirone	tablets	10mg; (60/6x10/), in blister	Egis Pharmaceuticals PLC, 1165 Budapest, Bokenyfoldi st. 118-120 - batch releaser, packager, Egis Pharmaceuticals PLC, 9900, Kormend, Matyas Kiraly u. 65, Hungary- bulk manufacturer	Hungary	Egis Pharmaceuticals PLC, 1106 Budapest, Kereszturi ut 30- 38	Hungary	R	15376/1 30.07.2020
10	Meloxicam DC	meloxicam	solution for injection	10mg/ml; (3) ampoules 1,5ml	Zhangjiakou Kaiwei Pharmaceutical Co. Ltd., No 27, Lingyuan Road, Zhangjiakou, Heibei Province	China	Dahnsen Trading Pharmaceutical Company Limited, HoChiMinh city, 44A Dang Dung street, Tan Dinh ward, District 1	Vietnam	R	14326/1 30.07.2020
11	Rinomaris	xylometazoline (xylometazoline hydrochloride)	spray nasal	0,5mg/ml; 10ml and 15ml plastic vial	JADRAN-GALENSKI LABORATORIJ d.d., Svilno 20, 51000 Rijeka	Croatia	JADRAN- GALENSKI LABORATORIJ d.d., Svilno 20, 51000 Rijeka	Croatia	OTC	17580/1 30.07.2020

12	Rinomaris	xylometazoline (xylometazoline hydrochloride)	spray nasal	1mg/ml; 10ml and 15ml plastic vial	JADRAN-GALENSKI LABORATORIJ d.d., Svilno 20, 51000 Rijeka	Croatia	JADRAN-GALENSKI LABORATORIJ d.d., Svilno 20, 51000 Rijeka	Croatia	OTC	17581/1 30.07.2020
13	Flavamed effervescent tablets	ambroxol (ambroxol hydrochloride)	tablets effervescent	60mg; (10) aluminium or plastic container	Berlin-Chemie AG, Glienicker Weg 125, 12489 Berlin-batch releaser (bulk manufacturer, primary and secondary packager-Hermes Arzneimittel GmbH, Hans-Urmiler Ring 52, 82515 Wolfratshausen, Germany)	Germany	Berlin-Chemie AG, Glienicker Weg 125, 12489 Berlin	Germany	OTC	14785/1 30.07.2020
14	Tobradex	tobramycin, dexamethasone	drops eye (suspension)	3mg/ml+1mg/ml; 5ml plastic vial	S.A. Alcon-Couvreur N.V., Rijksweg 14 2870 Puurs	Belgium	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	R	18048/2 30.07.2020
15	Tobradex	tobramycin, dexamethasone	ointment eye	3mg/g+1mg/g; 3,5g aluminium tube	S.A. Alcon-Couvreur N.V., Rijksweg 14 2870 Puurs	Belgium	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	R	18047/2 30.07.2020
16	Deep Relief	ibuprofen, levomenthol(menthol)	gel for external use	50mg/g+30mg/g; 15g aluminium tube, 50g aluminium tube, 100g aluminium tube	The Mentholatum Company Limited, 1 Redwood Avenue, Peel Park Campus, East Kilbride, G74 5PE, Scotland	UK	The Mentholatum Company Limited, 1 Redwood Avenue, Peel Park Campus, East Kilbride, G74 5PE, Scotland	UK	OTC	14787/1 30.07.2020

