

Marketing authorisations granted in October 2019

PL Number	Grant Date	MA Holder	Licensed Name(s)	Active Ingredient	Quantity	Units	Legal Status
PL 34111/0002	01/10/2019	XEOLAS PHARMACEUTICALS LIMITED	OMEPRAZOLE 2MG/ML, POWDER FOR ORAL SUSPENSION	OMEPRAZOLE	2	MILLIGRAMS	POM
PL 34111/0003	01/10/2019	XEOLAS PHARMACEUTICALS LIMITED	OMEPRAZOLE 4MG/ML, POWDER FOR ORAL SUSPENSION	OMEPRAZOLE	4	MILLIGRAMS	POM
PL 20416/0554	02/10/2019	CRESCENT PHARMA LIMITED	POSACONAZOLE CRESCENT 40 MG/ML ORAL SUSPENSION	POSACONAZOLE	40	MILLIGRAMS PER MILLILITRE	POM
PL 47848/0016	02/10/2019	AXUNIO PHARMA GMBH	AMBRISANTAN AXUNIO 5 MG FILM-COATED TABLETS	AMBRISANTAN	5	MILLIGRAMS	POM
PL 47848/0017	02/10/2019	AXUNIO PHARMA GMBH	AMBRISANTAN AXUNIO 10 MG FILM-COATED TABLETS	AMBRISANTAN	10	MILLIGRAMS	POM
PL 08828/0281	03/10/2019	FRESENIUS KABI LIMITED	ANIDULAFUNGIN FRESENIUS KABI 100 MG POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION	ANIDULAFUNGIN	100	MILLIGRAMS	POM
PL 44041/0099	03/10/2019	NOUMED LIFE SCIENCES LIMITED	BEZAFIBRATE 200MG FILM-COATED TABLETS	BEZAFIBRATE	200	MILLIGRAMS	POM
PL 04854/0165	04/10/2019	GEDEON RICHTER PLC	KLIMEDIX 1 MG/2 MG FILM-COATED TABLETS	DROSPIRENONE	2.000	MILLIGRAMS	POM
PL 04854/0165	04/10/2019	GEDEON RICHTER PLC	KLIMEDIX 1 MG/2 MG FILM-COATED TABLETS	ESTRADIOL HEMIHYDRATE	1.030	MILLIGRAMS	POM
PL 17683/0141	04/10/2019	ALFRED E TIEFENBACHER GMBH & CO KG	DASATINIB TIEFENBACHER 20 MG FILM-COATED TABLETS	DASATINIB	20.00	MILLIGRAMS	POM
PL 17683/0142	04/10/2019	ALFRED E TIEFENBACHER GMBH & CO KG	DASATINIB TIEFENBACHER 50 MG FILM-COATED TABLETS	DASATINIB	50.00	MILLIGRAMS	POM
PL 17683/0143	04/10/2019	ALFRED E TIEFENBACHER GMBH & CO KG	DASATINIB TIEFENBACHER 70 MG FILM-COATED TABLETS	DASATINIB	70.00	MILLIGRAMS	POM
PL 17683/0144	04/10/2019	ALFRED E TIEFENBACHER GMBH & CO KG	DASATINIB TIEFENBACHER 80 MG FILM-COATED TABLETS	DASATINIB	80.00	MILLIGRAMS	POM
PL 17683/0145	04/10/2019	ALFRED E TIEFENBACHER GMBH & CO KG	DASATINIB TIEFENBACHER 100 MG FILM-COATED TABLETS	DASATINIB	100.00	MILLIGRAMS	POM
PL 17683/0146	04/10/2019	ALFRED E TIEFENBACHER GMBH & CO KG	DASATINIB TIEFENBACHER 140 MG FILM-COATED TABLETS	DASATINIB	140.00	MILLIGRAMS	POM
PL 21880/0228	04/10/2019	MEDREICH PLC	NEFOPAM HYDROCHLORIDE 30MG FILM-COATED TABLETS	NEFOPAM HYDROCHLORIDE	30	MILLIGRAMS	POM
PL 32870/0054	04/10/2019	USV EUROPE LIMITED	ZOLEDRONIC ACID USV 4 MG/5 ML CONCENTRATE FOR SOLUTION FOR INFUSION	ZOLEDRONIC ACID MONOHYDRATE	4.264	MILLIGRAMS	POM
PL 08215/0109	08/10/2019	KENT PHARMACEUTICALS LIMITED	NORTRIPTYLINE 10 MG CAPSULES	NORTRIPTYLINE HYDROCHLORIDE	11.40	MILLIGRAMS	POM
PL 08215/0110	08/10/2019	KENT PHARMACEUTICALS LIMITED	NORTRIPTYLINE 25 MG CAPSULES	NORTRIPTYLINE HYDROCHLORIDE	28.50	MILLIGRAMS	POM
