

Marketing authorisations granted in January 2016

PL Number	Grant Date	MA Holder	Licensed Name(s)	Active Ingredient	Quantity	Units	Legal Status
PL 01656/0203	04/01/2016	KRKA DD NOVO MESTO	IMATINIB 100 MG FILM-COATED TABLETS	IMATINIB MESILATE	119.50	MILLIGRAMMES	POM
PL 01656/0204	04/01/2016	KRKA DD NOVO MESTO	IMATINIB 400 MG FILM-COATED TABLETS	IMATINIB MESILATE	478.00	MILLIGRAMMES	POM
PL 11204/0315	06/01/2016	STADA ARZNEIMITTEL AG	LANSOPRAZOLE 30MG ORODISPERSIBLE TABLETS	LANSOPRAZOLE	30.000	MILLIGRAMMES	POM
PL 39307/0041	06/01/2016	SYRI LIMITED	DIPYRIDAMOLE 200MG/5ML ORAL SUSPENSION	DIPYRIDAMOLE	200.00	MILLIGRAMMES PER 5 MILLILITRES	POM
PL 00010/0654	07/01/2016	BAYER PLC	CANESTEN THRUSH INTERNAL CREAM 10% W/W VAGINAL CREAM	CLOTRIMAZOLE	10.0	GRAMMES	P
PL 28176/0170	07/01/2016	STRIDES ARCOLAB INTERNATIONAL LIMITED	STRIVIT-D3 800 IU CAPSULES, SOFT	COLECALCIFEROL	0.020	MILLIGRAMMES	POM
PL 08553/0547	08/01/2016	DR REDDY'S LABORATORIES (UK) LIMITED	PEMETREXED 100 MG POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION	PEMETREXED DISODIUM	110.28	MILLIGRAMMES	POM
PL 08553/0548	08/01/2016	DR REDDY'S LABORATORIES (UK) LIMITED	PEMETREXED 500 MG POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION	PEMETREXED DISODIUM	551.40	MILLIGRAMMES	POM
PL 25258/0171	08/01/2016	GLENMARK PHARMACEUTICALS EUROPE LIMITED	CARLOSAFINE 35 MICROGRAMS/H TRANSDERMAL PATCH	BUPRENORPHINE	20	MILLIGRAMMES	POM
PL 25258/0172	08/01/2016	GLENMARK PHARMACEUTICALS EUROPE LIMITED	CARLOSAFINE 52.5 MICROGRAMS/H TRANSDERMAL PATCH	BUPRENORPHINE	30.00	MILLIGRAMMES	POM
PL 25258/0173	08/01/2016	GLENMARK PHARMACEUTICALS EUROPE LIMITED	CARLOSAFINE 70 MICROGRAMS/H TRANSDERMAL PATCH	BUPRENORPHINE	40	MILLIGRAMMES	POM
PL 17780/0752	11/01/2016	WINTHROP PHARMACEUTICALS UK LIMITED	OLMESARTAN 10 MG FILM-COATED TABLETS	OLMESARTAN MEDOXOMIL	10	MILLIGRAMMES	POM
PL 17780/0754	11/01/2016	WINTHROP PHARMACEUTICALS UK LIMITED	OLMESARTAN 20MG FILM-COATED TABLETS	OLMESARTAN MEDOXOMIL	20	MILLIGRAMMES	POM
PL 17780/0755	11/01/2016	WINTHROP PHARMACEUTICALS UK LIMITED	OLMESARTAN 40MG FILM-COATED TABLETS	OLMESARTAN MEDOXOMIL	40.00	MILLIGRAMMES	POM
PL 20075/0387	11/01/2016	ACCORD HEALTHCARE LIMITED	MITOMYCIN 2 MG POWDER FOR SOLUTION FOR INJECTION/INFUSION OR INTRAVESICAL	MITOMYCIN	2.00	MILLIGRAMMES	POM
PL 20075/0388	11/01/2016	ACCORD HEALTHCARE LIMITED	MITOMYCIN 10 MG POWDER FOR SOLUTION FOR INJECTION/INFUSION OR INTRAVESICAL	MITOMYCIN	10.00	MILLIGRAMMES	POM
