

Marketing authorisations granted in March 2018

PL Number	Grant Date	MA Holder	Licensed Name(s)	Active Ingredient	Quantity	Units	Legal Status
PL 00063/0753	01/03/2018	RECKITT BENCKISER HEALTHCARE (UK) LIMITED	GAVICON DOUBLE ACTION PEPPERMINT FLAVOUR ORAL SUSPENSION	CALCIUM CARBONATE	325.00	MILLIGRAMMES PER 10 MILLILITRE	GSL
PL 00063/0753	01/03/2018	RECKITT BENCKISER HEALTHCARE (UK) LIMITED	GAVICON DOUBLE ACTION PEPPERMINT FLAVOUR ORAL SUSPENSION	SODIUM ALGINATE	500	MILLIGRAMMES PER 10 MILLILITRE	GSL
PL 00063/0753	01/03/2018	RECKITT BENCKISER HEALTHCARE (UK) LIMITED	GAVICON DOUBLE ACTION PEPPERMINT FLAVOUR ORAL SUSPENSION	SODIUM HYDROGEN CARBONATE	213.00	MILLIGRAMMES PER 10 MILLILITRE	GSL
PL 00037/0674	02/03/2018	ABBOTT LABORATORIES LIMITED	ABBOTT IBUPROFEN 400MG TABLETS	IBUPROFEN	400	MILLIGRAMMES	POM
PL 20416/0478	02/03/2018	CRESCENT PHARMA LIMITED	BICALUTAMIDE 50MG FILM-COATED TABLETS	BICALUTAMIDE	50	MILLIGRAMMES	POM
PL 20416/0479	02/03/2018	CRESCENT PHARMA LIMITED	BICALUTAMIDE 150MG FILM-COATED TABLETS	BICALUTAMIDE	150	MILLIGRAMMES	POM
PL 43801/0024	02/03/2018	SCIECURE PHARMA LIMITED	TELMISARTAN/HYDROCHLOROTHIAZIDE 40 MG/12.5 MG TABLETS	HYDROCHLOROTHIAZIDE	12.5	MILLIGRAMMES	POM
PL 43801/0024	02/03/2018	SCIECURE PHARMA LIMITED	TELMISARTAN/HYDROCHLOROTHIAZIDE 40 MG/12.5 MG TABLETS	TELMISARTAN	40	MILLIGRAMMES	POM
PL 43801/0025	02/03/2018	SCIECURE PHARMA LIMITED	TELMISARTAN HYDROCHLOROTHIAZIDE 80/12.5MG TABLETS	HYDROCHLOROTHIAZIDE	12.5	MILLIGRAMMES	POM
PL 43801/0025	02/03/2018	SCIECURE PHARMA LIMITED	TELMISARTAN HYDROCHLOROTHIAZIDE 80/12.5MG TABLETS	TELMISARTAN	80	MILLIGRAMMES	POM
PL 43801/0026	02/03/2018	SCIECURE PHARMA LIMITED	TELMISARTAN HYDROCHLOROTHIAZIDE 80/25MG TABLETS	HYDROCHLOROTHIAZIDE	25	MILLIGRAMMES	POM
PL 43801/0026	02/03/2018	SCIECURE PHARMA LIMITED	TELMISARTAN HYDROCHLOROTHIAZIDE 80/25MG TABLETS	TELMISARTAN	80	MILLIGRAMMES	POM
PL 08553/0621	05/03/2018	DR REDDY'S LABORATORIES (UK) LIMITED	ARONIX 50 MG FILM-COATED TABLETS	SILDENAFIL CITRATE	70.24	MILLIGRAMMES	POM
PL 30652/0007	05/03/2018	LABORATOIRES BIOGARAN	SITAGLIPTIN BIOGARAN 25 MG FILM-COATED TABLETS	SITAGLIPTIN TARTRATE HEMIHYDRATE	34.76	MILLIGRAMMES	POM
PL 30652/0008	05/03/2018	LABORATOIRES BIOGARAN	SITAGLIPTIN BIOGARAN 50 MG FILM-COATED TABLETS	SITAGLIPTIN TARTRATE HEMIHYDRATE	69.52	MILLIGRAMMES	POM
