

Rejection for registration (2019)

N	Date	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
1	18.01.2019	BacTRONN	sulfamethoxazole, trimethoprim	tablets	400mg+80mg; (100/10x10/) in blister	Medicon Pharmaceuticals Ltd, Industrial Plot No.17/A-1, Block-D, Section-10, Mirpur, Dhaka-1216	Bangladesh	Medicon Pharmaceuticals Ltd, Industrial Plot No.17/A-1, Block-D, Section-10, Mirpur, Dhaka-1216	Bangladesh	R
2	18.01.2019	BacTRONN Forte	sulfamethoxazole, trimethoprim	tablets	800mg+160mg; (10/1x10/) in blister	Medicon Pharmaceuticals Ltd, Industrial Plot No.17/A-1, Block-D, Section-10, Mirpur, Dhaka-1216	Bangladesh	Medicon Pharmaceuticals Ltd, Industrial Plot No.17/A-1, Block-D, Section-10, Mirpur, Dhaka-1216	Bangladesh	R
3	26.01.2019	Diclosan	diclofenac (diclofenac sodium), nicotinic acid	gel	10mg/g+10mg/g; 40g aluminium tube	'Lubnypharm' PJSC, 37500, Poltava region, Lubny, Petrovskogo str. 16	Ukraine	'Lubnypharm' PJSC, 37500, Poltava region, Lubny, Petrovskogo str. 16	Ukraine	OTC

4	12.04.2019	Arpoya	aripiprazole	tablets orodispersible	10mg; (28/2x14/) in blister	Pharmathen International S.A., Industrial Park Sapes, Rodopi Prefecture, Block No 5, Rodopi 69300	Greece	Pharmathen S.A., Dervenakion 6, 15351 Pallini, Attiki	Greece	R
5	12.04.2019	Farmorubicin Rapid Dissolution	epirubicin (epirubicin hydrochloride)	powder lyophilized for solution for infusion	10mg; glass vial and solvent in ampoule 5ml	Actavis Italy S.p.A., Viale Pasteur, 10, 20014 Nerviano, Milan	Italy	Pfizer H.C.P. Corporation, 235, East 42nd street, New York 10017	USA	R
6	12.04.2019	Farmorubicin Rapid Dissolution	epirubicin (epirubicin hydrochloride)	powder lyophilized for solution for infusion	50mg; glass vial	Actavis Italy S.p.A., Viale Pasteur, 10, 20014 Nerviano, Milan	Italy	Pfizer H.C.P. Corporation, 235, East 42nd street, New York 10017	USA	R
7	12.04.2019	Repoitin 2000	epoetin alfa	solution for injection	2000IU/0,5ml; pre-filled syringes 0,5ml	Serum Institute of India Pvt Ltd., 212/2, Hadapsar, Pune 411028	India	Serum Institute of India Pvt Ltd., 212/2, Hadapsar, Pune 411028	India	R
8	12.04.2019	Repoitin 4000	epoetin alfa	solution for injection	4000IU/0,4ml; pre-filled syringes 0,4ml	Serum Institute of India Pvt Ltd., 212/2, Hadapsar, Pune 411028	India	Serum Institute of India Pvt Ltd., 212/2, Hadapsar, Pune 411028	India	R
9	12.04.2019	Urizol 200mg	flavoxate	tablets film-coated	200mg; (10/1x10/) in blister	Tufenkji Group LLC, Kochinyan 13/16, Yerevan-batch releaser, secondary packager, Synokem Pharmaceuticals Ltd, Plot No 35-36; Sector-6(A), IIE, Ranipur, Haridwar, Uttarakhand, India-bulk	Republic of Armenia	Tufenkji Group LLC, Kochinyan 13/16, Yerevan	Republic of Armenia	R

10	10.05.2019	Zvezdochka Lor	benzydamine (benzydamine hydrochloride)	spray for topical use	1,5mg/ml; (1) plastic vial 30ml with pump dispenser	Danapha Pharmaceutical JSC, 253 Dung Si Thanh Khe str., Thanh Khe District, Danang city	Vietnam	"DANSON -BG" OOD, 26, "Otetz Paisij" str., Radomir, 2400	Bulgaria	OTC
11	10.05.2019	Zvezdochka Lor	benzydamine (benzydamine hydrochloride)	spray for topical use	3mg/ml; (1) plastic vial 15ml with pump dispenser	Danapha Pharmaceutical JSC, 253 Dung Si Thanh Khe str., Thanh Khe District, Danang city	Vietnam	"DANSON -BG" OOD, 26, "Otetz Paisij" str., Radomir, 2400	Bulgaria	OTC
12	23.05.2019	Lamotrin	lamotrigine	tablets	25mg; (30/3x10/) in blister, (60/6x10/) in blister	Pharma Start LLC, Boulevard I. Lepse, 8, 03124, Kiev	Ukraine	Pharma Start LLC, Boulevard I. Lepse, 8, 03124, Kiev	Ukraine	R
13	23.05.2019	Lamotrin	lamotrigine	tablets	50mg; (30/3x10/) in blister, (60/6x10/) in blister	Pharma Start LLC, Boulevard I. Lepse, 8, 03124, Kiev	Ukraine	Pharma Start LLC, Boulevard I. Lepse, 8, 03124, Kiev	Ukraine	R

