

Marketing authorisations granted in August 2016

PL Number	Grant Date	MA Holder	Licensed Name(s)	Active Ingredient	Quantity	Units	Legal Status
PL 16363/0461	01/08/2016	MILPHARM LIMITED	AZITHROMYCIN 250 MG FILM-COATED TABLETS	AZITHROMYCIN DIHYDRATE	262.000	MILLIGRAMMES	POM
PL 16363/0462	01/08/2016	MILPHARM LIMITED	AZITHROMYCIN 500 MG FILM-COATED TABLETS	AZITHROMYCIN DIHYDRATE	524.000	MILLIGRAMMES	POM
PL 29831/0619	01/08/2016	WOCKHARDT UK LIMITED	MILRINONE 1MG/ML SOLUTION FOR INJECTION/INFUSION	MILRINONE	1.00	MILLIGRAMMES PER MILLILITRE	POM
PL 41344/0017	01/08/2016	COLONIS PHARMA LIMITED	DONEPEZIL HYDROCHLORIDE 2MG/ML ORAL SOLUTION	DONEPEZIL HYDROCHLORIDE	2.0	MILLIGRAMMES	POM
PL 00031/0837	02/08/2016	ROCHE PRODUCTS LIMITED	ROCEPHIN 2G POWDER FOR SOLUTION FOR INFUSION	CEFTRIAXONE SODIUM	2000.00	MILLIGRAMMES	POM
PL 00031/0838	02/08/2016	ROCHE PRODUCTS LIMITED	ROCEPHIN 500MG POWDER AND SOLVENT FOR SOLUTION FOR INJECTION	CEFTRIAXONE SODIUM	500.00	MILLIGRAMMES	POM
PL 00031/0839	02/08/2016	ROCHE PRODUCTS LIMITED	ROCEPHIN 1G POWDER AND SOLVENT FOR SOLUTION FOR INJECTION	CEFTRIAXONE SODIUM	1000.00	MILLIGRAMMES	POM
PL 00031/0840	02/08/2016	ROCHE PRODUCTS LIMITED	ROCEPHIN 250MG POWDER AND SOLVENT FOR SOLUTION FOR INJECTION	CEFTRIAXONE SODIUM	250.00	MILLIGRAMMES	POM
PL 00031/0841	02/08/2016	ROCHE PRODUCTS LIMITED	ROCEPHIN 1G POWDER AND SOLVENT FOR SOLUTION FOR INJECTION	CEFTRIAXONE SODIUM	1000.00	MILLIGRAMMES	POM
PL 00289/1998	03/08/2016	TEVA UK LIMITED	SITAGLIPTIN TEVA 25 MG FILM-COATED TABLETS	SITAGLIPTIN MALATE	33.230	MILLIGRAMMES	POM
PL 00289/1999	03/08/2016	TEVA UK LIMITED	SITAGLIPTIN TEVA 50 MG FILM-COATED TABLETS	SITAGLIPTIN MALATE	66.460	MILLIGRAMMES	POM
PL 00289/2000	03/08/2016	TEVA UK LIMITED	SITAGLIPTIN TEVA 100 MG FILM-COATED TABLETS	SITAGLIPTIN MALATE	132.920	MILLIGRAMMES	POM
PL 21880/0175	03/08/2016	MEDREICH PLC	IBUPROFEN 200 MG FILM-COATED TABLETS	IBUPROFEN	200	MILLIGRAMMES	GSL
PL 21880/0176	03/08/2016	MEDREICH PLC	IBUPROFEN 400 MG FILM-COATED TABLETS	IBUPROFEN	400	MILLIGRAMMES	P
PL 21880/0177	03/08/2016	MEDREICH PLC	IBUPROFEN 600 MG FILM-COATED TABLETS	IBUPROFEN	600	MILLIGRAMMES	POM
PL 21880/0189	03/08/2016	MEDREICH PLC	IBUPROFEN 200MG FILM-COATED TABLETS	IBUPROFEN	200	MILLIGRAMMES	P
PL 35104/0020	03/08/2016	PHOENIX LABS	PREDNISOLONE 5MG SOLUBLE TABLETS	PREDNISOLONE SODIUM PHOSPHATE	6.72	MILLIGRAMMES	POM
