

Marketing authorisations granted in September 2016

PL Number	Grant Date	MA Holder	Licensed Name(s)	Active Ingredient	Quantity	Units	Legal Status
PL 35507/0151	01/09/2016	LUPIN (EUROPE) LIMITED	ABACAVIR/LAMIVUDINE LUPIN 600 MG / 300 MG FILM-COATED TABLETS	ABACAVIR HYDROCHLORIDE	676.401	MILLIGRAMMES	POM
PL 35507/0151	01/09/2016	LUPIN (EUROPE) LIMITED	ABACAVIR/LAMIVUDINE LUPIN 600 MG / 300 MG FILM-COATED TABLETS	LAMIVUDINE	300.00	MILLIGRAMMES	POM
PL 44041/0006	01/09/2016	NOUMED LIFE SCIENCES LIMITED	CO-AMOXICLAV 500MG/125MG FILM-COATED TABLETS	AMOXICILLIN TRIHYDRATE	575	MILLIGRAMMES	POM
PL 44041/0006	01/09/2016	NOUMED LIFE SCIENCES LIMITED	CO-AMOXICLAV 500MG/125MG FILM-COATED TABLETS	POTASSIUM CLAVULANATE	148.875	MILLIGRAMMES	POM
PL 25258/0199	05/09/2016	GLENMARK PHARMACEUTICALS EUROPE LIMITED	ETORICOXIB 30 MG FILM-COATED TABLETS	ETORICOXIB	30.0	MILLIGRAMMES	POM
PL 25258/0200	05/09/2016	GLENMARK PHARMACEUTICALS EUROPE LIMITED	ETORICOXIB 60 MG FILM-COATED TABLETS	ETORICOXIB	60.0	MILLIGRAMMES	POM
PL 25258/0201	05/09/2016	GLENMARK PHARMACEUTICALS EUROPE LIMITED	ETORICOXIB 90 MG FILM-COATED TABLETS	ETORICOXIB	90.0	MILLIGRAMMES	POM
PL 25258/0202	05/09/2016	GLENMARK PHARMACEUTICALS EUROPE LIMITED	ETORICOXIB 120 MG FILM-COATED TABLETS	ETORICOXIB	120.0	MILLIGRAMMES	POM
PL 39307/0001	05/09/2016	SYRI LIMITED	SYRISAL 1 MMOL/ML ORAL SOLUTION	SODIUM CHLORIDE	5.844	GRAMMES	POM
PL 42357/0188	06/09/2016	AMNEAL PHARMA EUROPE LIMITED	PANTOPRAZOLE 40 MG POWDER FOR SOLUTION FOR INJECTION	PANTOPRAZOLE SODIUM SESQUIHYDRATE	40.00	MILLIGRAMMES	POM
PL 08553/0579	07/09/2016	DR REDDY'S LABORATORIES (UK) LIMITED	EFAVIRENZ 600 MG FILM-COATED TABLETS	EFAVIRENZ	600.00	MILLIGRAMMES	POM
PL 06831/0284	08/09/2016	GENUS PHARMACEUTICALS LIMITED	BENZYLPENICILLIN SODIUM 1200MG POWDER FOR INJECTION	BENZYLPENICILLIN SODIUM	1200	MILLIGRAMMES	POM
PL 29978/0005	08/09/2016	MERZ PHARMACEUTICALS GMBH	BOCOUTURE 100 UNITS POWDER FOR SOLUTION FOR INJECTION	BOTULINUM TYPE A TOXIN - HAEMAGGLUTININ COMPLEX	0.8	NANOGRAMMES	POM
PL 16363/0464	09/09/2016	MILPHARM LIMITED	CETIRIZINE HYDROCHLORIDE 10 MG FILM-COATED TABLETS	CETIRIZINE DIHYDROCHLORIDE	10.00	MILLIGRAMMES	P