14	23.05.2019	Lamotrin	lamotrigine	tablets	100mg; (30/3x10/) in blister, (60/6x10/) in blister	Pharma Start LLC, Boulevard I. Lepse, 8, 03124, Kiev	Ukraine	Pharma Start LLC, Boulevard I. Lepse, 8, 03124, Kiev	Ukraine	R
15	23.05.2019	Endulin	insulin glargine	solution for injection	100IU/ml; (1) glass vial 3ml	Biocon Ltd, Plot No. 2-4, Phase-IV, Bommasandra-Jigani Link Road, Bommasandra Post, Bangalore-560 099	India	Mylan Pharmaceuticals Pvt Ltd, Plot No: 1/-A/2, MIDC, Industrial Estate, Taloja, Panvel, Raigad, Maharashtra-410208	India	R
16	23.05.2019	Endulin	insulin glargine	solution for injection	100IU/ml; (1) glass vial 10ml	Biocon Ltd, Plot No. 2-4, Phase-IV, Bommasandra-Jigani Link Road, Bommasandra Post, Bangalore-560 099	India	Mylan Pharmaceuticals Pvt Ltd, Plot No: 1/-A/2, MIDC, Industrial Estate, Taloja, Panvel, Raigad,	India	R
17	23.05.2019	Endulin	insulin glargine	solution for injection	100IU/ml; (1) glass cartridge 3ml	Biocon Ltd, Plot No. 2-4, Phase-IV, Bommasandra-Jigani Link Road, Bommasandra Post, Bangalore-560 099	India	Mylan Pharmaceuticals Pvt Ltd, Plot No: 1/-A/2, MIDC, Industrial Estate, Taloja, Panvel, Raigad, Maharashtra-410208	India	R

18	08.08.2019	Allercaps	cetirizine (cetirizine hydrochloride)	capsules	5mg; (20/2x10/) in blister	Minskintercaps U.V., 26/3, Inzhenernaya str., 220075, Minsk	Belarus	Minskintercaps U.V., 26, Inzhenernaya str., 220075, Minsk	Belarus	OTC
19	08.08.2019	Allercaps	cetirizine (cetirizine hydrochloride)	capsules	10mg; (20/2x10/) in blister	Minskintercaps U.V., 26/3, Inzhenernaya str., 220075, Minsk	Belarus	Minskintercaps U.V., 26, Inzhenernaya str., 220075, Minsk	Belarus	OTC
20	08.08.2019	Micro-vitam	L-alanine, L-arginine, L-valine, L-histidine, glycine, L-isoleucine, L-leucine, L-lysine, L-methionine, L-proline, L-threonine, L-tryptophan, L-phenylalanine, L-tyrosine, L-cysteine, L-cystine, L-aspartic acid, L-serine, L-glutamine	solution for infusion	0.05mg/ml+0.07mg/ml+0.04mg/ml+0.02mg/ml+0.05mg/ml+0.04mg/ml+0.1mg/ml+0.03mg/ml+0.03mg/ml+0.04mg/ml+0.06mg/ml+0.02mg/ml+0.03mg/ml+0.04mg/ml+0.1mcg/ml+0.01mg/ml+0.06mg/ml+0.05mg/ml+0.1mg/ml; vial	Ekohimtech LLC, 65, Ulyanov str., Liter 3G, Ufa	Russia	Farma-Kar LLC, 19/5, Parpetsi, Yerevan	Republic of Armenia	OTC
21	09.09.2019	Holyflox	levofloxacin (levofloxacin hemihydrate)	solution for infusion	5mg/ml; 100ml plastic container	Abaris Healthcare Pvt. LTD, Survey No.1407/1411, Village Rajpur, Taluka Kadi, Dist.Mehsana-382740.Gujarat	India	HOLYHEAD PHARMACEUTICA LS PVT.LTD. D101, Gymkhana palm height, Dhampur,	India	R
22	09.09.2019	Holymet	metronidazole	solution for infusion	5mg/ml;100ml plastic container	Abaris Healthcare Pvt. LTD, Survey No.1407/1411, Village Rajpur, Taluka Kadi, Dist.Mehsana-382740.Gujarat	India	HOLYHEAD PHARMACEUTICA LS PVT.LTD. D101, Gymkhana palm height, Dhampur, Ghatikia,	India	R