17	Azibiot	azithromycin (azithromycin dihydrate)	tablets film-coated	500mg; (3/1x3/), 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	14892/2 30.07.2020
18	Credanil 25/250	levodopa, carbidopa	tablets	250mg+25mg; (50/5x10/) in blisters	Remedica Ltd, Limassol Industrial Estate, Aharnon street, 3056 Limassol	Cyprus	Remedica Ltd, Limassol Industrial Estate, Aharnon street, 3056 Limassol	Cyprus	R	14597/2 30.07.2020
19	Dimex	diphenhydramine (diphenhydramine hydrochloride), ammonium chloride	syrup	1.992mg/ml+19.92mg/ml; 125ml glass or plastic bottle and measuring cup	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia - batch releaser, Sopharma JSC, Vrabevo vlg. 5660, district of Lovetch, Bulgaria-bulk manufacturer, primary and secondary packager	Bulgaria	Sopharma JSC, str. Iliensko shosse 16, 1220 Sofia	Bulgaria	OTC	14883/1 30.07.2020
20	Amaryl	glimepiride	tablets	1mg; (30/1x30/) in blister	SANOFI S.P.A., S.S. 17 km 22, 67019 Scoppito (AQ)	Italy	Sanofi-Aventis Deutschland GmbH, Bruningstrasse 50, D-65926 Frankfurt am Main	Germany	R	16921/1 30.07.2020
21	Amaryl	glimepiride	tablets	2mg; (30/2x15/) in blister	SANOFI S.P.A., S.S. 17 km 22, 67019 Scoppito (AQ)	Italy	Sanofi-Aventis Deutschland GmbH, Bruningstrasse 50, D-65926 Frankfurt am Main	Germany	R	16923/1 30.07.2020

22	Amaryl	glimepiride	tablets	4mg; (30/2x15/) in blister	SANOFI S.P.A., S.S. 17 km 22, 67019 Scoppito (AQ)	Italy	Sanofi-Aventis Deutschland GmbH, Bruningstrasse 50, D-65926 Frankfurt am Main	Germany	R	16922/1 30.07.2020
23	Nakom	levodopa, carbidopa	tablets	250mg+25mg; (100/10x10/) in blister	Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	R	18638/2 30.07.2020
24	Ferrum Lek	iron (III)-hydroxide dextran complex	solution for i/m injection	50mg/ml; (5) ampoules 2ml, (50) ampoules 2ml	Lek d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	Lek d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	R	19069/2 30.07.2020
25	Afinitor	everolimus	tablets	10mg; (30/3x10/) in blister	Novartis Pharma Stein AG, Schaffhauserstrasse, 4332 Stein	Switzerland	Novartis Pharma AG, 35, Lichtstrasse, 4056 Basel	Switzerland	R	15498/1 30.07.2020
26	Glivec	imatinib (imatinib mesylate)	tablets film-coated	400mg; (30/3x10/) in blister	Novartis Pharma Stein AG, Schaffhauserstrasse, 4332 Stein	Switzerland	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	R	15233/1 30.07.2020
27	Glivec	imatinib (imatinib mesylate)	tablets film-coated	400mg; (30/3x10/) in blister	Novartis Pharma Produktions GmbH, Oeflinger Strasse 44, 79664 Wehr	Germany	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	R	16976/1 30.07.2020



28	Glivec	imatinib (imatinib mesylate)	tablets film-coated	100mg; (60/6x10/) in blister	Novartis Pharma Produktions GmbH, Oeflinger Strasse 44, 79664 Wehr	Germany	Novartis Pharma AG, Lichtstrasse 35, 4056 Basel	Switzerland	R	17496/1 30.07.2020
29	Afinitor	everolimus	tablets	5mg; (30/3x10/) in blister	Novartis Pharma Stein AG, Schaffhauserstrasse, 4332 Stein	Switzerland	Novartis Pharma AG, 35, Lichtstrasse, 4056 Basel	Switzerland	R	15497/1 30.07.2020
30	Faspic	ibuprofen	tablets film-coated	400mg; (6/1x6), (12/2x6/), (24/4x6/) and (30/5x6/) in blister	Zambon S.P.A., Via della Chimica, 9, Vicenza, 36100	Italy	Zambon S.P.A., Via Lillo del Duca, 10, Bresso, 20091	Italy	OTC	17264/1 30.07.2020
31	Bupivacaine WPW Spinal 0,5% Heavy	bupivacaine (bupivacaine hydrochloride)	solution for injection	5mg/ml; (5) ampoules 4ml	Warsaw Pharmaceutical Works "Polfa" S.A., Karolkowa 22/24 str., 01-207 Warsaw	Poland	Warsaw Pharmaceutical Works "Polfa" S.A., Karolkowa 22/24 str., 01-207 Warsaw	Poland	R	18971/1 30.07.2020
32	Azithromycin-Asteria	azithromycin (azithromycin dihydrate)	tablets film-coated	250mg; (6/1x6/) in blister	ONE PHARMA INDUSTRIAL PHARMACEUTICAL COMPANY SOCIETE ANONYME, 60th km N.N.R. Athinon-Lamias, Sximatari Voiotias, 32009	Greece	PHARMANEL COMMERCIAL PHARMACEUTICAL S.A.106 Marathonos Ave., 15344 Gerakas Attikis	Greece	R	18416/2 30.07.2020