PL 33155/0041	09/09/2016	RIVOPHARM (UK) LIMITED	RASAGILINE RIVOPHARM 1MG TABLETS	RASAGILINE HEMITARTRATE	1.438	MILLIGRAMMES	POM
PL 41344/0035	09/09/2016	COLONIS PHARMA LIMITED	RANITIDINE 30MG/ML ORAL SOLUTION	RANITIDINE HYDROCHLORIDE	33.5	MILLIGRAMMES PER MILLILITRE	POM
PL 44570/0002	09/09/2016	QILU PHARMA SPAIN SL	OXALIPLATIN 5MG/ML CONCENTRATE FOR SOLUTION FOR INFUSION	OXALIPLATIN	5	MILLIGRAMMES	POM
PL 16363/0468	12/09/2016	MILPHARM LIMITED	ABACAVIR/LAMIVUDINE MILPHARM 600 MG/300 MG FILM-COATED TABLETS	ABACAVIR SULFATE	702.780	MILLIGRAMMES	POM
PL 16363/0468	12/09/2016	MILPHARM LIMITED	ABACAVIR/LAMIVUDINE MILPHARM 600 MG/300 MG FILM-COATED TABLETS	LAMIVUDINE	300.000	MILLIGRAMMES	POM
PL 29831/0653	12/09/2016	WOCKHARDT UK LIMITED	LINEZOLID 600 MG FILM-COATED TABLETS	LINEZOLID	600.00	MILLIGRAMMES	POM
PL 40170/0004	12/09/2016	DSM SINOCEM PHARMACEUTICALS NETHERLANDS BV	ROSUVASTATIN DSM SINOCEM 5 MG FILM-COATED TABLETS	ROSUVASTATIN CALCIUM	5.200	MILLIGRAMMES	POM
PL 40170/0005	12/09/2016	DSM SINOCEM PHARMACEUTICALS NETHERLANDS BV	ROSUVASTATIN DSM SINOCEM 10 MG FILM-COATED TABLETS	ROSUVASTATIN CALCIUM	10.400	MILLIGRAMMES	POM
PL 40170/0006	12/09/2016	DSM SINOCEM PHARMACEUTICALS NETHERLANDS BV	ROSUVASTATIN DSM SINOCEM 20 MG FILM-COATED TABLETS	ROSUVASTATIN CALCIUM	20.800	MILLIGRAMMES	POM
PL 40170/0007	12/09/2016	DSM SINOCEM PHARMACEUTICALS NETHERLANDS BV	ROSUVASTATIN DSM SINOCEM 40 MG FILM-COATED TABLETS	ROSUVASTATIN CALCIUM	41.600	MILLIGRAMMES	POM
PL 37222/0036	13/09/2016	HETERO EUROPE SL	LINEZOLID 600 MG FILM-COATED TABLETS	LINEZOLID	600.00	MILLIGRAMMES	POM
PL 30306/0710	14/09/2016	ACTAVIS GROUP PTC EHF	CO-CODAMOL 15/500MG FILM-COATED TABLETS	CODEINE PHOSPHATE HEMIHYDRATE	15	MILLIGRAMMES	POM
PL 30306/0710	14/09/2016	ACTAVIS GROUP PTC EHF	CO-CODAMOL 15/500MG FILM-COATED TABLETS	PARACETAMOL	500	MILLIGRAMMES	POM
PL 00289/1971	15/09/2016	TEVA UK LIMITED	LEVOTHYROXINE 12.5 MICROGRAM TABLETS	LEVOTHYROXINE SODIUM	12.5	MICROGRAMMES	POM
PL 00289/1972	15/09/2016	TEVA UK LIMITED	LEVOTHYROXINE 25 MICROGRAM TABLETS	LEVOTHYROXINE SODIUM	25	MICROGRAMMES	POM

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PL 00289/1973	15/09/2016	TEVA UK LIMITED	LEVOTHYROXINE 75 MICROGRAM TABLETS	LEVOTHYROXINE SODIUM	75	MICROGRAMMES	POM
