

Marketing authorisations granted in September 2017

PL Number	Grant Date	MA Holder	Licensed Name(s)	Active Ingredient	Quantity	Units	Legal Status
PL 20075/0536	01/09/2017	ACCORD HEALTHCARE LIMITED	ABACA VIR/LAMIVUDINE ACCORD 600 MG/300 MG FILM-COATED TABLETS	ABACA VIR HYDROCHLORIDE	676.401	MILLIGRAMMES	POM
PL 20075/0536	01/09/2017	ACCORD HEALTHCARE LIMITED	ABACA VIR/LAMIVUDINE ACCORD 600 MG/300 MG FILM-COATED TABLETS	LAMIVUDINE	300.00	MILLIGRAMMES	POM
PL 44041/0041	01/09/2017	NOUMED LIFE SCIENCES LIMITED	NEXOCIN EC 250 MG GASTRO-RESISTANT TABLETS	NAPROXEN	250.00	MILLIGRAMMES	POM
PL 44041/0042	01/09/2017	NOUMED LIFE SCIENCES LIMITED	NEXOCIN EC 375 MG GASTRO-RESISTANT TABLETS	NAPROXEN	375.00	MILLIGRAMMES	POM
PL 44041/0043	01/09/2017	NOUMED LIFE SCIENCES LIMITED	NEXOCIN EC 500 MG GASTRO-RESISTANT TABLETS	NAPROXEN	500.00	MILLIGRAMMES	POM
PL 00142/0856	04/09/2017	ACTAVIS UK LIMITED	ENTECAVIR 0.5 MG FILM-COATED TABLETS	ENTECAVIR	0.500	MILLIGRAMMES	POM
PL 00142/0857	04/09/2017	ACTAVIS UK LIMITED	ENTECAVIR 1MG FILM-COATED TABLETS	ENTECAVIR	1.000	MILLIGRAMMES	POM
PL 42357/0226	05/09/2017	AMNEAL PHARMA EUROPE LIMITED	DUOMEVOLEN 200 MG/245 MG FILM-COATED TABLETS	EMTRICITABINE	200.00	MILLIGRAMMES	POM
PL 42357/0226	05/09/2017	AMNEAL PHARMA EUROPE LIMITED	DUOMEVOLEN 200 MG/245 MG FILM-COATED TABLETS	TENOFOVIR DISOPROXIL PHOSPHATE	291.00	MILLIGRAMMES	POM
PL 43801/0034	05/09/2017	SCIECURE PHARMA LIMITED	ARIPIRAZOLE SCIECURE 10 MG ORODISPERSIBLE TABLETS	ARIPIRAZOLE	10	MILLIGRAMMES	POM
PL 43801/0035	05/09/2017	SCIECURE PHARMA LIMITED	ARIPIRAZOLE SCIECURE 15 MG ORODISPERSIBLE TABLETS	ARIPIRAZOLE	15	MILLIGRAMMES	POM
PL 08553/0602	06/09/2017	DR REDDY'S LABORATORIES (UK) LIMITED	EFAVIRENZ/EMTRICITABINE/TENOFOVIR DISOPROXIL DR. REDDY'S 600 MG/200 MG//245 MG FILM-COATED TABLETS	EFAVIRENZ	600.0	MILLIGRAMMES	POM
PL 08553/0602	06/09/2017	DR REDDY'S LABORATORIES (UK) LIMITED	EFAVIRENZ/EMTRICITABINE/TENOFOVIR DISOPROXIL DR. REDDY'S 600 MG/200 MG//245 MG FILM-COATED TABLETS	EMTRICITABINE	200.0	MILLIGRAMMES	POM
PL 08553/0602	06/09/2017	DR REDDY'S LABORATORIES (UK) LIMITED	EFAVIRENZ/EMTRICITABINE/TENOFOVIR DISOPROXIL DR. REDDY'S 600 MG/200 MG//245 MG FILM-COATED TABLETS	TENOFOVIR DISOPROXIL SUCCINATE	300.6	MILLIGRAMMES	POM
PL 47517/0001	06/09/2017	SUNSTAR FRANCE	PAROEX 1.2 MG/ML MOUTHWASH	CHLORHEXIDINE DIGLUCONATE	1.2	MILLIGRAMMES PER MILLILITRE	P