PL 17815/0074	08/10/2019	XELLIA PHARMACEUTICALS APS	MICAFUNGIN XELLIA 50 MG POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION	MICAFUNGIN SODIUM	50.9	MILLIGRAMS	POM
PL 17815/0075	08/10/2019	XELLIA PHARMACEUTICALS APS	MICAFUNGIN XELLIA 100 MG POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION	MICAFUNGIN SODIUM	101.7	MILLIGRAMS	POM
PL 45043/0002	08/10/2019	NEON HEALTHCARE LIMITED	CLOFARABINE NEON HEALTHCARE 1 MG/ML CONCENTRATE FOR SOLUTION FOR INFUSION	CLOFARABINE	1	MILLIGRAMS PER MILLILITRE	POM
PL 34771/0262	10/10/2019	MACLEODS PHARMA UK LIMITED	SILDENAFIL MACLEODS 20MG FILM-COATED TABLETS	SILDENAFIL CITRATE	28.096	MILLIGRAMS	POM
PL 45043/0009	10/10/2019	NEON HEALTHCARE LIMITED	POSACONAZOLE 40 MG/ML ORAL SUSPENSION	POSACONAZOLE	40.00	MILLIGRAMS PER MILLILITRE	POM
PL 49565/0003	10/10/2019	NORTH STAR HEALTHCARE LIMITED	CIPROFLOXACIN 250 MG FILM COATED TABLETS	CIPROFLOXACIN HYDROCHLORIDE	291.00	MILLIGRAMS	POM
PL 49565/0004	10/10/2019	NORTH STAR HEALTHCARE LIMITED	CIPROFLOXACIN 750 MG FILM COATED TABLETS	CIPROFLOXACIN HYDROCHLORIDE	873.00	MILLIGRAMS	POM
PL 40546/0144	11/10/2019	ARISTO PHARMA GMBH	DARIFENACIN ARISTO 15 MG PROLONGED-RELEASE TABLETS	DARIFENACIN HYDROBROMIDE	17.846	MILLIGRAMS	POM
PL 49518/0003	11/10/2019	WELLNEX GMBH	INHATEC 50 MICROGRAM/500 MICROGRAM/ DOSE INHALATION POWDER, PRE-DISPENSED	FLUTICASON PROPRIONATE	0.5	MILLIGRAMS	POM
PL 49518/0003	11/10/2019	WELLNEX GMBH	INHATEC 50 MICROGRAM/500 MICROGRAM/ DOSE INHALATION POWDER, PRE-DISPENSED	SALMETEROL XINAFOATE	0.073	MILLIGRAMS	POM
PL 00289/2322	14/10/2019	TEVA UK LIMITED	MICAFUNGIN TEVA 50 MG POWDER FOR SOLUTION FOR INFUSION	MICAFUNGIN SODIUM	50.86	MILLIGRAMS	POM
PL 00289/2323	14/10/2019	TEVA UK LIMITED	MICAFUNGIN TEVA 100 MG POWDER FOR SOLUTION FOR INFUSION	MICAFUNGIN SODIUM	101.73	MILLIGRAMS	POM
PL 04416/1566	14/10/2019	SANDOZ LIMITED	DAILYPORT 0.5 MG PROLONGED-RELEASE HARD CAPSULES	TACROLIMUS MONOHYDRATE	0.511	MILLIGRAMS	POM

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PL 04416/1567	14/10/2019	SANDOZ LIMITED	DAILIPOINT 1 MG PROLONGED-RELEASE HARD CAPSULES	TACROLIMUS MONOHYDRATE	1.022	MILLIGRAMS	POM
PL 04416/1568	14/10/2019	SANDOZ LIMITED	DAILIPOINT 2 MG PROLONGED-RELEASE HARD CAPSULES	TACROLIMUS MONOHYDRATE	2.045	MILLIGRAMS	POM
PL 04416/1569	14/10/2019	SANDOZ LIMITED	DAILIPOINT 3 MG PROLONGED-RELEASE HARD CAPSULES	TACROLIMUS MONOHYDRATE	3.067	MILLIGRAMS	POM
PL 04416/1570	14/10/2019	SANDOZ LIMITED	DAILIPOINT 5 MG PROLONGED-RELEASE HARD CAPSULES	TACROLIMUS MONOHYDRATE	5.112	MILLIGRAMS	POM
PL 28278/0012	15/10/2019	IPCA LABORATORIES UK LIMITED	AMLODIPINE IPCA 5 MG TABLETS	AMLODIPINE BESILATE	6.935	MILLIGRAMS	POM
PL 28278/0013	15/10/2019	IPCA LABORATORIES UK LIMITED	AMLODIPINE IPCA 10 MG TABLETS	AMLODIPINE BESILATE	13.88	MILLIGRAMS	POM
PL 34771/0259	15/10/2019	MACLEODS PHARMA UK LIMITED	MACSUTRA 50 MG FILM-COATED TABLETS	SILDENAFIL CITRATE	70.24	MILLIGRAMS	POM