PL 00010/0590	16/09/2016	BAYER PLC	DOTAGRAF 0.5 MMOL/ML SOLUTION FOR INJECTION	GADOTERIC ACID	279.32	MILLIGRAMMES PER MILLILITRE	POM
PL 00289/2049	16/09/2016	TEVA UK LIMITED	VENLAFAXINE TEVA XL 225 MG PROLONGED RELEASE CAPSULES, HARD	VENLAFAXINE HYDROCHLORIDE	254.700	MILLIGRAMMES	POM
PL 00289/2050	16/09/2016	TEVA UK LIMITED	VENLAFAXINE TEVA XL 225 MG PROLONGED RELEASE CAPSULES, HARD	VENLAFAXINE HYDROCHLORIDE	254.700	MILLIGRAMMES	POM
PL 20416/0331	16/09/2016	CRESCENT PHARMA LIMITED	VALSARTAN 40 MG FILM-COATED TABLETS	VALSARTAN	40.0	MILLIGRAMMES	POM
PL 20416/0332	16/09/2016	CRESCENT PHARMA LIMITED	VALSARTAN 80 MG FILM-COATED TABLETS	VALSARTAN	80.0	MILLIGRAMMES	POM
PL 20416/0333	16/09/2016	CRESCENT PHARMA LIMITED	VALSARTAN 160 MG FILM-COATED TABLETS	VALSARTAN	160.0	MILLIGRAMMES	POM
PL 20416/0334	16/09/2016	CRESCENT PHARMA LIMITED	VALSARTAN 320 MG FILM-COATED TABLETS	VALSARTAN	320.0	MILLIGRAMMES	POM
PL 01502/0101	20/09/2016	HAMELN PHARMACEUTICALS LIMITED	DEXAMETHASONE 3.3 MG/ML SOLUTION FOR INJECTION	DEXAMETHASONE SODIUM PHOSPHATE	4.37	MILLIGRAMMES	POM
PL 01502/0101	20/09/2016	HAMELN PHARMACEUTICALS LIMITED	DEXAMETHASONE 3.3 MG/ML SOLUTION FOR INJECTION	DEXAMETHASONE SODIUM PHOSPHATE	8.74	MILLIGRAMMES	POM
PL 17299/0002	20/09/2016	TIOFARMA BV	FLUDROCORTISONE ACETATE 0.1 MG TABLETS	FLUDROCORTISONE ACETATE	0.1	MILLIGRAMMES	POM
PL 31308/0044	20/09/2016	MAX REMEDIES LIMITED	LOPERAMIDE 2MG CAPSULES	LOPERAMIDE HYDROCHLORIDE	2	MILLIGRAMMES	P
PL 30306/0777	21/09/2016	ACTAVIS GROUP PTC EHF	ROSUVASTATIN 5MG FILM-COATED TABLETS	ROSUVASTATIN ZINC	5.34	MILLIGRAMMES	POM
PL 30306/0778	21/09/2016	ACTAVIS GROUP PTC EHF	ROSUVASTATIN 10MG FILM-COATED TABLETS	ROSUVASTATIN ZINC	10.68	MILLIGRAMMES	POM
PL 30306/0779	21/09/2016	ACTAVIS GROUP PTC EHF	ROSUVASTATIN 20MG FILM-COATED TABLETS	ROSUVASTATIN ZINC	21.36	MILLIGRAMMES	POM
PL 30306/0780	21/09/2016	ACTAVIS GROUP PTC EHF	ROSUVASTATIN 40MG FILM-COATED TABLETS	ROSUVASTATIN ZINC	42.72	MILLIGRAMMES	POM
PL 39307/0066	21/09/2016	SYRI LIMITED	TRAZODONE HYDROCHLORIDE 50MG/5ML SUGAR FREE ORAL SOLUTION	TRAZODONE HYDROCHLORIDE	50.00	MILLIGRAMMES	POM
