

Marketing authorisations granted in May 2019

PL Number	Grant Date	MA Holder	Licensed Name(s)	Active Ingredient	Quantity	Units	Legal Status
PL 44041/0088	01/05/2019	NOUMED LIFE SCIENCES LIMITED	PARACETAMOL 1000MG TABLETS	PARACETAMOL	1000	MILLIGRAMS	POM
PL 44041/0089	01/05/2019	NOUMED LIFE SCIENCES LIMITED	PARACETAMOL 1000MG TABLETS	PARACETAMOL	1000	MILLIGRAMS	POM
PL 37222/0066	03/05/2019	HETERO EUROPE SL	EMTRICITABIN/TENOFOVIRDISOPROXIL AMAROX 200MG/245 MG FILM-COATED TABLETS	EMTRICITABINE	200	MILLIGRAMS	POM
PL 37222/0066	03/05/2019	HETERO EUROPE SL	EMTRICITABIN/TENOFOVIRDISOPROXIL AMAROX 200MG/245 MG FILM-COATED TABLETS	TENOFOVIR DISOPROXIL FUMARATE	300	MILLIGRAMS	POM
PL 42357/0286	03/05/2019	AMNEAL PHARMA EUROPE LIMITED	PREGABALIN AMNEAL 25 MG HARD CAPSULES	PREGABALIN	25	MILLIGRAMS	POM
PL 42357/0287	03/05/2019	AMNEAL PHARMA EUROPE LIMITED	PREGABALIN AMNEAL 50 MG HARD CAPSULES	PREGABALIN	50	MILLIGRAMS	POM
PL 42357/0288	03/05/2019	AMNEAL PHARMA EUROPE LIMITED	PREGABALIN AMNEAL 75 MG HARD CAPSULES	PREGABALIN	75	MILLIGRAMS	POM
PL 42357/0289	03/05/2019	AMNEAL PHARMA EUROPE LIMITED	PREGABALIN AMNEAL 100 MG HARD CAPSULES	PREGABALIN	100	MILLIGRAMS	POM
PL 42357/0290	03/05/2019	AMNEAL PHARMA EUROPE LIMITED	PREGABALIN AMNEAL 150 MG HARD CAPSULES	PREGABALIN	150	MILLIGRAMS	POM
PL 42357/0291	03/05/2019	AMNEAL PHARMA EUROPE LIMITED	PREGABALIN AMNEAL 200 MG HARD CAPSULES	PREGABALIN	200	MILLIGRAMS	POM
PL 42357/0292	03/05/2019	AMNEAL PHARMA EUROPE LIMITED	PREGABALIN AMNEAL 225 MG HARD CAPSULES	PREGABALIN	225	MILLIGRAMS	POM
PL 42357/0293	03/05/2019	AMNEAL PHARMA EUROPE LIMITED	PREGABALIN AMNEAL 300 MG HARD CAPSULES	PREGABALIN	300	MILLIGRAMS	POM
PL 16363/0570	07/05/2019	MILPHARM LIMITED	LACOSAMIDE MILPHARM 50 MG FILM-COATED TABLETS	LACOSAMIDE	50	MILLIGRAMS	POM
PL 16363/0571	07/05/2019	MILPHARM LIMITED	LACOSAMIDE MILPHARM 100 MG FILM-COATED TABLETS	LACOSAMIDE	100	MILLIGRAMS	POM
PL 16363/0572	07/05/2019	MILPHARM LIMITED	LACOSAMIDE MILPHARM 150 MG FILM-COATED TABLETS	LACOSAMIDE	150	MILLIGRAMS	POM
PL 16363/0573	07/05/2019	MILPHARM LIMITED	LACOSAMIDE MILPHARM 200 MG FILM-COATED TABLETS	LACOSAMIDE	200	MILLIGRAMS	POM
PL 00129/0362	08/05/2019	PROCTER & GAMBLE (HEALTH & BEAUTY CARE) LIMITED	SYMPTOMED 1000MG/12.2 MG POWDER FOR ORAL SOLUTION	PARACETAMOL	1000.0	MILLIGRAMS	GSL