PL 30652/0009	05/03/2018	LABORATOIRES BIOGARAN	SITAGLIPTIN BIOGARAN 100 MG FILM-COATED TABLETS	SITAGLIPTIN TARTRATE HEMIHYDRATE	139.04	MILLIGRAMMES	POM
PL 41102/0001	05/03/2018	GH PHARMA (UK) LIMITED	METARAMINOL 10 MG/ML SOLUTION FOR INJECTION OR INFUSION	METARAMINOL TARTRATE	10.00	GRAMMES PER MILLILITRE	POM
PL 11587/0096	06/03/2018	MEDAC GESELLSCHAFT FUR KLINISCHE SPEZIALPRAPARATE MBH	ETOPOSIDE 20 MG/ML CONCENTRATE FOR SOLUTION FOR INFUSION	ETOPOSIDE	100	MILLIGRAMMES	POM
PL 11587/0096	06/03/2018	MEDAC GESELLSCHAFT FUR KLINISCHE SPEZIALPRAPARATE MBH	ETOPOSIDE 20 MG/ML CONCENTRATE FOR SOLUTION FOR INFUSION	ETOPOSIDE	1000	MILLIGRAMMES	POM
PL 11587/0096	06/03/2018	MEDAC GESELLSCHAFT FUR KLINISCHE SPEZIALPRAPARATE MBH	ETOPOSIDE 20 MG/ML CONCENTRATE FOR SOLUTION FOR INFUSION	ETOPOSIDE	500	MILLIGRAMMES	POM
PL 25258/0263	06/03/2018	GLENMARK PHARMACEUTICALS EUROPE LIMITED	NORTRIPTYLINE 10 MG FILM-COATED TABLETS	NORTRIPTYLINE HYDROCHLORIDE	11.380	MILLIGRAMMES	POM
PL 25258/0264	06/03/2018	GLENMARK PHARMACEUTICALS EUROPE LIMITED	NORTRIPTYLINE 25MG FILM-COATED TABLETS	NORTRIPTYLINE HYDROCHLORIDE	28.450	MILLIGRAMMES	POM
PL 25258/0265	06/03/2018	GLENMARK PHARMACEUTICALS EUROPE LIMITED	NORTRIPTYLINE 50MG FILM-COATED TABLETS	NORTRIPTYLINE HYDROCHLORIDE	56.900	MILLIGRAMMES	POM
PL 43461/0047	06/03/2018	FLAMINGO PHARMA (UK) LIMITED	ALLOPURINOL 100MG TABLETS	ALLOPURINOL	100	MILLIGRAMMES	POM
PL 43461/0048	06/03/2018	FLAMINGO PHARMA (UK) LIMITED	ALLOPURINOL 300MG TABLETS	ALLOPURINOL	300	MILLIGRAMMES	POM
PL 30652/0010	07/03/2018	LABORATOIRES BIOGARAN	SITAGLIPTIN 25 MG FILM-COATED TABLETS	SITAGLIPTIN TARTRATE HEMIHYDRATE	34.76	MILLIGRAMMES	POM
PL 30652/0011	07/03/2018	LABORATOIRES BIOGARAN	SITAGLIPTIN 50 MG FILM-COATED TABLETS	SITAGLIPTIN TARTRATE HEMIHYDRATE	69.52	MILLIGRAMMES	POM
PL 30652/0012	07/03/2018	LABORATOIRES BIOGARAN	SITAGLIPTIN 100 MG FILM-COATED TABLETS	SITAGLIPTIN TARTRATE HEMIHYDRATE	139.04	MILLIGRAMMES	POM
PL 41344/0036	07/03/2018	COLONIS PHARMA LIMITED	NORTRIPTYLINE 10 MG HARD CAPSULES	NORTRIPTYLINE HYDROCHLORIDE	11.38	MILLIGRAMMES	POM
PL 41344/0037	07/03/2018	COLONIS PHARMA LIMITED	NORTRIPTYLINE 25 MG HARD CAPSULES	NORTRIPTYLINE HYDROCHLORIDE	28.46	MILLIGRAMMES	POM
PL 00289/2154	08/03/2018	TEVA UK LIMITED	GABAPENTIN TEVA 50 MG/ML ORAL SOLUTION	GABAPENTIN	50.00	MILLIGRAMMES PER MILLILITRE	POM