PL 17907/0542	22/09/2016	BRISTOL LABORATORIES LIMITED	SOLIFENACIN SUCCINATE 5 MG FILM-COATED TABLETS	SOLIFENACIN SUCCINATE	5.00	MILLIGRAMMES	POM
PL 17907/0543	22/09/2016	BRISTOL LABORATORIES LIMITED	SOLIFENACIN SUCCINATE 10 MG FILM-COATED TABLETS	SOLIFENACIN SUCCINATE	10.00	MILLIGRAMMES	POM
PL 17907/0565	22/09/2016	BRISTOL LABORATORIES LIMITED	MAJOVEN XL 37.5 MG PROLONGED RELEASE CAPSULES, HARD	VENLAFAXINE HYDROCHLORIDE POLYMORPHIC FORM B	42.450	MILLIGRAMMES	POM
PL 17907/0566	22/09/2016	BRISTOL LABORATORIES LIMITED	MAJOVEN XL 75 MG PROLONGED RELEASE CAPSULES, HARD	VENLAFAXINE HYDROCHLORIDE POLYMORPHIC FORM B	84.900	MILLIGRAMMES	POM
PL 17907/0567	22/09/2016	BRISTOL LABORATORIES LIMITED	MAJOVEN XL 150 MG PROLONGED RELEASE CAPSULES, HARD	VENLAFAXINE HYDROCHLORIDE POLYMORPHIC FORM B	169.800	MILLIGRAMMES	POM
PL 28176/0175	22/09/2016	STRIDES ARCOLAB INTERNATIONAL LIMITED	STRIGOL PAEDIATRIC 6.86G POWDER FOR ORAL SOLUTION	MACROGOL 3350	6562.50	MILLIGRAMMES	POM
PL 28176/0175	22/09/2016	STRIDES ARCOLAB INTERNATIONAL LIMITED	STRIGOL PAEDIATRIC 6.86G POWDER FOR ORAL SOLUTION	POTASSIUM CHLORIDE	23.30	MILLIGRAMMES	POM
PL 28176/0175	22/09/2016	STRIDES ARCOLAB INTERNATIONAL LIMITED	STRIGOL PAEDIATRIC 6.86G POWDER FOR ORAL SOLUTION	SODIUM CHLORIDE	175.35	MILLIGRAMMES	POM
PL 28176/0175	22/09/2016	STRIDES ARCOLAB INTERNATIONAL LIMITED	STRIGOL PAEDIATRIC 6.86G POWDER FOR ORAL SOLUTION	SODIUM HYDROGEN CARBONATE	89.25	MILLIGRAMMES	POM
PL 28176/0176	22/09/2016	STRIDES ARCOLAB INTERNATIONAL LIMITED	STRIGOL 13.72G POWDER FOR ORAL SOLUTION	MACROGOL 3350	13125.50	MILLIGRAMMES	P
PL 28176/0176	22/09/2016	STRIDES ARCOLAB INTERNATIONAL LIMITED	STRIGOL 13.72G POWDER FOR ORAL SOLUTION	POTASSIUM CHLORIDE	46.60	MILLIGRAMMES	P
PL 28176/0176	22/09/2016	STRIDES ARCOLAB INTERNATIONAL LIMITED	STRIGOL 13.72G POWDER FOR ORAL SOLUTION	SODIUM CHLORIDE	350.70	MILLIGRAMMES	P

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PL 28176/0176	22/09/2016	STRIDES ARCOLAB INTERNATIONAL LIMITED	STRIGOL 13.72G POWDER FOR ORAL SOLUTION	SODIUM HYDROGEN CARBONATE	178.50	MILLIGRAMMES	P
PL 17589/0012	23/09/2016	DEMO SA PHARMACEUTICAL INDUSTRY	CALCIUM GLUCONATE 10% W/V SOLUTION FOR INJECTION	CALCIUM GLUCONATE MONOHYDRATE	95.0	MILLIGRAMMES	POM