PL 39352/0394	07/09/2017	KOSEI PHARMA UK LIMITED	LEVONORGESTREL 1.5 MG TABLET	LEVONORGESTREL	1.50	MILLIGRAMMES	POM
PL 04416/1493	08/09/2017	SANDOZ LIMITED	EFAVIRENZ/EMTRICITABINE/TENOFOVIR DISOPROXIL 600 MG/200 MG/245 MG FILM-COATED TABLETS	EFAVIRENZ	600.0	MILLIGRAMMES	POM
PL 04416/1493	08/09/2017	SANDOZ LIMITED	EFAVIRENZ/EMTRICITABINE/TENOFOVIR DISOPROXIL 600 MG/200 MG/245 MG FILM-COATED TABLETS	EMTRICITABINE	200.0	MILLIGRAMMES	POM
PL 04416/1493	08/09/2017	SANDOZ LIMITED	EFAVIRENZ/EMTRICITABINE/TENOFOVIR DISOPROXIL 600 MG/200 MG/245 MG FILM-COATED TABLETS	TENOFOVIR DISOPROXIL SUCCINATE	300.6	MILLIGRAMMES	POM
PL 25258/0231	12/09/2017	GLENMARK PHARMACEUTICALS EUROPE LIMITED	SOLIFENACIN SUCCINATE 5 MG FILM-COATED TABLETS	SOLIFENACIN SUCCINATE	5	MILLIGRAMMES	POM
PL 25258/0232	12/09/2017	GLENMARK PHARMACEUTICALS EUROPE LIMITED	SOLIFENACIN SUCCINATE 10 MG FILM-COATED TABLETS	SOLIFENACIN SUCCINATE	10	MILLIGRAMMES	POM
PL 17907/0602	13/09/2017	BRISTOL LABORATORIES LIMITED	ARIPIRAZOLE 5 MG TABLETS	ARIPIRAZOLE	73.200	MILLIGRAMMES	POM
PL 17907/0603	13/09/2017	BRISTOL LABORATORIES LIMITED	ARIPIRAZOLE 10 MG TABLETS	ARIPIRAZOLE	10.0	MILLIGRAMMES	POM
PL 17907/0604	13/09/2017	BRISTOL LABORATORIES LIMITED	ARIPIRAZOLE 15 MG TABLETS	ARIPIRAZOLE	15.000	MILLIGRAMMES	POM
PL 17907/0605	13/09/2017	BRISTOL LABORATORIES LIMITED	ARIPIRAZOLE 20 MG TABLETS	ARIPIRAZOLE	20.000	MILLIGRAMMES	POM
PL 17907/0606	13/09/2017	BRISTOL LABORATORIES LIMITED	ARIPIRAZOLE 30 MG TABLETS	ARIPIRAZOLE	30.000	MILLIGRAMMES	POM
PL 20416/0441	14/09/2017	CRESCENT PHARMA LIMITED	SOLIFENACIN SUCCINATE 5 MG FILM-COATED TABLETS	SOLIFENACIN SUCCINATE	5	MILLIGRAMMES	POM
PL 20416/0442	14/09/2017	CRESCENT PHARMA LIMITED	SOLIFENACIN SUCCINATE 10MG FILM-COATED TABLETS	SOLIFENACIN SUCCINATE	10	MILLIGRAMMES	POM
PL 41284/0003	14/09/2017	PHARMANOVIA AS	DROPIZOL 10 MG/ML ORAL DROPS, SOLUTION	OPIUM	10	MILLIGRAMMES PER MILLILITRE	POM
PL 47015/0002	14/09/2017	AS KALCEKS	TRAMADOL 50 MG/ML SOLUTION FOR INJECTION/INFUSION	TRAMADOL HYDROCHLORIDE	50.00	MILLIGRAMMES PER MILLILITRE	POM
PL 17299/0003	15/09/2017	TIOFARMA BV	COLCHICINE TIOFARMA 500 MICROGRAM TABLETS	COLCHICINE	0.54	MILLIGRAMMES	POM

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PL 17299/0004	15/09/2017	TIOFARMA BV	COLCHICINE TIOFARMA 1000 MICROGRAM TABLETS	COLCHICINE	1.08	MILLIGRAMMES	POM