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PL 37222/0037	08/03/2018	HETERO EUROPE SL	ERLOTINIB AMAROX 25 MG FILM-COATED TABLETS	ERLOTINIB HYDROCHLORIDE	27.317	MILLIGRAMMES	POM
PL 37222/0038	08/03/2018	HETERO EUROPE SL	ERLOTINIB AMAROX 100 MG FILM-COATED TABLETS	ERLOTINIB HYDROCHLORIDE	109.27	MILLIGRAMMES	POM
PL 37222/0039	08/03/2018	HETERO EUROPE SL	ERLOTINIB AMAROX 150 MG FILM-COATED TABLETS	ERLOTINIB HYDROCHLORIDE	163.900	MILLIGRAMMES	POM
PL 20491/0003	09/03/2018	TOR GENERICS LIMITED	PYRIDOXINE 10MG TABLETS	PYRIDOXINE HYDROCHLORIDE	10.00	MILLIGRAMMES	POM
PL 00289/2165	12/03/2018	TEVA UK LIMITED	PRASUGREL TEVA 5 MG FILM-COATED TABLETS	PRASUGREL HYDROBROMIDE	6.085	MILLIGRAMMES	POM
PL 00289/2166	12/03/2018	TEVA UK LIMITED	PRASUGREL TEVA 10 MG FILM-COATED TABLETS	PRASUGREL HYDROBROMIDE	12.170	MILLIGRAMMES	POM
PL 16363/0499	12/03/2018	MILPHARM LIMITED	ERTAPENEM MILPHARM 1 G POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION	ERTAPENEM SODIUM	1213.36	MILLIGRAMMES	POM
PL 03194/0127	13/03/2018	FERRING PHARMACEUTICALS LIMITED	TESTAVAN 20 MG/G TRANSDERMAL GEL	TESTOSTERONE	1.71	GRAMMES	POM
PL 00289/2189	14/03/2018	TEVA UK LIMITED	ERLOTINIB 25 MG FILM-COATED TABLETS	ERLOTINIB HYDROCHLORIDE	27.32	MILLIGRAMMES	POM
PL 00289/2190	14/03/2018	TEVA UK LIMITED	ERLOTINIB 100 MG FILM-COATED TABLETS	ERLOTINIB HYDROCHLORIDE	109.28	MILLIGRAMMES	POM
PL 00289/2191	14/03/2018	TEVA UK LIMITED	ERLOTINIB 150 MG FILM-COATED TABLETS	ERLOTINIB HYDROCHLORIDE	163.93	MILLIGRAMMES	POM
PL 25298/0128	14/03/2018	BROWN & BURK UK LIMITED	NEFOPAM HYDROCHLORIDE 30 MG FILM-COATED TABLETS	NEFOPAM HYDROCHLORIDE	30	MILLIGRAMMES	POM
PL 04416/1499	15/03/2018	SANDOZ LIMITED	SOLIFENACIN SUCCINATE SANDOZ 5 MG FILM-COATED TABLETS	SOLIFENACIN SUCCINATE	5.00	MILLIGRAMMES	POM
PL 04416/1500	15/03/2018	SANDOZ LIMITED	SOLIFENACIN SUCCINATE SANDOZ 10 MG FILM-COATED TABLETS	SOLIFENACIN SUCCINATE	10.00	MILLIGRAMMES	POM
PL 35533/0119	15/03/2018	ASPIRE PHARMA LIMITED	LACOSAMIDE ASPIRE 50 MG FILM-COATED TABLETS	LACOSAMIDE	50.00	MILLIGRAMMES	POM
PL 35533/0120	15/03/2018	ASPIRE PHARMA LIMITED	LACOSAMIDE ASPIRE 100 MG FILM-COATED TABLETS	LACOSAMIDE	100.00	MILLIGRAMMES	POM
PL 35533/0121	15/03/2018	ASPIRE PHARMA LIMITED	LACOSAMIDE ASPIRE 150 MG FILM-COATED TABLETS	LACOSAMIDE	150.00	MILLIGRAMMES	POM