PL 44041/0008	03/08/2016	NOUMED LIFE SCIENCES LIMITED	CITALOPRAM 10MG TABLETS	CITALOPRAM HYDROBROMIDE	20	MILLIGRAMMES	POM
PL 44041/0009	03/08/2016	NOUMED LIFE SCIENCES LIMITED	CITALOPRAM 20MG TABLETS	CITALOPRAM HYDROBROMIDE	20	MILLIGRAMMES	POM
PL 44041/0010	03/08/2016	NOUMED LIFE SCIENCES LIMITED	CITALOPRAM 40MG TABLETS	CITALOPRAM HYDROBROMIDE	49.960	MILLIGRAMMES	POM
PL 40546/0018	04/08/2016	ARISTO PHARMA GMBH	RASAGILINE ARISTO 1 MG TABLETS	RASAGILINE TARTRATE	1.438	MILLIGRAMMES	POM
PL 01656/0205	05/08/2016	KRKA DD NOVO MESTO	DEXAMETHASONE 4 MG TABLETS	DEXAMETHASONE	4.00	MILLIGRAMMES	POM
PL 01656/0206	05/08/2016	KRKA DD NOVO MESTO	DEXAMETHASONE 8 MG TABLETS	DEXAMETHASONE	8.00	MILLIGRAMMES	POM
PL 01656/0207	05/08/2016	KRKA DD NOVO MESTO	DEXAMETHASONE 20 MG TABLETS	DEXAMETHASONE	20.00	MILLIGRAMMES	POM
PL 01656/0208	05/08/2016	KRKA DD NOVO MESTO	DEXAMETHASONE 40 MG TABLETS	DEXAMETHASONE	40.00	MILLIGRAMMES	POM
PL 20072/0243	05/08/2016	AMDIPHARM UK LIMITED	DETRUNORM 15MG FILM-COATED TABLETS	PROPIPERINE HYDROCHLORIDE	15.00	MILLIGRAMMES	POM
PL 20075/0435	05/08/2016	ACCORD HEALTHCARE LIMITED	IBUPROFEN 200 MG FILM-COATED TABLETS	IBUPROFEN	200.000	MILLIGRAMMES	POM
PL 20075/0436	05/08/2016	ACCORD HEALTHCARE LIMITED	IBUPROFEN 400 MG FILM-COATED TABLETS	IBUPROFEN	400.000	MILLIGRAMMES	POM
PL 20075/0437	05/08/2016	ACCORD HEALTHCARE LIMITED	IBUPROFEN 600 MG FILM-COATED TABLETS	IBUPROFEN	600.000	MILLIGRAMMES	POM

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PL 27925/0088	05/08/2016	ORION CORPORATION	METHOTREXATE ORION 2.5 MG TABLETS	METHOTREXATE DISODIUM	2.742	MILLIGRAMMES	POM
PL 27925/0089	05/08/2016	ORION CORPORATION	METHOTREXATE ORION 10 MG TABLETS	METHOTREXATE DISODIUM	10.97	MILLIGRAMMES	POM
PL 00289/2011	08/08/2016	TEVA UK LIMITED	ROSUVASTATIN 5 MG FILM-COATED TABLETS	ROSUVASTATIN CALCIUM	5.21	MILLIGRAMMES	POM
PL 00289/2012	08/08/2016	TEVA UK LIMITED	ROSUVASTATIN 10 MG FILM-COATED TABLETS	ROSUVASTATIN CALCIUM	10.42	MILLIGRAMMES	POM
PL 00289/2013	08/08/2016	TEVA UK LIMITED	ROSUVASTATIN 20 MG FILM-COATED TABLETS	ROSUVASTATIN CALCIUM	20.83	MILLIGRAMMES	POM
PL 00289/2014	08/08/2016	TEVA UK LIMITED	ROSUVASTATIN 40 MG FILM-COATED TABLETS	ROSUVASTATIN CALCIUM	41.68	MILLIGRAMMES	POM
PL 16363/0506	08/08/2016	MILPHARM LIMITED	ROSUVASTATIN 5 MG FILM-COATED TABLETS	ROSUVASTATIN CALCIUM	5.197	MILLIGRAMMES	POM