PL 20416/0264	15/09/2017	CRESCENT PHARMA LIMITED	ESCITALOPRAM 5MG FILM-COATED TABLETS	ESCITALOPRAM OXALATE	6.390	MILLIGRAMMES	POM
PL 20416/0265	15/09/2017	CRESCENT PHARMA LIMITED	ESCITALOPRAM 10MG FILM-COATED TABLETS	ESCITALOPRAM OXALATE	12.780	MILLIGRAMMES	POM
PL 20416/0266	15/09/2017	CRESCENT PHARMA LIMITED	ESCITALOPRAM 15MG FILM-COATED TABLETS	ESCITALOPRAM OXALATE	19.170	MILLIGRAMMES	POM
PL 20416/0267	15/09/2017	CRESCENT PHARMA LIMITED	ESCITALOPRAM 20MG FILM-COATED TABLETS	ESCITALOPRAM OXALATE	25.560	MILLIGRAMMES	POM
PL 23218/0164	15/09/2017	LABORATORIOS LICONSA SA	DULOXETINE 30 MG HARD GASTRO-RESISTANT CAPSULES	DULOXETINE HYDROCHLORIDE	33.61	MILLIGRAMMES	POM
PL 23218/0165	15/09/2017	LABORATORIOS LICONSA SA	DULOXETINE 60 MG HARD GASTRO-RESISTANT CAPSULES	DULOXETINE HYDROCHLORIDE	67.22	MILLIGRAMMES	POM
PL 43461/0009	15/09/2017	FLAMINGO PHARMA (UK) LIMITED	GLICLAZIDE 80MG TABLETS	GLICLAZIDE	80.00	MILLIGRAMMES	POM
PL 43461/0010	15/09/2017	FLAMINGO PHARMA (UK) LIMITED	GLICLAZIDE 40MG TABLETS	GLICLAZIDE	40.00	MILLIGRAMMES	POM
PL 44400/0006	18/09/2017	L M MANUFACTURING LIMITED	SOLIFENACIN SUCCINATE 1 MG/ML ORAL SOLUTION	SOLIFENACIN SUCCINATE	1.00	MILLIGRAMMES PER MILLILITRE	POM
PL 48035/0001	18/09/2017	NEURAXPHARM ARZNEIMITTEL GMBH	ZONISAMIDE NEURAXPHARM 25 MG CAPSULES, HARD	ZONISAMIDE	25.00	MILLIGRAMMES	POM
PL 48035/0002	18/09/2017	NEURAXPHARM ARZNEIMITTEL GMBH	ZONISAMIDE NEURAXPHARM 50 MG CAPSULES, HARD	ZONISAMIDE	50.00	MILLIGRAMMES	POM
PL 48035/0003	18/09/2017	NEURAXPHARM ARZNEIMITTEL GMBH	ZONISAMIDE NEURAXPHARM 100 MG CAPSULES, HARD	ZONISAMIDE	100.00	MILLIGRAMMES	POM
PL 17496/0025	19/09/2017	DALKEITH LABORATORIES LIMITED	CHLORPHENAMINE 2MG/5ML ORAL SOLUTION	CHLORPHENAMINE MALEATE	2	MILLIGRAMMES	P
PL 35507/0193	20/09/2017	LUPIN (EUROPE) LIMITED	EMOLOZA 250/30 MICROGRAMS FILM-COATED TABLETS	ETHINYLESTRADIOL	0.035	MILLIGRAMMES	POM
PL 35507/0193	20/09/2017	LUPIN (EUROPE) LIMITED	EMOLOZA 250/30 MICROGRAMS FILM-COATED TABLETS	NORGESTIMATE	0.25	MILLIGRAMMES	POM
PL 35667/0011	21/09/2017	FARMALIDER SA	PARACETAMOL FARMALIDER 500 MG TABLETS	PARACETAMOL	500.00	MILLIGRAMMES	POM
PL 35667/0012	21/09/2017	FARMALIDER SA	PARACETAMOL FARMALIDER 1000 MG TABLETS	PARACETAMOL	1000	MILLIGRAMMES	POM
PL 41947/0018	21/09/2017	ELC GROUP SRO	CEFTRIAZONE 500 MG POWDER FOR SOLUTION FOR INJECTION	CEFTRIAZONE SODIUM	596.40	MILLIGRAMMES	POM