PL 35533/0122	15/03/2018	ASPIRE PHARMA LIMITED	LACOSAMIDE ASPIRE 200 MG FILM-COATED TABLETS	LACOSAMIDE	200.00	NANOGRAMMES	POM
PL 42714/0001	15/03/2018	BESINS HEALTHCARE (UK) LIMITED	ESTRIOL BESINS 0.03 MG PESSARY	ESTRIOL	0.03	MILLIGRAMMES	POM
PL 46476/0002	15/03/2018	PHARMACEUTICAL DEVELOPMENT AND SERVICES SRL	NITISINONE 5 MG HARD CAPSULES	NITISINONE	5	MILLIGRAMMES	POM
PL 46476/0003	15/03/2018	PHARMACEUTICAL DEVELOPMENT AND SERVICES SRL	NITISINONE 10 MG HARD CAPSULES	NITISINONE	10	MILLIGRAMMES	POM
PL 16239/0048	16/03/2018	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S A	SKUDEXA 75 MG/25 MG GRANULES FOR ORAL SOLUTION IN SACHET	DEKXETOPROFEN TROMETAMOL	25	MILLIGRAMMES	POM
PL 16239/0048	16/03/2018	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S A	SKUDEXA 75 MG/25 MG GRANULES FOR ORAL SOLUTION IN SACHET	TRAMADOL HYDROCHLORIDE	75	MILLIGRAMMES	POM
PL 39307/0085	16/03/2018	SYRI LIMITED	ALIMEMAZINE TARTRATE 7.5MG/5ML SYRUP	ALIMEMAZINE TARTRATE	7.50	MILLIGRAMMES	POM
PL 39307/0086	16/03/2018	SYRI LIMITED	ALIMEMAZINE TARTRATE 30MG/5ML SYRUP	ALIMEMAZINE TARTRATE	30.00	MILLIGRAMMES	POM
PL 44041/0040	19/03/2018	NOUMED LIFE SCIENCES LIMITED	MEBEVERINE HYDROCHLORIDE 135MG FILM-COATED TABLETS	MEBEVERINE HYDROCHLORIDE	135	MILLIGRAMMES	POM
PL 44041/0054	19/03/2018	NOUMED LIFE SCIENCES LIMITED	NOUMED IBS RELIEF 135MG FILM-COATED TABLETS	MEBEVERINE HYDROCHLORIDE	135	MILLIGRAMMES	P
PL 08215/0107	20/03/2018	KENT PHARMACEUTICALS LIMITED	ANAGRELIDE 0.5MG HARD CAPSULES	ANAGRELIDE HYDROCHLORIDE MONOHYDRATE	0.61	MILLIGRAMMES	POM
PL 29831/0673	20/03/2018	WOCKHARDT UK LIMITED	PREGABALIN WOCKHARDT 20MG/ML ORAL SOLUTION	PREGABALIN	20.00	MILLIGRAMMES PER MILLILITRE	POM
PL 15413/0065	21/03/2018	HIKMA FARMACEUTICA (PORTUGAL) SA	IRINOTECAN 20MG/ML CONCENTRATE FOR SOLUTION FOR INFUSION	IRINOTECAN HYDROCHLORIDE TRIHYDRATE	20	MILLIGRAMMES	POM
PL 39280/0006	21/03/2018	SYNCHRONY PHARMA LIMITED	MAGNESIUM SULFATE 10% W/V SOLUTION FOR INFUSION	MAGNESIUM SULFATE HEPTAHYDRATE	1	GRAMMES	POM

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PL 39280/0007	21/03/2018	SYNCHRONY PHARMA LIMITED	MAGNESIUM SULFATE 20% W/V SOLUTION FOR INFUSION	MAGNESIUM SULFATE HEPTAHYDRATE	2	GRAMMES	POM