PL 20075/0389	11/01/2016	ACCORD HEALTHCARE LIMITED	MITOMYCIN 20 MG POWDER FOR SOLUTION FOR INJECTION/INFUSION OR INTRAVESICAL	MITOMYCIN	20.00	MILLIGRAMMES	POM
PL 00289/1968	12/01/2016	TEVA UK LIMITED	CINACALCET TEVA 30 MG FILM-COATED TABLETS	CINACALCET HYDROCHLORIDE	33.06	MILLIGRAMMES	POM
PL 00289/1969	12/01/2016	TEVA UK LIMITED	CINACALCET TEVA 60 MG FILM-COATED TABLETS	CINACALCET HYDROCHLORIDE	66.12	MILLIGRAMMES	POM
PL 00289/1970	12/01/2016	TEVA UK LIMITED	CINACALCET TEVA 90 MG FILM-COATED TABLETS	CINACALCET HYDROCHLORIDE	99.18	MILLIGRAMMES	POM
PL 17907/0439	12/01/2016	BRISTOL LABORATORIES LIMITED	HYDROCORTISONE 10MG TABLETS	HYDROCORTISONE	10.000	MILLIGRAMMES	POM
PL 17907/0440	12/01/2016	BRISTOL LABORATORIES LIMITED	HYDROCORTISONE 20MG TABLETS	HYDROCORTISONE	20.000	MILLIGRAMMES	POM
PL 27925/0087	12/01/2016	ORION CORPORATION	NAPROXEN ORION 25 MG/ML ORAL SUSPENSION	NAPROXEN	25	MILLIGRAMMES PER MILLILITRE	POM

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PL 04416/1412	13/01/2016	SANDOZ LIMITED	EPLERENONE 25 MG FILM-COATED TABLETS	EPLERENONE	25.00	MILLIGRAMMES	POM
PL 04416/1413	13/01/2016	SANDOZ LIMITED	EPLERENONE 50 MG FILM-COATED TABLETS	EPLERENONE	50.00	MILLIGRAMMES	POM
PL 04569/1496	13/01/2016	GENERICS (UK) LIMITED	METHYLPHENIDATE HYDROCHLORIDE 5 MG TABLETS	METHYLPHENIDATE HYDROCHLORIDE	5.0	MILLIGRAMMES	POM
PL 04569/1497	13/01/2016	GENERICS (UK) LIMITED	METHYLPHENIDATE HYDROCHLORIDE 10 MG TABLETS	METHYLPHENIDATE HYDROCHLORIDE	10.0	MILLIGRAMMES	POM
PL 04569/1498	13/01/2016	GENERICS (UK) LIMITED	METHYLPHENIDATE HYDROCHLORIDE 20 MG TABLETS	METHYLPHENIDATE HYDROCHLORIDE	20.0	MILLIGRAMMES	POM
PL 31599/0013	13/01/2016	TAMARANG SA	PEMETREXED 100 MG POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION	PEMETREXED DISODIUM	100.0	MILLIGRAMMES	POM
PL 31599/0014	13/01/2016	TAMARANG SA	PEMETREXED 500 MG POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION	PEMETREXED DISODIUM	500.0	MILLIGRAMMES	POM
PL 36884/0007	13/01/2016	MORPHARMA LIMITED	OLMESARTAN 10 MG FILM-COATED TABLETS	OLMESARTAN MEDOXOMIL	10.00	MILLIGRAMMES	POM
PL 36884/0008	13/01/2016	MORPHARMA LIMITED	OLMESARTAN 20 MG FILM-COATED TABLETS	OLMESARTAN MEDOXOMIL	20.00	MILLIGRAMMES	POM
PL 36884/0009	13/01/2016	MORPHARMA LIMITED	OLMESARTAN 40 MG FILM-COATED TABLETS	OLMESARTAN MEDOXOMIL	40.00	MILLIGRAMMES	POM