PL 44041/0061	18/10/2019	NOUMED LIFE SCIENCES LIMITED	TADALAFIL 2.5 MG FILM-COATED TABLETS	TADALAFIL	2.50	MILLIGRAMS	POM
PL 44041/0062	18/10/2019	NOUMED LIFE SCIENCES LIMITED	TADALAFIL 5 MG FILM-COATED TABLETS	TADALAFIL	5	MILLIGRAMS	POM
PL 44041/0063	18/10/2019	NOUMED LIFE SCIENCES LIMITED	TADALAFIL 10 MG FILM-COATED TABLETS	TADALAFIL	10	MILLIGRAMS	POM
PL 44041/0064	18/10/2019	NOUMED LIFE SCIENCES LIMITED	TADALAFIL 20 MG FILM-COATED TABLETS	TADALAFIL	20	MILLIGRAMS	POM
PL 25298/0151	22/10/2019	BROWN & BURK UK LIMITED	DISULFIRAM 200 MG TABLETS	DISULFIRAM	200	MILLIGRAMS	POM
PL 17780/0819	24/10/2019	ZENTIVA PHARMA UK LIMITED	POSACONAZOLE ZENTIVA 100 MG GASTRO-RESISTANT TABLETS	POSACONAZOLE	100	MILLIGRAMS	POM
PL 20693/0015	24/10/2019	PIERRE FABRE DERMATOLOGIE	TOLAK 40MG/G CREAM	FLUOROURACIL	40	MILLIGRAMS PER GRAM	POM
PL 48468/0022	24/10/2019	VIVALABS EUROPE LIMITED	CARBOCISTEINE 375 MG CAPSULES, HARD	CARBOCISTEINE	375.00	MILLIGRAMS	POM
PL 00289/2332	25/10/2019	TEVA UK LIMITED	POSACONAZOLE TEVA 100 MG GASTRO-RESISTANT TABLETS	POSACONAZOLE	100	MILLIGRAMS	POM
PL 04416/1571	25/10/2019	SANDOZ LIMITED	POSACONAZOLE SANDOZ 100 MG GASTRO-RESISTANT TABLETS	POSACONAZOLE	100	MILLIGRAMS	POM
PL 16363/0620	25/10/2019	MILPHARM LIMITED	ATENOLOL 25 MG FILM-COATED TABLETS	ATENOLOL	25	MILLIGRAMS	POM
PL 16363/0621	25/10/2019	MILPHARM LIMITED	ATENOLOL 50 MG FILM-COATED TABLETS	ATENOLOL	50	MILLIGRAMS	POM
PL 16363/0622	25/10/2019	MILPHARM LIMITED	ATENOLOL 100 MG FILM-COATED TABLETS	ATENOLOL	100	MILLIGRAMS	POM
PL 30684/0300	25/10/2019	DAWA LIMITED	TADALAFIL 2.5 MG FILM-COATED TABLETS	TADALAFIL	2.5	MILLIGRAMS	POM
PL 30684/0301	25/10/2019	DAWA LIMITED	TADALAFIL 5 MG FILM-COATED TABLETS	TADALAFIL	5	MILLIGRAMS	POM
PL 30684/0302	25/10/2019	DAWA LIMITED	TADALAFIL 10 MG FILM-COATED TABLETS	TADALAFIL	10	MILLIGRAMS	POM
PL 30684/0303	25/10/2019	DAWA LIMITED	TADALAFIL 20 MG FILM-COATED TABLETS	TADALAFIL	20	MILLIGRAMS	POM
PL 00063/0763	28/10/2019	RECKITT BENCKISER HEALTHCARE (UK) LIMITED	STREFEN 8.75MG/DOSE OROMUCOSAL SPRAY, SOLUTION	FLURBIPROFEN	8.75	MILLIGRAMS	POM
PL 00240/0427	28/10/2019	THORNTON & ROSS LIMITED	POSACONAZOLE STADA 100 MG GASTRO-RESISTANT TABLETS	POSACONAZOLE	100	MILLIGRAMS	POM
PL 32870/0055	28/10/2019	USV EUROPE LIMITED	OLOPATADINE USV 1MG/ML EYE DROPS, SOLUTION	OLOPATADINE HYDROCHLORIDE	1.110	MILLIGRAMS PER MILLILITRE	POM
PL 04569/1789	30/10/2019	GENERICS (UK) LIMITED	POSACONAZOLE MYLAN 100 MG GASTRO-RESISTANT TABLETS	POSACONAZOLE	100	MILLIGRAMS	POM
PL 49565/0001	30/10/2019	NORTH STAR HEALTHCARE LIMITED	AMOXICILLIN SUGAR FREE SUSPENSION 125MG/5ML	AMOXICILLIN TRIHYDRATE	144.850	MILLIGRAMS	POM
PL 49565/0002	30/10/2019	NORTH STAR HEALTHCARE LIMITED	AMOXICILLIN SUGAR FREE SUSPENSION 250MG/5ML	AMOXICILLIN TRIHYDRATE	288.700	MILLIGRAMS	POM