PL 16363/0491	27/09/2016	MILPHARM LIMITED	LINEZOLID 600 MG FILM-COATED TABLETS	LINEZOLID	600.00	MILLIGRAMMES	POM
PL 04917/0143	28/09/2016	PINEWOOD LABORATORIES LIMITED	ACIDEX ADVANCE ORAL SUSPENSION (ANISEED FLAVOUR)	POTASSIUM BICARBONATE	200.00	MILLIGRAMMES PER MILLILITRE	GSL
PL 04917/0143	28/09/2016	PINEWOOD LABORATORIES LIMITED	ACIDEX ADVANCE ORAL SUSPENSION (ANISEED FLAVOUR)	SODIUM ALGINATE	1000.0	MILLIGRAMMES PER MILLILITRE	GSL
PL 04917/0144	28/09/2016	PINEWOOD LABORATORIES LIMITED	ACIDEX ADVANCE ORAL SUSPENSION (PEPPERMINT FLAVOUR)	POTASSIUM BICARBONATE	200.00	MILLIGRAMMES PER MILLILITRE	GSL
PL 04917/0144	28/09/2016	PINEWOOD LABORATORIES LIMITED	ACIDEX ADVANCE ORAL SUSPENSION (PEPPERMINT FLAVOUR)	SODIUM ALGINATE	1000.0	MILLIGRAMMES PER MILLILITRE	GSL
PL 42831/0003	28/09/2016	WARREN GENERICS SRO	ALLOPURINOL 100 MG TABLETS	ALLOPURINOL	100	MILLIGRAMMES	POM
PL 42831/0004	28/09/2016	WARREN GENERICS SRO	ALLOPURINOL 300 MG TABLETS	ALLOPURINOL	300.0	MILLIGRAMMES	POM
PL 17907/0430	29/09/2016	BRISTOL LABORATORIES LIMITED	MEBEVERINE HYDROCHLORIDE 135MG COATED TABLETS	MEBEVERINE HYDROCHLORIDE	135.00	MILLIGRAMMES	POM
PL 17907/0557	29/09/2016	BRISTOL LABORATORIES LIMITED	IBICO 135MG COATED TABLETS	MEBEVERINE HYDROCHLORIDE	135.00	MILLIGRAMMES	P
PL 40369/0008	29/09/2016	EVER NEURO PHARMA GMBH	ATOSIBAN EVER PHARMA 6.75 MG/0.9 ML SOLUTION FOR INJECTION	ATOSIBAN ACETATE	6.75	MILLIGRAMMES	POM
PL 40369/0009	29/09/2016	EVER NEURO PHARMA GMBH	ATOSIBAN EVER PHARMA 37.5 MG/5 ML CONCENTRATE FOR SOLUTION FOR INFUSION	ATOSIBAN ACETATE	37.5	MILLIGRAMMES	POM
PL 40369/0010	29/09/2016	EVER NEURO PHARMA GMBH	ATOSIBAN EVER PHARMA 75 MG/10 ML CONCENTRATE FOR SOLUTION FOR INFUSION	ATOSIBAN ACETATE	75	MILLIGRAMMES	POM
PL 44041/0028	29/09/2016	NOUMED LIFE SCIENCES LIMITED	RANITIDINE 75MG FILM-COATED TABLETS	RANITIDINE HYDROCHLORIDE	83.700	MILLIGRAMMES	GSL
PL 44452/0001	29/09/2016	BRIDGING PHARMA LIMITED	MOC SOP 13.8G SACHET, POWDER FOR ORAL SOLUTION	MACROGOL 3350	13.125	GRAMMES	P
PL 44452/0001	29/09/2016	BRIDGING PHARMA LIMITED	MOC SOP 13.8G SACHET, POWDER FOR ORAL SOLUTION	POTASSIUM CHLORIDE	0.0466	GRAMMES	P