PL 00129/0362	08/05/2019	PROCTER & GAMBLE (HEALTH & BEAUTY CARE) LIMITED	SYMPTOMED 1000MG/12.2 MG POWDER FOR ORAL SOLUTION	PHENYLEPHRINE HYDROCHLORIDE	12.2	MILLIGRAMS	GSL
PL 37222/0059	08/05/2019	HETERO EUROPE SL	SILDENAFIL AMAROX 20 MG FILM-COATED TABLETS	SILDENAFIL CITRATE	28.096	MILLIGRAMS	POM
PL 44041/0085	08/05/2019	NOUMED LIFE SCIENCES LIMITED	RELIMOL 500MG TABLETS	PARACETAMOL	500	MILLIGRAMS	GSL
PL 44041/0086	08/05/2019	NOUMED LIFE SCIENCES LIMITED	PARACETAMOL 500MG TABLETS	PARACETAMOL	500	MILLIGRAMS	P
PL 44041/0087	08/05/2019	NOUMED LIFE SCIENCES LIMITED	PARACETAMOL 500MG TABLETS	PARACETAMOL	500	MILLIGRAMS	POM
PL 31599/0015	09/05/2019	TAMARANG SA	EVEROLIMUS 2.5 MG TABLETS	EVEROLIMUS	2.5	MILLIGRAMS	POM
PL 31599/0016	09/05/2019	TAMARANG SA	EVEROLIMUS 5 MG TABLETS	EVEROLIMUS	5.00	MILLIGRAMS	POM
PL 31599/0017	09/05/2019	TAMARANG SA	EVEROLIMUS 10 MG TABLETS	EVEROLIMUS	10.00	MILLIGRAMS	POM
PL 31750/0150	09/05/2019	SUN PHARMACEUTICAL INDUSTRIES EUROPE BV	MIDAZOLAM 1 MG/ML SOLUTION FOR INJECTION/INFUSION IN PRE-FILLED SYRINGE	MIDAZOLAM	1.00	MILLIGRAMS PER MILLILITRE	POM
PL 31750/0151	09/05/2019	SUN PHARMACEUTICAL INDUSTRIES EUROPE BV	MIDAZOLAM 2 MG/ML SOLUTION FOR INJECTION/INFUSION IN PRE-FILLED SYRINGE	MIDAZOLAM	2.00	MILLIGRAMS PER MILLILITRE	POM
PL 15764/0130	10/05/2019	STRANDHAVEN LIMITED	EROPID 50 MG FILM-COATED TABLETS	SILDENAFIL CITRATE	50	MILLIGRAMS	POM
PL 20117/0287	10/05/2019	MORNINGSIDE HEALTHCARE LIMITED	POSACONAZOLE 40MG/ML ORAL SUSPENSION	POSACONAZOLE	40	MILLIGRAMS PER MILLILITRE	POM
PL 35533/0132	13/05/2019	ASPIRE PHARMA LIMITED	LIBRACHROM 2% W/V EYE DROPS, SOLUTION	SODIUM CROMOGLICATE	20	MILLIGRAMS PER MILLILITRE	P

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PL 25258/0288	14/05/2019	GLENMARK PHARMACEUTICALS EUROPE LIMITED	EFAVIRENZ/EMTRICITABINE/TENOFOVIR DISOPROXIL GLENMARK 600 MG/200 MG/245 MG FILM-COATED TABLETS	EFAVIRENZ	600.00	MILLIGRAMS	POM
PL 25258/0288	14/05/2019	GLENMARK PHARMACEUTICALS EUROPE LIMITED	EFAVIRENZ/EMTRICITABINE/TENOFOVIR DISOPROXIL GLENMARK 600 MG/200 MG/245 MG FILM-COATED TABLETS	EMTRICITABINE	200.00	MILLIGRAMS	POM
PL 25258/0288	14/05/2019	GLENMARK PHARMACEUTICALS EUROPE LIMITED	EFAVIRENZ/EMTRICITABINE/TENOFOVIR DISOPROXIL GLENMARK 600 MG/200 MG/245 MG FILM-COATED TABLETS	TENOFOVIR DISOPROXIL FUMARATE	300.00	MILLIGRAMS	POM