33	Azithromycin-Asteria	azithromycin (azithromycin dihydrate)	tablets film-coated	500mg; (3/1x3/) in blister	ONE PHARMA INDUSTRIAL PHARMACEUTICAL COMPANY SOCIETE ANONYME, 60th km N.N.R. Athinon-Lamias, Sximatari Voiotias, 32009	Greece	PHARMANEL COMMERCIAL PHARMACEUTICAL S.A.106 Marathonos Ave., 15344 Gerakas Attikis	Greece	R	18417/2 30.07.2020
34	Ulcavis	bismuth tripotassium dicitrate (bismuth oxide)	tablets film-coated	120mg; (28/2x14/), (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	R	16657/1 30.07.2020
35	Ketonal	ketoprofen	solution for injection	50mg/ml; (10) ampoules 2ml	Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	Lek Pharmaceuticals d.d., Verovskova Str. 57, 1526 Ljubljana	Slovenia	R	18587/1 30.07.2020
36	Mildronat	meldonium (meldonium dihydrate)	capsules	500mg; (20/2x10/) and (60/6x10/) in blister	Grindeks JSC, Krustpils street 53, LV-1057, Riga	Latvia	Grindeks JSC, Krustpils street 53, LV-1057, Riga	Latvia	R	17185/1 30.07.2020
37	Aluvia	lopinavir, ritonavir	tablets film-coated	100mg+25mg; (60) in plastic container	AbbVie Deutschland GmbH & Co. KG, Knolstrasse, 67061 Ludwigshafen	Germany	AbbVie Biopharmaceuticals GmbH, Neuhofstrasse 23, 6341 Baar	Switzerland	R	15252/2 30.07.2020
38	Aluvia	lopinavir, ritonavir	tablets film-coated	200mg+50mg; (120) in plastic container	AbbVie Deutschland GmbH & Co. KG, Knolstrasse, 67061 Ludwigshafen	Germany	AbbVie Biopharmaceuticals GmbH, Neuhofstrasse 23, 6341 Baar	Switzerland	R	16930/2 30.07.2020