PL 44452/0001	29/09/2016	BRIDGING PHARMA LIMITED	MOC SOP 13.8G SACHET, POWDER FOR ORAL SOLUTION	SODIUM BICARBONATE	0.1785	GRAMMES	P
PL 44452/0001	29/09/2016	BRIDGING PHARMA LIMITED	MOC SOP 13.8G SACHET, POWDER FOR ORAL SOLUTION	SODIUM CHLORIDE	0.3507	GRAMMES	P
PL 10590/0067	30/09/2016	GALDERMA (UK) LIMITED	EPIDUO 0.3% / 2.5% GEL	ADAPALENE	3.0	MILLIGRAMMES PER GRAM	POM
PL 10590/0067	30/09/2016	GALDERMA (UK) LIMITED	EPIDUO 0.3% / 2.5% GEL	BENZOYL PEROXIDE	25.0	MILLIGRAMMES PER GRAM	POM
PL 12063/0138	30/09/2016	WRAFTON LABORATORIES LIMITED	LOPERAMIDE HYDROCHLORIDE AND SIMETICONE 2 MG / 125 MG TABLETS	LOPERAMIDE HYDROCHLORIDE	2	MILLIGRAMMES	GSL
PL 12063/0138	30/09/2016	WRAFTON LABORATORIES LIMITED	LOPERAMIDE HYDROCHLORIDE AND SIMETICONE 2 MG / 125 MG TABLETS	SIMETICONE	125	MILLIGRAMMES	GSL
PL 12063/0139	30/09/2016	WRAFTON LABORATORIES LIMITED	LOPERAMIDE HYDROCHLORIDE AND SIMETICONE 2 MG / 125 MG TABLETS	LOPERAMIDE HYDROCHLORIDE	2	MILLIGRAMMES	P
PL 12063/0139	30/09/2016	WRAFTON LABORATORIES LIMITED	LOPERAMIDE HYDROCHLORIDE AND SIMETICONE 2 MG / 125 MG TABLETS	SIMETICONE	125	MILLIGRAMMES	P
PL 20075/0452	30/09/2016	ACCORD HEALTHCARE LIMITED	GABAPENTIN ACCORD 100MG HARD CAPSULES	GABAPENTIN	100	MILLIGRAMMES	POM
PL 20075/0453	30/09/2016	ACCORD HEALTHCARE LIMITED	GABAPENTIN ACCORD 300MG HARD CAPSULES	GABAPENTIN	300	MILLIGRAMMES	POM
PL 20075/0454	30/09/2016	ACCORD HEALTHCARE LIMITED	GABAPENTIN ACCORD 400MG HARD CAPSULES	GABAPENTIN	400	MILLIGRAMMES	POM
PL 31750/0091	30/09/2016	SUN PHARMACEUTICAL INDUSTRIES EUROPE BV	VECURONIUM SUN 10 MG POWDER FOR SOLUTION FOR INJECTION/INFUSION	VECURONIUM BROMIDE	10.00	MILLIGRAMMES	POM

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PL 43801/0038	30/09/2016	SCIECURE PHARMA LIMITED	ARIPIPRAZOLE 5 MG TABLETS	ARIPIPRAZOLE	5.00	MILLIGRAMMES	POM
PL 43801/0039	30/09/2016	SCIECURE PHARMA LIMITED	ARIPIPRAZOLE 10 MG TABLETS	ARIPIPRAZOLE	10.00	MILLIGRAMMES	POM
PL 43801/0040	30/09/2016	SCIECURE PHARMA LIMITED	ARIPIPRAZOLE 15 MG TABLETS	ARIPIPRAZOLE	15.00	MILLIGRAMMES	POM
PL 43801/0041	30/09/2016	SCIECURE PHARMA LIMITED	ARIPIPRAZOLE 30 MG TABLETS	ARIPIPRAZOLE	30.00	MILLIGRAMMES	POM