PL 01656/0281	15/05/2019	KRKA DD NOVO MESTO	ATORVASTATIN 10 MG FILM-COATED TABLETS	ATORVASTATIN CALCIUM TRIHYDRATE	10.845	MILLIGRAMS	POM
PL 01656/0282	15/05/2019	KRKA DD NOVO MESTO	ATORVASTATIN 20 MG FILM-COATED TABLETS	ATORVASTATIN CALCIUM TRIHYDRATE	21.69	MILLIGRAMS	POM
PL 01656/0283	15/05/2019	KRKA DD NOVO MESTO	ATORVASTATIN 40 MG FILM-COATED TABLETS	ATORVASTATIN CALCIUM TRIHYDRATE	43.38	MILLIGRAMS	POM
PL 20075/1219	15/05/2019	ACCORD HEALTHCARE LIMITED	EMTRICITABINE/TENOFOVIR DISOPROXIL ACCORDPHARMA 200 MG/245 MG FILM-COATED TABLETS	EMTRICITABINE	200	MILLIGRAMS	POM
PL 20075/1219	15/05/2019	ACCORD HEALTHCARE LIMITED	EMTRICITABINE/TENOFOVIR DISOPROXIL ACCORDPHARMA 200 MG/245 MG FILM-COATED TABLETS	TENOFOVIR DISOPROXIL FUMARATE	300	MILLIGRAMS	POM
PL 08553/0617	16/05/2019	DR REDDY'S LABORATORIES (UK) LIMITED	ALITRETINOIN 30 MG CAPSULES, SOFT	ALITRETINOIN	30	MILLIGRAMS	POM
PL 31862/0020	17/05/2019	CREO PHARMA LIMITED	ARIPIRAZOLE 1MG/ML ORAL SOLUTION	ARIPIRAZOLE	1.00	MILLIGRAMS	POM
PL 36687/0399	17/05/2019	TORRENT PHARMA (UK) LIMITED	CINACALCET 30 MG FILM-COATED TABLETS	CINACALCET HYDROCHLORIDE	33.060	MILLIGRAMS	POM
PL 36687/0400	17/05/2019	TORRENT PHARMA (UK) LIMITED	CINACALCET 60 MG FILM-COATED TABLETS	CINACALCET HYDROCHLORIDE	66.120	MILLIGRAMS	POM
PL 36687/0401	17/05/2019	TORRENT PHARMA (UK) LIMITED	CINACALCET 90 MG FILM-COATED TABLETS	CINACALCET HYDROCHLORIDE	99.180	MILLIGRAMS	POM
PL 39360/0025	17/05/2019	ABDI FARMA UNIPESOAAL LIMITADA	BENZYDAMINE HYDROCHLORIDE 0.30 % W/V OROMUCOSAL SPRAY	BENZYDAMINE HYDROCHLORIDE	3	MILLIGRAMS PER MILLILITRE	POM
PL 42459/0006	17/05/2019	INFIRST HEALTHCARE LIMITED	IBUPROFEN INFIRST HEALTHCARE LTD 200 MG SOFT CAPSULES	IBUPROFEN	200	MILLIGRAMS	P
PL 48037/0013	20/05/2019	PASSAUER PHARMA GMBH	OLANZAPINE 5 MG ORODISPERSIBLE TABLETS	OLANZAPINE	5.00	MILLIGRAMS	POM
PL 48037/0014	20/05/2019	PASSAUER PHARMA GMBH	OLANZAPINE 10 MG ORODISPERSIBLE TABLETS	OLANZAPINE	10.00	MILLIGRAMS	POM
PL 48037/0015	20/05/2019	PASSAUER PHARMA GMBH	OLANZAPINE 15 MG ORODISPERSIBLE TABLETS	OLANZAPINE	15.00	MILLIGRAMS	POM
PL 48037/0016	20/05/2019	PASSAUER PHARMA GMBH	OLANZAPINE 20 MG ORODISPERSIBLE TABLETS	OLANZAPINE	20.00	MILLIGRAMS	POM
PL 02855/0313	22/05/2019	OMEGA PHARMA LIMITED	NYTOL LIQUID CARAMEL FLAVOUR 10MG/5ML ORAL SOLUTION	DIPHENHYDRAMINE HYDROCHLORIDE	10.00	MILLIGRAMS	P