PL 12762/0515	14/01/2016	MERCURY PHARMACEUTICALS LIMITED	URSODEOXYCHOLIC ACID 250 MG CAPSULES, HARD	URSODEOXYCHOLIC ACID	250.00	MILLIGRAMMES	POM
PL 12308/0026	15/01/2016	GUERBET	PHYBAG 9 MG/ML, SOLUTION FOR INJECTION	SODIUM CHLORIDE	9.00	MILLIGRAMMES	P
PL 28176/0163	15/01/2016	STRIDES ARCOLAB INTERNATIONAL LIMITED	LEVETIRACETAM STRIDES 100 MG/ML ORAL SOLUTION	LEVETIRACETAM	100.00	MILLIGRAMMES	POM
PL 41222/0001	15/01/2016	ROTOP PHARMAKA AG	TEKTROTYD 16 MICROGRAM KIT FOR RADIOPHARMACEUTICAL PREPARATION	ETHYLENEDIAMINE DIACETIC ACID	10	MILLIGRAMMES	POM
PL 41222/0001	15/01/2016	ROTOP PHARMAKA AG	TEKTROTYD 16 MICROGRAM KIT FOR RADIOPHARMACEUTICAL PREPARATION	HYNIC-(D-PHE(1), TYR(3)-OCTREOTIDE).TFA	16.00	MICROGRAMMES	POM
PL 01502/0097	18/01/2016	HAMELN PHARMACEUTICALS LIMITED	OXYTOCIN 10 IU/ML CONCENTRATE FOR SOLUTION FOR INFUSION	OXYTOCIN	10	INTERNATIONAL UNITS	POM
PL 17780/0718	18/01/2016	WINTHROP PHARMACEUTICALS UK LIMITED	AMLODIPINE/VALSARTAN 5MG/80 MG FILM-COATED TABLETS	AMLODIPINE BESILATE	6.935	MILLIGRAMMES	POM
PL 17780/0718	18/01/2016	WINTHROP PHARMACEUTICALS UK LIMITED	AMLODIPINE/VALSARTAN 5MG/80 MG FILM-COATED TABLETS	VALSARTAN	80.000	MILLIGRAMMES	POM
PL 17780/0719	18/01/2016	WINTHROP PHARMACEUTICALS UK LIMITED	AMLODIPINE/VALSARTAN 5MG/160 MG FILM-COATED TABLETS	AMLODIPINE BESILATE	6.935	MILLIGRAMMES	POM
PL 17780/0719	18/01/2016	WINTHROP PHARMACEUTICALS UK LIMITED	AMLODIPINE/VALSARTAN 5MG/160 MG FILM-COATED TABLETS	VALSARTAN	160.000	MILLIGRAMMES	POM
PL 17780/0720	18/01/2016	WINTHROP PHARMACEUTICALS UK LIMITED	AMLODIPINE/VALSARTAN 10 MG/160 MG FILM-COATED TABLETS	AMLODIPINE BESILATE	13.870	MILLIGRAMMES	POM
PL 17780/0720	18/01/2016	WINTHROP PHARMACEUTICALS UK LIMITED	AMLODIPINE/VALSARTAN 10 MG/160 MG FILM-COATED TABLETS	VALSARTAN	160.000	MILLIGRAMMES	POM
PL 17780/0721	18/01/2016	WINTHROP PHARMACEUTICALS UK LIMITED	ASBIMA 5MG/80MG FILM-COATED TABLETS	AMLODIPINE BESILATE	6.935	MILLIGRAMMES	POM

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PL 17780/0721	18/01/2016	WINTHROP PHARMACEUTICALS UK LIMITED	ASBIMA 5MG/80MG FILM-COATED TABLETS	VALSARTAN	80.000	MILLIGRAMMES	POM
PL 17780/0722	18/01/2016	WINTHROP PHARMACEUTICALS UK LIMITED	ASBIMA 5MG/160MG FILM-COATED TABLETS	AMLODIPINE BESILATE	6.935	MILLIGRAMMES	POM
PL 17780/0722	18/01/2016	WINTHROP PHARMACEUTICALS UK LIMITED	ASBIMA 5MG/160MG FILM-COATED TABLETS	VALSARTAN	160.000	MILLIGRAMMES	POM
PL 17780/0723	18/01/2016	WINTHROP PHARMACEUTICALS UK LIMITED	ASBIMA 10MG/160MG FILM-COATED TABLETS	AMLODIPINE BESILATE	13.870	MILLIGRAMMES	POM