23	09.09.2019	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
24	23.09.2019	Biogest	progesterone	pessaries vaginal or rectal	200mg; (30/6x5/) in strip	Marcyrl Pharmaceuticals Industries, West Extension-Block 20005, El-Obour city 11828	Egypt	Marcyrl Pharmaceuticals Industries, El Obour City, The West Extension, Block 20005,Cairo	Egypt	R
25	23.09.2019	Biogest	progesterone	pessaries vaginal or rectal	400mg; (30/6x5/) in strip	Marcyrl Pharmaceuticals Industries, West Extension-Block 20005, El-Obour city 11828	Egypt	Marcyrl Pharmaceuticals Industries, El Obour City, The West Extension, Block 20005,Cairo	Egypt	R
26	23.09.2019	Fortrustep	dapoxetine (dapoxetine hydrochloride)	tablets film-coated	60mg; (6/1x6/) in blister	Marcyrl Pharmaceuticals Industries, West Extension-Block 20005, El-Obour city 11828	Egypt	Marcyrl Pharmaceuticals Industries, El Obour City, The West Extension, Block 20005,Cairo	Egypt	R

27	14.11.2019	Luteina	progesterone	tablets vaginal	100mg; (30/3x10/) in blister and applicator	Pharmaceutical Works Polfa in Pabianice JSC, 5 Marszalka J. Pilsudskiego Str., 95-200 Pabianice	Poland	Pharmaceutical Works Polfa in Pabianice JSC, 5 Marszalka J. Pilsudskiego Str., 95-200 Pabianice	Poland	R
28	14.11.2019	Luteina	progesterone	tablets vaginal	200mg; (30/3x10/) in blister and applicator	Pharmaceutical Works Polfa in Pabianice JSC, 5 Marszalka J. Pilsudskiego Str., 95-200 Pabianice	Poland	Pharmaceutical Works Polfa in Pabianice JSC, 5 Marszalka J. Pilsudskiego Str., 95-200 Pabianice	Poland	R
29	11.10.209	Oxydon	oxycodone (oxycodone hydrochloride)	tablets	5mg; (100) plastic container	Raha Pharmaceutical Company, No 11, Soffeh Ind. Zone, 7th Km of Shiraz Road, Isfahan	Iran	Raha Pharmaceutical Company, No 11, Soffeh Ind. Zone, 7th Km of Shiraz Road, Isfahan	Iran	R
30	03.12.2019	MNGROW	nicarbazine, maduramicin (maduramicin ammonium)	powder for oral use	80mg/g+7,5mg/g; 20kg pack, 25kg pack	Impextraco NV, Wiekevorstsesteenweg 38, B-2220 Heist-OP-Den-Berg	Belgium	Impextraco NV, Wiekevorstsesteenweg 38, B-2220 Heist-OP-Den-Berg	Belgium	OTC
31	03.12.2019	Robimpex 66	robenidin (robenidin hydrochloride)	powder for oral use	66mg/g; 25kg pack	Impextraco NV, Wiekevorstsesteenweg 38, B-2220 Heist-OP-Den-Berg	Belgium	Impextraco NV, Wiekevorstsesteenweg 38, B-2220 Heist-OP-Den-Berg	Belgium	OTC

32	12.12.2019	Rengalin	affinity purified antibodies to bradykinin, affinity purified antibodies to histamine, affinity purified antibodies to morphine	solution oral	6mg+6mg+6mg; glass bottle 100ml	NPF Materia Medica Holding LLC, 54, Buguruslanskaya st., Chelyabinsk 454139	Russia	NPF Materia Medica Holding LLC, 9 bld., 3rd Samotychny per., Moscow 127473	Russia	OTC
33	26.12.2019	Novex Cetirizine	cetirizine (cetirizine dihydrochloride)	solution oral	5mg/5ml; 60ml glass bottle and measuring spoon	Herbion Pakistan Pvt. Ltd., Industrial Triangle, Kahuta Road, Humak, Islamabad	Pakistan	Herbion Pakistan Pvt. Ltd., Plot 30, Sector 28, Korangi Industrial Area, Karachi 74900	Pakistan	OTC