PL 36722/0109	22/03/2018	SPECIAL CONCEPT DEVELOPMENT (UK) LIMITED	METFORMIN 500 MG FILM-COATED TABLET	METFORMIN HYDROCHLORIDE	500.000	MILLIGRAMMES	POM
PL 36722/0110	22/03/2018	SPECIAL CONCEPT DEVELOPMENT (UK) LIMITED	METFORMIN 850 MG FILM-COATED TABLET	METFORMIN HYDROCHLORIDE	850.000	MILLIGRAMMES	POM
PL 36722/0111	22/03/2018	SPECIAL CONCEPT DEVELOPMENT (UK) LIMITED	METFORMIN 1000 MG FILM-COATED TABLET	METFORMIN HYDROCHLORIDE	1000.000	MILLIGRAMMES	POM
PL 41344/0039	22/03/2018	COLONIS PHARMA LIMITED	HYDROCORTISONE 10MG SOLUBLE TABLETS	HYDROCORTISONE SODIUM PHOSPHATE	13.42	MILLIGRAMMES	POM
PL 41344/0040	22/03/2018	COLONIS PHARMA LIMITED	HYDROCORTISONE 20MG SOLUBLE TABLETS	HYDROCORTISONE SODIUM PHOSPHATE	26.84	MILLIGRAMMES	POM
PL 43461/0049	22/03/2018	FLAMINGO PHARMA (UK) LIMITED	BETAHISTINE DIHYDROCHLORIDE 8MG TABLETS	BETAHISTINE DIHYDROCHLORIDE	8	MILLIGRAMMES	POM
PL 43461/0050	22/03/2018	FLAMINGO PHARMA (UK) LIMITED	BETAHISTINE DIHYDROCHLORIDE 16MG TABLETS	BETAHISTINE DIHYDROCHLORIDE	16	MILLIGRAMMES	POM
PL 00240/0411	23/03/2018	THORNTON & ROSS LIMITED	THORNTON & ROSS DRY COUGH 1.36G/5ML ORAL SOLUTION	GLYCEROL	1.36	GRAMMES PER 5 MILLILITRES	GSL
PL 20075/0667	23/03/2018	ACCORD HEALTHCARE LIMITED	PARACETAMOL 1000 MG SOLUBLE TABLETS	PARACETAMOL	1000	MILLIGRAMMES	P
PL 20154/0041	23/03/2018	IVOWEN LIMITED	ARIPIRAZOLE TABLETS 5 MG	ARIPIRAZOLE	5	MILLIGRAMMES	POM
PL 20154/0042	23/03/2018	IVOWEN LIMITED	ARIPIRAZOLE TABLETS 10 MG	ARIPIRAZOLE	10	MILLIGRAMMES	POM
PL 20154/0043	23/03/2018	IVOWEN LIMITED	ARIPIRAZOLE TABLETS 15 MG	ARIPIRAZOLE	15	MILLIGRAMMES	POM
PL 20154/0044	23/03/2018	IVOWEN LIMITED	ARIPIRAZOLE TABLETS 30 MG	ARIPIRAZOLE	30	MILLIGRAMMES	POM
PL 41222/0004	23/03/2018	ROTOP PHARMAKA AG	TETROFOSMIN ROTOP 0.23 MG KIT FOR RADIOPHARMACEUTICAL PREPARATION	TETROFOSMIN	0.340	MILLIGRAMMES	POM
PL 44710/0024	26/03/2018	KINEDEXE UK LIMITED	MEBEVERINE HYDROCHLORIDE 50MG/5ML ORAL SUSPENSION	MEBEVERINE HYDROCHLORIDE	50.00	MILLIGRAMMES	POM
PL 20395/0250	27/03/2018	RELONCHEM LIMITED	RANITIDINE 75MG FILM-COATED TABLETS	RANITIDINE HYDROCHLORIDE	84	MILLIGRAMMES	P
PL 20416/0547	27/03/2018	CRESCENT PHARMA LIMITED	MONTELUKAST 10 MG FILM-COATED TABLETS	MONTELUKAST SODIUM	10.40	MILLIGRAMMES	POM
PL 35646/0065	27/03/2018	ALKEM PHARMA GMBH	EZETIMIBE 10 MG TABLETS	EZETIMIBE	10.000	MILLIGRAMMES	POM