PL 17780/0723	18/01/2016	WINTHROP PHARMACEUTICALS UK LIMITED	ASBIMA 10MG/160MG FILM-COATED TABLETS	VALSARTAN	160.000	MILLIGRAMMES	POM
PL 17907/0525	18/01/2016	BRISTOL LABORATORIES LIMITED	LINEZOLID 600MG FILM COATED TABLETS	LINEZOLID	600.000	MILLIGRAMMES	POM
PL 04569/1506	19/01/2016	GENERICS (UK) LIMITED	MOLATIVE PAEDIATRIC 6.9 G POWDER FOR ORAL SOLUTION	MACROGOL 3350	6.5625	GRAMMES	POM
PL 04569/1506	19/01/2016	GENERICS (UK) LIMITED	MOLATIVE PAEDIATRIC 6.9 G POWDER FOR ORAL SOLUTION	POTASSIUM CHLORIDE	0.0233	GRAMMES	POM
PL 04569/1506	19/01/2016	GENERICS (UK) LIMITED	MOLATIVE PAEDIATRIC 6.9 G POWDER FOR ORAL SOLUTION	SODIUM CHLORIDE	0.1754	GRAMMES	POM
PL 04569/1506	19/01/2016	GENERICS (UK) LIMITED	MOLATIVE PAEDIATRIC 6.9 G POWDER FOR ORAL SOLUTION	SODIUM HYDROGEN CARBONATE	0.0893	GRAMMES	POM
PL 00165/0388	20/01/2016	PFIZER CONSUMER HEALTHCARE LIMITED	ROBICOLD SINUS RELIEF 200MG / 30MG LIQUID CAPSULES	IBUPROFEN	200.00	MILLIGRAMMES	P
PL 00165/0388	20/01/2016	PFIZER CONSUMER HEALTHCARE LIMITED	ROBICOLD SINUS RELIEF 200MG / 30MG LIQUID CAPSULES	PSEUDOEPHEDRINE HYDROCHLORIDE	30.00	MILLIGRAMMES	P
PL 00165/0389	20/01/2016	PFIZER CONSUMER HEALTHCARE LIMITED	IBUPROFEN/ PSEUDOEPHEDRINE HYDROCHLORIDE PFIZER 200 MG/ 30 MG CAPSULES	IBUPROFEN	200	MILLIGRAMMES	P
PL 00165/0389	20/01/2016	PFIZER CONSUMER HEALTHCARE LIMITED	IBUPROFEN/ PSEUDOEPHEDRINE HYDROCHLORIDE PFIZER 200 MG/ 30 MG CAPSULES	PSEUDOEPHEDRINE HYDROCHLORIDE	30	MILLIGRAMMES	P
PL 15413/0048	20/01/2016	HIKMA FARMACEUTICA (PORTUGAL) SA	FLUOROURACIL 50 MG/ML SOLUTION FOR INJECTION/INFUSION	FLUOROURACIL	50.0	MILLIGRAMMES PER MILLILITRE	POM
PL 17907/0526	22/01/2016	BRISTOL LABORATORIES LIMITED	CELECOXIB CAPSULES, HARD 100MG	CELECOXIB	100.000	MILLIGRAMMES	POM
PL 17907/0527	22/01/2016	BRISTOL LABORATORIES LIMITED	CELECOXIB CAPSULES, HARD 200MG	CELECOXIB	200.000	MILLIGRAMMES	POM
PL 16046/0017	25/01/2016	L MOLTENI & C DEI F.LLI ALITTI SOCIETA DI ESERCIZIO SP	OXYCODONE MOLTENI 10 MG/ML SOLUTION FOR INJECTION OR INFUSION	OXYCODONE HYDROCHLORIDE	10	MILLIGRAMMES	POM
PL 16046/0018	25/01/2016	L MOLTENI & C DEI F.LLI ALITTI SOCIETA DI ESERCIZIO SP	OXYCODONE MOLTENI 50 MG/ML SOLUTION FOR INJECTION OR INFUSION	OXYCODONE HYDROCHLORIDE	50	MILLIGRAMMES	POM
PL 17589/0007	25/01/2016	DEMO SA PHARMACEUTICAL INDUSTRY	CALCIUM CHLORIDE 10% W/V SOLUTION FOR INFUSION	CALCIUM CHLORIDE DIHYDRATE	100.0	MILLIGRAMMES	POM