PL 16363/0507	08/08/2016	MILPHARM LIMITED	ROSUVASTATIN 10 MG FILM-COATED TABLETS	ROSUVASTATIN CALCIUM	10.00	MILLIGRAMMES	POM
PL 16363/0508	08/08/2016	MILPHARM LIMITED	ROSUVASTATIN 20 MG FILM-COATED TABLETS	ROSUVASTATIN CALCIUM	20.790	MILLIGRAMMES	POM
PL 16363/0509	08/08/2016	MILPHARM LIMITED	ROSUVASTATIN 40 MG FILM-COATED TABLETS	ROSUVASTATIN CALCIUM	41.580	MILLIGRAMMES	POM
PL 20046/0304	08/08/2016	FOCUS PHARMACEUTICALS LIMITED	NORTRIPTYLINE 10MG FILM-COATED TABLETS	NORTRIPTYLINE HYDROCHLORIDE	11.38	MILLIGRAMMES	POM
PL 20046/0305	08/08/2016	FOCUS PHARMACEUTICALS LIMITED	NORTRIPTYLINE 25MG FILM-COATED TABLETS	NORTRIPTYLINE HYDROCHLORIDE	28.46	MILLIGRAMMES	POM
PL 20046/0306	08/08/2016	FOCUS PHARMACEUTICALS LIMITED	NORTRIPTYLINE 50MG FILM-COATED TABLETS	NORTRIPTYLINE HYDROCHLORIDE	56.9	MILLIGRAMMES	POM
PL 00031/0842	09/08/2016	ROCHE PRODUCTS LIMITED	ROCEPHIN 500 MG/2ML POWDER AND SOLVENT FOR SOLUTION FOR INJECTION	CEFTRIAXONE SODIUM	500	MILLIGRAMMES	POM
PL 36722/0032	11/08/2016	SPECIAL CONCEPT DEVELOPMENT (UK) LIMITED	BENDROFLUMETHIAZIDE 2.5MG TABLETS	BENDROFLUMETHIAZIDE	2.5	MILLIGRAMMES	POM
PL 36722/0033	11/08/2016	SPECIAL CONCEPT DEVELOPMENT (UK) LIMITED	BENDROFLUMETHIAZIDE 5MG TABLETS	BENDROFLUMETHIAZIDE	5	MILLIGRAMMES	POM
PL 00289/2037	12/08/2016	TEVA UK LIMITED	MOMETASONE FUROATE 50 MICROGRAMS/ACTUATION NASAL SPRAY SUSPENSION	MOMETASONE FUROATE MONOHYDRATE	0.052	MILLIGRAMMES	POM
PL 20663/0003	12/08/2016	ITALFARMACO SA	BLISSEL 50 MICROGRAMS/G VAGINAL GEL	ESTRIOL	50	MICROGRAMMES	POM
PL 16363/0465	15/08/2016	MILPHARM LIMITED	RISPERIDONE 1 MG/ML ORAL SOLUTION	RISPERIDONE	1	MILLIGRAMMES PER MILLILITRE	POM
PL 44041/0033	15/08/2016	NOUMED LIFE SCIENCES LIMITED	TERBINAFINE 250 MG TABLETS	TERBINAFINE HYDROCHLORIDE	281.25	MILLIGRAMMES	POM
PL 20905/0002	17/08/2016	PHARMA STULLN GMBH	KETOFALL 0.25 MG/ML EYE DROPS, SOLUTION IN SINGLE-DOSE CONTAINER	KETOTIFEN HYDROGEN FUMARATE	0.345	MILLIGRAMMES PER MILLILITRE	POM
PL 41344/0019	17/08/2016	COLONIS PHARMA LIMITED	METFORMIN COLONIS 500MG/5ML ORAL SOLUTION	METFORMIN HYDROCHLORIDE	100.00	MILLIGRAMMES	POM
PL 41344/0020	17/08/2016	COLONIS PHARMA LIMITED	METFORMIN COLONIS 850MG/5ML ORAL SOLUTION	METFORMIN HYDROCHLORIDE	170.00	MILLIGRAMMES	POM
PL 41344/0021	17/08/2016	COLONIS PHARMA LIMITED	METFORMIN COLONIS 1000MG/5ML ORAL SOLUTION	METFORMIN HYDROCHLORIDE	200.00	MILLIGRAMMES	POM