PL 30684/0246	22/05/2019	DAWA LIMITED	CLARITHROMYCIN 250MG FILM-COATED TABLETS	CLARITHROMYCIN	250	MILLIGRAMS	POM
PL 30684/0247	22/05/2019	DAWA LIMITED	CLARITHROMYCIN 500 MG FILM-COATED TABLETS	CLARITHROMYCIN	500	MILLIGRAMS	POM
PL 40546/0149	22/05/2019	ARISTO PHARMA GMBH	DRONEDARONE ARISTO 400 MG FILM-COATED TABLETS	DRONEDARONE HYDROCHLORIDE	426.20	MILLIGRAMS	POM
PL 42289/0010	22/05/2019	WAVE PHARMA LIMITED	CARBIMAZOLE 5 MG TABLETS	CARBIMAZOLE	5	MILLIGRAMS	POM
PL 42289/0011	22/05/2019	WAVE PHARMA LIMITED	CARBIMAZOLE 20 MG TABLETS	CARBIMAZOLE	20	MILLIGRAMS	POM
PL 12308/0032	23/05/2019	GUERBET	OPTIRAY 350 MG IML, SOLUTION FOR INJECTION/INFUSION, MULTIDOSE CONTAINER	IOVERSOL	741	MILLIGRAMS PER MILLILITRE	POM
PL 46973/0003	24/05/2019	NAARI BV	DIENOGEST 2 MG TABLET	DIENOGEST	2	MILLIGRAMS	POM
PL 00289/2219	29/05/2019	TEVA UK LIMITED	OLATUTON 10 MG POWDER AND SOLVENT FOR PROLONGED-RELEASE SUSPENSION FOR INJECTION	NO ACTIVES PRESENT	0.00	NONE	POM
PL 00289/2219	29/05/2019	TEVA UK LIMITED	OLATUTON 10 MG POWDER AND SOLVENT FOR PROLONGED-RELEASE SUSPENSION FOR INJECTION	OCTREOTIDE ACETATE	11.20	MILLIGRAMS	POM
PL 00289/2220	29/05/2019	TEVA UK LIMITED	OLATUTON 20 MG POWDER AND SOLVENT FOR PROLONGED-RELEASE SUSPENSION FOR INJECTION	NO ACTIVES PRESENT	0.00	NONE	POM

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PL 00289/2220	29/05/2019	TEVA UK LIMITED	OLATUTON 20 MG POWDER AND SOLVENT FOR PROLONGED-RELEASE SUSPENSION FOR INJECTION	OCTREOTIDE ACETATE	22.4	MILLIGRAMS	POM
PL 00289/2221	29/05/2019	TEVA UK LIMITED	OLATUTON 30 MG POWDER AND SOLVENT FOR PROLONGED-RELEASE SUSPENSION FOR INJECTION	NO ACTIVES PRESENT	0.00	NONE	POM
PL 00289/2221	29/05/2019	TEVA UK LIMITED	OLATUTON 30 MG POWDER AND SOLVENT FOR PROLONGED-RELEASE SUSPENSION FOR INJECTION	OCTREOTIDE ACETATE	36.6	MILLIGRAMS	POM
PL 04416/1563	29/05/2019	SANDOZ LIMITED	SAXAGLIPTIN SANDOZ 2.5 MG FILM-COATED TABLETS	SAXAGLIPTIN HYDROCHLORIDE	2.789	MILLIGRAMS	POM
PL 04416/1564	29/05/2019	SANDOZ LIMITED	SAXAGLIPTIN SANDOZ 5 MG FILM-COATED TABLETS	SAXAGLIPTIN HYDROCHLORIDE	5.578	MILLIGRAMS	POM
PL 30684/0285	29/05/2019	DAWA LIMITED	ACETAZOLAMIDE DAWA 250MG TABLETS	ACETAZOLAMIDE	250	MILLIGRAMS	POM