PL 41947/0019	21/09/2017	ELC GROUP SRO	CEFTRIAZONE 1G POWDER FOR SOLUTION FOR INJECTION /INFUSION	CEFTRIAZONE SODIUM	1.196	MILLIGRAMMES	POM
PL 41947/0020	21/09/2017	ELC GROUP SRO	CEFTRIAZONE 2G POWDER FOR SOLUTION FOR INJECTION /INFUSION	CEFTRIAZONE SODIUM	2.386	GRAMMES	POM
PL 17815/0065	22/09/2017	XELLIA PHARMACEUTICALS APS	DAPTOMYCIN 350 MG POWDER FOR SOLUTION FOR INJECTION/INFUSION	DAPTOMYCIN	350.00	MILLIGRAMMES	POM
PL 17815/0066	22/09/2017	XELLIA PHARMACEUTICALS APS	DAPTOMYCIN 500 MG POWDER FOR SOLUTION FOR INJECTION/INFUSION	DAPTOMYCIN	500.00	MILLIGRAMMES	POM
PL 30652/0006	25/09/2017	LABORATOIRES BIOGARAN	BIMATOPROST / TIMOLOL BIOGARAN 0,3 MG / ML + 5 MG / ML EYE DROPS, SOLUTION	BIMATOPROST	0.3	MILLIGRAMMES PER MILLILITRE	POM
PL 30652/0006	25/09/2017	LABORATOIRES BIOGARAN	BIMATOPROST / TIMOLOL BIOGARAN 0,3 MG / ML + 5 MG / ML EYE DROPS, SOLUTION	TIMOLOL	5.0	MILLIGRAMMES PER MILLILITRE	POM
PL 40546/0010	25/09/2017	ARISTO PHARMA GMBH	ABACAVIR/LAMIVUDINE ARISTO 600 MG/300 MG FILM-COATED TABLETS	ABACAVIR HYDROCHLORIDE	676.401	MILLIGRAMMES	POM
PL 40546/0010	25/09/2017	ARISTO PHARMA GMBH	ABACAVIR/LAMIVUDINE ARISTO 600 MG/300 MG FILM-COATED TABLETS	LAMIVUDINE	300.000	MILLIGRAMMES	POM
PL 41386/0003	25/09/2017	KLINGE PHARMA GMBH	ABACAVIR/LAMIVUDINE 600 MG/300 MG FILM-COATED TABLETS	ABACAVIR HYDROCHLORIDE	676.401	MILLIGRAMMES	POM
PL 41386/0003	25/09/2017	KLINGE PHARMA GMBH	ABACAVIR/LAMIVUDINE 600 MG/300 MG FILM-COATED TABLETS	LAMIVUDINE	1	PERCENT VOLUME IN VOLUME	POM
PL 41386/0003	25/09/2017	KLINGE PHARMA GMBH	ABACAVIR/LAMIVUDINE 600 MG/300 MG FILM-COATED TABLETS	LAMIVUDINE	300	MILLIGRAMMES	POM
PL 22363/0013	26/09/2017	KAPPLER PHARMA CONSULT GMBH	ESOMEPRAZOLE 20 MG GASTRO-RESISTANT TABLETS	ESOMEPRAZOLE MAGNESIUM	22.263	MILLIGRAMMES	POM

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PL 25258/0243	26/09/2017	GLENMARK PHARMACEUTICALS EUROPE LIMITED	ABACAVIR/LAMIVUDINE GLENMARK 600 MG/300 MG FILM-COATED TABLETS	ABACAVIR HYDROCHLORIDE	676.401	MILLIGRAMMES	POM
PL 25258/0243	26/09/2017	GLENMARK PHARMACEUTICALS EUROPE LIMITED	ABACAVIR/LAMIVUDINE GLENMARK 600 MG/300 MG FILM-COATED TABLETS	LAMIVUDINE	300.000	MILLIGRAMMES	POM
PL 16363/0519	27/09/2017	MILPHARM LIMITED	NEBIVOLOL 2.5 MG TABLETS	NEBIVOLOL HYDROCHLORIDE	2.725	MILLIGRAMMES	POM
PL 16363/0520	27/09/2017	MILPHARM LIMITED	NEBIVOLOL 5MG TABLETS	NEBIVOLOL HYDROCHLORIDE	5.450	MILLIGRAMMES	POM