PL 44041/0002	17/08/2016	NOUMED LIFE SCIENCES LIMITED	AMOXICILLIN 500 MG CAPSULES	AMOXICILLIN TRIHYDRATE	575.00	MILLIGRAMMES	POM
PL 30306/0701	18/08/2016	ACTAVIS GROUP PTC EHF	OLMESARTAN 10 MG FILM-COATED TABLETS	OLMESARTAN MEDOXOMIL	10	MILLIGRAMMES	POM
PL 30306/0702	18/08/2016	ACTAVIS GROUP PTC EHF	OLMESARTAN 20 MG FILM-COATED TABLETS	OLMESARTAN MEDOXOMIL	20.000	MILLIGRAMMES	POM
PL 30306/0703	18/08/2016	ACTAVIS GROUP PTC EHF	OLMESARTAN 40 MG FILM-COATED TABLETS	OLMESARTAN MEDOXOMIL	40.000	MILLIGRAMMES	POM
PL 39307/0056	19/08/2016	SYRI LIMITED	METOCLOPRAMIDE HYDROCHLORIDE 5MG/5ML ORAL SOLUTION	METOCLOPRAMIDE HYDROCHLORIDE	5.00	MILLIGRAMMES	POM

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PL 20117/0096	23/08/2016	MORNINGSIDE HEALTHCARE LIMITED	LYMECYCLINE 408 MG CAPSULES, HARD	LYMECYCLINE	408.00	MILLIGRAMMES	POM
PL 25258/0188	23/08/2016	GLENMARK PHARMACEUTICALS EUROPE LIMITED	ALTRUDYNT 5 MG HARD CAPSULES	TACROLIMUS	5.000	MILLIGRAMMES	POM
PL 35501/0004	23/08/2016	HCS BVBA	RASAGILINE HCS 1MG TABLETS	RASAGILINE HEMITARTRATE	1.44	MILLIGRAMMES	POM
PL 42117/0005	23/08/2016	TILLOMED LABORATORIES LIMITED	ZOLEDRONIC ACID 5 MG SOLUTION FOR INFUSION	ZOLEDRONIC ACID	0.0533	MILLIGRAMMES	POM
PL 43659/0025	24/08/2016	PRIMEGEN LIMITED	DEXAMFETAMINE SULFATE 5 MG TABLETS	DEXAMFETAMINE SULFATE	5.00	MILLIGRAMMES	POM
PL 44710/0011	24/08/2016	KINEDEXE UK LIMITED	DEXAMFETAMINE SULFATE 5 MG TABLETS	DEXAMFETAMINE SULFATE	5.00	MILLIGRAMMES	POM
PL 31750/0063	25/08/2016	SUN PHARMACEUTICAL INDUSTRIES EUROPE BV	TETRABENAZINE 12.5 MG TABLETS	TETRABENAZINE	12.5	MILLIGRAMMES	POM
PL 31750/0064	25/08/2016	SUN PHARMACEUTICAL INDUSTRIES EUROPE BV	TETRABENAZINE 25 MG TABLETS	TETRABENAZINE	25	MILLIGRAMMES	POM
PL 33155/0042	25/08/2016	RIVOPHARM (UK) LIMITED	ONEXILA XL 10MG PROLONGED-RELEASE TABLETS	OXYCODONE HYDROCHLORIDE	10.00	MILLIGRAMMES	POM
PL 33155/0044	25/08/2016	RIVOPHARM (UK) LIMITED	ONEXILA XL 20MG PROLONGED-RELEASE TABLETS	OXYCODONE HYDROCHLORIDE	20.00	MILLIGRAMMES	POM
PL 33155/0045	25/08/2016	RIVOPHARM (UK) LIMITED	ONEXILA XL 40MG PROLONGED-RELEASE TABLETS	OXYCODONE HYDROCHLORIDE	40.00	MILLIGRAMMES	POM
PL 33155/0046	25/08/2016	RIVOPHARM (UK) LIMITED	ONEXILA XL 80MG PROLONGED-RELEASE TABLETS	OXYCODONE HYDROCHLORIDE	80.00	MILLIGRAMMES	POM
PL 20416/0325	26/08/2016	CRESCENT PHARMA LIMITED	IRBESARTAN 75 MG FILM-COATED TABLETS	IRBESARTAN	75	MILLIGRAMMES	POM