PL 36390/0251	29/05/2019	CIPLA (EU) LIMITED	BEMOPRO 50 MICROGRAMS PER ACTUATION PRESSURISED INHALATION SOLUTION	BECLOMETASONE DIPROPIONATE	50.0	MICROGRAMS PER ACTUATION	POM
PL 36390/0252	29/05/2019	CIPLA (EU) LIMITED	BEMOPRO 100 MICROGRAMS PER ACTUATION PRESSURISED INHALATION SOLUTION	BECLOMETASONE DIPROPIONATE	100.0	MICROGRAMS PER ACTUATION	POM
PL 46788/0013	29/05/2019	ALTAN PHARMA LIMITED	DEXEMETOMIDINE ALTAN 100 MICROGRAMS/ML CONCENTRATE FOR SOLUTION FOR INFUSION	DEXEMETOMIDINE HYDROCHLORIDE	0.118	MILLIGRAMS PER MILLILITRE	POM
PL 11311/0613	30/05/2019	TILLOMED LABORATORIES LIMITED	TRANEXAMIC ACID 100 MG/ML SOLUTION FOR INJECTION	TRANEXAMIC ACID	100	MILLIGRAMS PER MILLILITRE	POM
PL 20416/0600	30/05/2019	CRESCENT PHARMA LIMITED	QUETIAPINE 25 MG FILM-COATED TABLETS	QUETIAPINE FUMARATE	28.78	MILLIGRAMS	POM
PL 20416/0601	30/05/2019	CRESCENT PHARMA LIMITED	QUETIAPINE 100 MG FILM-COATED TABLETS	QUETIAPINE FUMARATE	115.12	MILLIGRAMS	POM
PL 20416/0602	30/05/2019	CRESCENT PHARMA LIMITED	QUETIAPINE 150 MG FILM-COATED TABLETS	QUETIAPINE FUMARATE	172.68	MILLIGRAMS	POM
PL 20416/0603	30/05/2019	CRESCENT PHARMA LIMITED	QUETIAPINE 200 MG FILM-COATED TABLETS	QUETIAPINE FUMARATE	230.24	MILLIGRAMS	POM
PL 20416/0604	30/05/2019	CRESCENT PHARMA LIMITED	QUETIAPINE 300 MG FILM-COATED TABLETS	QUETIAPINE FUMARATE	345.36	MILLIGRAMS	POM
PL 49518/0001	30/05/2019	WELLNEX GMBH	INHATEC 50 MICROGRAM/ 100 MICROGRAM/ DOSE INHALATION POWDER, PRE-DISPENSED	FLUTICASONE PROPIONATE	0.100	MILLIGRAMS	POM
PL 49518/0001	30/05/2019	WELLNEX GMBH	INHATEC 50 MICROGRAM/ 100 MICROGRAM/ DOSE INHALATION POWDER, PRE-DISPENSED	SALMETEROL XINAFOATE	0.050	MILLIGRAMS	POM
PL 49518/0002	30/05/2019	WELLNEX GMBH	INHATEC 50 MICROGRAM/ 250 MICROGRAM/ DOSE INHALATION POWDER, PRE-DISPENSED	FLUTICASONE PROPIONATE	0.25	MILLIGRAMS	POM
PL 49518/0002	30/05/2019	WELLNEX GMBH	INHATEC 50 MICROGRAM/ 250 MICROGRAM/ DOSE INHALATION POWDER, PRE-DISPENSED	SALMETEROL XINAFOATE	0.050	MILLIGRAMS	POM
PL 20491/0002	31/05/2019	TOR GENERICS LIMITED	RETINOL AND COLECALCIFEROL 4500 IU/450 IU CAPSULES, SOFT	COLECALCIFEROL	450	INTERNATIONAL UNITS	P
PL 20491/0002	31/05/2019	TOR GENERICS LIMITED	RETINOL AND COLECALCIFEROL 4500 IU/450 IU CAPSULES, SOFT	RETINOL PALMITATE	4500	INTERNATIONAL UNITS	P
PL 29831/0695	31/05/2019	WOCKHARDT UK LIMITED	IBUPROFEN 100 MG/5 ML ORAL SUSPENSION	IBUPROFEN	100.00	MILLIGRAMS PER 5 MILLILITRES	P