PL 00063/0755	28/03/2018	RECKITT BENCKISER HEALTHCARE (UK) LIMITED	GAVICON DOUBLE ACTION PEPPERMINT FLAVOUR CHEWABLE TABLETS	CALCIUM CARBONATE	187.50	TABLETS	GSL
PL 00063/0755	28/03/2018	RECKITT BENCKISER HEALTHCARE (UK) LIMITED	GAVICON DOUBLE ACTION PEPPERMINT FLAVOUR CHEWABLE TABLETS	SODIUM ALGINATE	250.00	MILLIGRAMMES	GSL
PL 00063/0755	28/03/2018	RECKITT BENCKISER HEALTHCARE (UK) LIMITED	GAVICON DOUBLE ACTION PEPPERMINT FLAVOUR CHEWABLE TABLETS	SODIUM HYDROGEN CARBONATE	106.5	MILLILITRES	GSL
PL 00289/2169	28/03/2018	TEVA UK LIMITED	URSODEOXYCHOLIC ACID 300 MG TABLETS	URSODEOXYCHOLIC ACID	300	MILLIGRAMMES	POM
PL 00289/2170	28/03/2018	TEVA UK LIMITED	URSODEOXYCHOLIC ACID 500MG TABLETS	URSODEOXYCHOLIC ACID	500	MILLIGRAMMES	POM
PL 14048/0256	28/03/2018	SYNTHON BV	BORTEZOMIB 1 MG POWDER FOR SOLUTION FOR INJECTION	BORTEZOMIB	1.00	MILLIGRAMMES	POM
PL 14048/0257	28/03/2018	SYNTHON BV	BORTEZOMIB 3.5 MG POWDER FOR SOLUTION FOR INJECTION	BORTEZOMIB	3.50	MILLIGRAMMES	POM
PL 22389/0003	29/03/2018	CALLISTO REGULATORY CONSULTING LIMITED	ASPIRIN 75 MG TABLETS	ACETYLSALICYLIC ACID	75.00	MILLIGRAMMES	POM
PL 28176/0177	29/03/2018	STRIDES ARCOLAB INTERNATIONAL LIMITED	IBUPROFEN LYSINE 342 MG FILM-COATED TABLETS	IBUPROFEN LYSINE	342.00	MILLIGRAMMES	POM
PL 28176/0178	29/03/2018	STRIDES ARCOLAB INTERNATIONAL LIMITED	IBUPROFEN LYSINE 684 MG FILM-COATED TABLETS	IBUPROFEN LYSINE	684.00	MILLIGRAMMES	POM
PL 39352/0386	29/03/2018	KOSEI PHARMA UK LIMITED	TADALAFIL KOSEI 2.5 MG FILM-COATED TABLETS	TADALAFIL	2.50	MILLIGRAMMES	POM
PL 39352/0387	29/03/2018	KOSEI PHARMA UK LIMITED	TADALAFIL KOSEI 5 MG FILM-COATED TABLETS	TADALAFIL	5.00	MILLIGRAMMES	POM

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PL 39352/0388	29/03/2018	KOSEI PHARMA UK LIMITED	TADALAFIL KOSEI 10 MG FILM-COATED TABLETS	TADALAFIL	10.00	MILLIGRAMMES	POM
PL 39352/0389	29/03/2018	KOSEI PHARMA UK LIMITED	TADALAFIL KOSEI 20 MG FILM-COATED TABLETS	TADALAFIL	20.00	MILLIGRAMMES	POM
PL 43801/0007	29/03/2018	SCIECURE PHARMA LIMITED	IRBESARTAN 75MG FILM COATED TABLETS	IRBESARTAN	75	MILLIGRAMMES	POM
PL 43801/0008	29/03/2018	SCIECURE PHARMA LIMITED	IRBESARTAN 150MG FILM COATED TABLETS	IRBESARTAN	150	MILLIGRAMMES	POM
PL 43801/0009	29/03/2018	SCIECURE PHARMA LIMITED	IRBESARTAN 300MG FILM COATED TABLETS	IRBESARTAN	300	MILLIGRAMMES	POM