PL 20416/0326	26/08/2016	CRESCENT PHARMA LIMITED	IRBESARTAN 150 MG FILM-COATED TABLETS	IRBESARTAN	150	MILLIGRAMMES	POM
PL 20416/0327	26/08/2016	CRESCENT PHARMA LIMITED	IRBESARTAN 300 MG FILM-COATED TABLETS	IRBESARTAN	300	MILLIGRAMMES	POM
PL 20416/0328	26/08/2016	CRESCENT PHARMA LIMITED	IRBESARTAN AND HYDROCHLOROTHIAZIDE 150MG / 12.5MG FILM-COATED TABLETS	HYDROCHLOROTHIAZIDE	12.5	MILLIGRAMMES	POM
PL 20416/0328	26/08/2016	CRESCENT PHARMA LIMITED	IRBESARTAN AND HYDROCHLOROTHIAZIDE 150MG / 12.5MG FILM-COATED TABLETS	IRBESARTAN	150	MILLIGRAMMES	POM
PL 20416/0329	26/08/2016	CRESCENT PHARMA LIMITED	IRBESARTAN AND HYDROCHLOROTHIAZIDE 300MG / 25MG FILM-COATED TABLETS	HYDROCHLOROTHIAZIDE	25	MILLIGRAMMES	POM
PL 20416/0329	26/08/2016	CRESCENT PHARMA LIMITED	IRBESARTAN AND HYDROCHLOROTHIAZIDE 300MG / 25MG FILM-COATED TABLETS	IRBESARTAN	300	MILLIGRAMMES	POM
PL 20416/0330	26/08/2016	CRESCENT PHARMA LIMITED	IRBESARTAN AND HYDROCHLOROTHIAZIDE 300MG / 12.5MG FILM-COATED TABLETS	HYDROCHLOROTHIAZIDE	12.5	MILLIGRAMMES	POM
PL 20416/0330	26/08/2016	CRESCENT PHARMA LIMITED	IRBESARTAN AND HYDROCHLOROTHIAZIDE 300MG / 12.5MG FILM-COATED TABLETS	IRBESARTAN	300	MILLIGRAMMES	POM
PL 24837/0077	30/08/2016	CONSILIENT HEALTH LIMITED	INVITA D3 5,600 IU SOFT CAPSULES	COLECALCIFEROL CONCENTRATE (OILY FORM)	5600	INTERNATIONAL UNITS	POM
PL 30306/0774	30/08/2016	ACTAVIS GROUP PTC EHF	NEFOPAM HYDROCHLORIDE 30MG FILM-COATED TABLETS	NEFOPAM HYDROCHLORIDE	30	MILLIGRAMMES	POM
PL 34771/0171	30/08/2016	MACLEODS PHARMA UK LIMITED	PROPYLTHIOURACIL 50MG TABLETS	PROPYLTHIOURACIL	50.000	MILLIGRAMMES	POM
PL 04416/1444	31/08/2016	SANDOZ LIMITED	ABACAVIR/LAMIVUDINE SANDOZ 600 MG/300 MG FILM-COATED TABLETS	ABACAVIR HYDROCHLORIDE	676.401	MILLIGRAMMES	POM
PL 04416/1444	31/08/2016	SANDOZ LIMITED	ABACAVIR/LAMIVUDINE SANDOZ 600 MG/300 MG FILM-COATED TABLETS	LAMIVUDINE	300.00	MILLIGRAMMES	POM
PL 04569/1611	31/08/2016	GENERIC (UK) LIMITED	ABACAVIR/LAMIVUDINE MYLAN 600 MG/300 MG FILM-COATED TABLETS	ABACAVIR HYDROCHLORIDE	676.401	MILLIGRAMMES	POM
PL 04569/1611	31/08/2016	GENERIC (UK) LIMITED	ABACAVIR/LAMIVUDINE MYLAN 600 MG/300 MG FILM-COATED TABLETS	LAMIVUDINE	300.000	MILLIGRAMMES	POM
PL 44041/0007	31/08/2016	NOUMED LIFE SCIENCES LIMITED	CIPROFLOXACIN 500 MG FILM-COATED TABLETS	CIPROFLOXACIN HYDROCHLORIDE	582	MILLIGRAMMES	POM