PL 30306/0654	25/01/2016	ACTAVIS GROUP PTC EHF	GEMCITABINE 40MG/ML CONCENTRATE FOR SOLUTION FOR INFUSION	GEMCITABINE HYDROCHLORIDE	45.6	MILLIGRAMMES	POM
PL 33831/0027	25/01/2016	BLUE BIO PHARMACEUTICALS LIMITED	CALCIUM CARBONATE/COLECALCIFEROL 1500MG/400IU CHEWABLE TABLETS	CALCIUM CARBONATE	1500.00	MILLIGRAMMES	P
PL 33831/0027	25/01/2016	BLUE BIO PHARMACEUTICALS LIMITED	CALCIUM CARBONATE/COLECALCIFEROL 1500MG/400IU CHEWABLE TABLETS	COLECALCIFEROL CONCENTRATE (POWDER)	400	INTERNATIONAL UNITS	P

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PL 34088/0041	25/01/2016	ALKALOID-INT DOO	ALKAPAMID XL 1.5 MG PROLONGED-RELEASE TABLETS	INDAPAMIDE	1.50	MILLIGRAMMES	POM
PL 17907/0502	26/01/2016	BRISTOL LABORATORIES LIMITED	DESLORATADINE 0.5MG/ML ORAL SOLUTION	DESLORATADINE	0.5	MILLIGRAMMES	POM
PL 16363/0447	27/01/2016	MILPHARM LIMITED	TADALAFIL MILPHARM 2.5 MG FILM-COATED TABLETS	TADALAFIL	2.500	MILLIGRAMMES	POM
PL 16363/0448	27/01/2016	MILPHARM LIMITED	TADALAFIL MILPHARM 5 MG FILM-COATED TABLETS	TADALAFIL	5.000	MILLIGRAMMES	POM
PL 16363/0449	27/01/2016	MILPHARM LIMITED	TADALAFIL MILPHARM 10 MG FILM-COATED TABLETS	TADALAFIL	10.000	MILLIGRAMMES	POM
PL 16363/0450	27/01/2016	MILPHARM LIMITED	TADALAFIL MILPHARM 20 MG FILM-COATED TABLETS	TADALAFIL	20.000	MILLIGRAMMES	POM
PL 04569/1570	28/01/2016	GENERICS (UK) LIMITED	BUPLAST 35 MICROGRAMS/H TRANSDERMAL PATCHES	BUPRENORPHINE	20.00	MILLIGRAMMES	POM
PL 04569/1571	28/01/2016	GENERICS (UK) LIMITED	BUPLAST 52.5 MICROGRAMS/H TRANSDERMAL PATCHES	BUPRENORPHINE	30.00	MILLIGRAMMES	POM
PL 04569/1572	28/01/2016	GENERICS (UK) LIMITED	BUPLAST 70 MICROGRAMS/H TRANSDERMAL PATCHES	BUPRENORPHINE	40.00	MILLIGRAMMES	POM
PL 20075/0238	28/01/2016	ACCORD HEALTHCARE LIMITED	OLMESARTAN MEDOXOMIL 10MG FILM COATED TABLET	OLMESARTAN MEDOXOMIL	10.000	MILLIGRAMMES	POM
PL 20075/0239	28/01/2016	ACCORD HEALTHCARE LIMITED	OLMESARTAN MEDOXOMIL 20MG FILM COATED TABLETS	OLMESARTAN MEDOXOMIL	20.000	MILLIGRAMMES	POM
PL 20075/0240	28/01/2016	ACCORD HEALTHCARE LIMITED	OLMESARTAN MEDOXOMIL 40MG FILM COATED TABLETS	OLMESARTAN MEDOXOMIL	40.000	MILLIGRAMMES	POM
PL 28444/0146	28/01/2016	ACTIVASE PHARMACEUTICALS LIMITED	GENLEV 100 MG/ML ORAL SOLUTION	LEVETIRACETAM	100	MILLIGRAMMES	POM
PL 29831/0585	28/01/2016	WOCKHARDT UK LIMITED	CHLORPHENAMINE 10MG/ML SOLUTION FOR INJECTION	CHLORPHENAMINE MALEATE	10.0	MILLIGRAMMES PER MILLILITRE	POM