39	AirFluSal Forspiro	salmeterol (salmeterol xinafoate), fluticasone (fluticasone propionate)	powder for inhalation	50mcg/dose+250mcg/dose; powder in blister (60 dose), in plastic inhaler	Aeropharm GmbH, Francois-Mitterrand-Alee 1, 07407 Rudolstadt	Germany	Sandoz Pharmaceuticals d.d., Verovskova Str. 57, 1000 Ljubljana	Slovenia	R	15023/1 30.07.2020
40	AirFluSal Forspiro	salmeterol (salmeterol xinafoate), fluticasone (fluticasone propionate)	powder for inhalation	50mcg/dose+500mcg/dose; powder in blister (60 dose), in plastic inhaler	Aeropharm GmbH, Francois-Mitterrand-Alee 1, 07407 Rudolstadt	Germany	Sandoz Pharmaceuticals d.d., Verovskova Str. 57, 1000 Ljubljana	Slovenia	R	15022/1 30.07.2020
41	Fastum gel	ketoprofen	gel	25mg/g; aluminium tube 30g, aluminium tube 50g, aluminium tube 100g	A. Menarini Manufacturing Logistics and Services S.r.l., Via Sette Santi, 3 50131 Firenze	Italy	A. Menarini Industrie Farmaceutiche Riunite S.r.l., Via Sette Santi, 3 50131 Firenze	Italy	R	14625/1 30.07.2020
42	Fastum gel	ketoprofen	gel	25mg/g; plastic tube 100g and pump dispenser	A. Menarini Manufacturing Logistics and Services S.r.l., Via Sette Santi, 3 50131 Firenze	Italy	A. Menarini Industrie Farmaceutiche Riunite S.r.l., Via Sette Santi, 3 50131 Firenze	Italy	R	14626/1 30.07.2020
43	Herceptin	trastuzumab	solution for s/c injection	600mg/5ml; glass vial 6ml	F. Hoffmann-La Roche Ltd., 4303 Kaiseraugst	Switzerland	F. Hoffmann-La Roche Ltd., Grenzacherstrasse, 124, CH-4070, Basel	Switzerland	R	18186/1 30.07.2020

44	Siofor 1000	metformin (metformin hydrochloride)	tablets film-coated	1000mg; (60/4x15/) in blister	Menarini-Von Heyden GmbH, Leipziger Strasse 7-13, 01097 Dresden	Germany	Laboratori Guidotti S.p.A., Via Livornese, 897 56122 La Vettola (Pisa)	Italy	R	15190/1 30.07.2020
45	Siofor 1000	metformin (metformin hydrochloride)	tablets film-coated	1000mg; (60/4x15/) in blister	Berlin-Chemie A.G.,Glienicker Weg 125, D-12489 Berlin-batch releaser, Dragenopharm Apotheker Puschl GmbH, Gollstrasse 1, 84529 Tittmoning, Germany-bulk manufacturer, packager	Germany	Laboratori Guidotti S.p.A., Via Livornese, 897 56122 La Vettola (Pisa)	Italy	R	15577/1 30.07.2020
46	Siofor 1000	metformin (metformin hydrochloride)	tablets film-coated	1000mg; (60/4x15/) in blister	Berlin-Chemie A.G.,Glienicker Weg 125, D-12489 Berlin-batch releaser, packager, Berlin-Chemie A.G., Tempelhofer Weg 83, D-12347 Berlin,Germany-bulk manufacturer	Germany	Laboratori Guidotti S.p.A., Via Livornese, 897 56122 La Vettola (Pisa)	Italy	R	17467/1 30.07.2020
47	Diclofenac	diclofenac (diclofenac sodium)	solution for injection	25mg/ml; (5) ampoules 3ml in blister	Hemofarm A.D., 26300 Vrsac, Beogradski put bb	Serbia	Hemofarm A.D., 26300 Vrsac, Beogradski put bb	Serbia	R	19194/1 30.07.2020
48	Celestoderm-V cream with Garamycin	betamethasone (betamethasone 17-valerate), gentamicin (gentamicin sulfate)	cream	1mg/g+1mg/g; aluminium tube 30g	Schering-Plough Labo N.V., Industriepark 30 B-2220, Heist-op-den-Berg	Belgium	Schering-Plough Central East AG, Weyrstrasse 20, CH-6000 Lucerne 6	Switzerland	R	18373/1 30.07.2020

49	Bifren	phenybut	capsules	250mg; (20/2x10/) in blister	Pharma Start LLC, Boulevard Vatslava Havela, 8, 03124, Kiev	Ukraine	Acino Ukraine LLC, Boulevard Vatslava Havela, 8, 03124, Kiev	Ukraine	R	18733/1 30.07.2020
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