

Marketing authorisations granted in August 2018

PL Number	Grant Date	MA Holder	Licensed Name(s)	Active Ingredient	Quantity	Units	Legal Status
PL 00289/2162	01/08/2018	TEVA UK LIMITED	DICYCLOVERINE HYDROCHLORIDE 10MG TABLETS	DICYCLOVERINE HYDROCHLORIDE	10.00	MILLIGRAMMES	POM
PL 00289/2163	01/08/2018	TEVA UK LIMITED	DICYCLOVERINE HYDROCHLORIDE 20MG TABLETS	DICYCLOVERINE HYDROCHLORIDE	20.00	MILLIGRAMMES	POM
PL 34771/0243	02/08/2018	MACLEODS PHARMA UK LIMITED	IVABRADINE 5MG FILM-COATED TABLETS	IVABRADINE OXALATE	5.96	MILLIGRAMMES	POM
PL 34771/0244	02/08/2018	MACLEODS PHARMA UK LIMITED	IVABRADINE 7.5. MG FILM-COATED TABLETS	IVABRADINE OXALATE	8.94	MILLIGRAMMES	POM
PL 00289/2182	03/08/2018	TEVA UK LIMITED	LENALIDOMIDE 2.5 MG HARD CAPSULES	LENALIDOMIDE HYDROCHLORIDE HYDRATE	3.025	MILLIGRAMMES	POM
PL 00289/2183	03/08/2018	TEVA UK LIMITED	LENALIDOMIDE 5 MG HARD CAPSULES	LENALIDOMIDE HYDROCHLORIDE HYDRATE	6.050	MILLIGRAMMES	POM
PL 00289/2184	03/08/2018	TEVA UK LIMITED	LENALIDOMIDE 7.5 MG HARD CAPSULES	LENALIDOMIDE HYDROCHLORIDE HYDRATE	9.075	MILLIGRAMMES	POM
PL 00289/2185	03/08/2018	TEVA UK LIMITED	LENALIDOMIDE 10 MG HARD CAPSULES	LENALIDOMIDE HYDROCHLORIDE HYDRATE	12.100	MILLIGRAMMES	POM
PL 00289/2186	03/08/2018	TEVA UK LIMITED	LENALIDOMIDE 15 MG HARD CAPSULES	LENALIDOMIDE HYDROCHLORIDE HYDRATE	18.150	MILLIGRAMMES	POM
PL 00289/2187	03/08/2018	TEVA UK LIMITED	LENALIDOMIDE 20 MG HARD CAPSULES	LENALIDOMIDE HYDROCHLORIDE HYDRATE	24.200	MILLIGRAMMES	POM
PL 00289/2188	03/08/2018	TEVA UK LIMITED	LENALIDOMIDE 25 MG HARD CAPSULES	LENALIDOMIDE HYDROCHLORIDE HYDRATE	30.250	MILLIGRAMMES	POM
PL 04509/0062	03/08/2018	ECOLAB LIMITED	PREVASE CHLORHEXIDINE GLUCONATE 0.5% W/V IN 70% V/V DEB CUTANEOUS SOLUTION	CHLORHEXIDINE GLUCONATE	2.5	PERCENT VOLUME IN VOLUME	GSL
PL 04509/0063	03/08/2018	ECOLAB LIMITED	PREVASE STAIN CHLORHEXIDINE GLUCONATE 0.5% W/V IN 70% V/V DEB CUTANEOUS SOLUTION	CHLORHEXIDINE GLUCONATE	2.5	PERCENT VOLUME IN VOLUME	GSL
PL 20416/0548	06/08/2018	CRESCENT PHARMA LIMITED	AZITHROMYCIN 250 MG CAPSULES	AZITHROMYCIN DIHYDRATE	262.02	MILLIGRAMMES	POM
PL 41094/0013	07/08/2018	ESSENTIAL PHARMACEUTICALS LIMITED	AMLODIPINE 1 MG/ML ORAL SUSPENSION	AMLODIPINE BESILATE	1.386	MILLIGRAMMES PER MILLILITRE	POM
PL 16363/0527	08/08/2018	MILPHARM LIMITED	RIVAROXABAN MILPHARM 10 MG FILM-COATED TABLETS	RIVAROXABAN	10.00	MILLIGRAMMES	POM
PL 16363/0528	08/08/2018	MILPHARM LIMITED	RIVAROXABAN MILPHARM 15 MG FILM-COATED TABLETS	RIVAROXABAN	15.00	MILLIGRAMMES	POM
PL 16363/0529	08/08/2018	MILPHARM LIMITED	RIVAROXABAN MILPHARM 20 MG FILM-COATED TABLETS	RIVAROXABAN	20.00	MILLIGRAMMES	POM
PL 16363/0533	08/08/2018	MILPHARM LIMITED	RIVAROXABAN MILPHARM 15 MG FILM-COATED TABLETS / RIVAROXABAN MILPHARM 20 MG FILM-COATED	RIVAROXABAN	15.00	MILLIGRAMMES	POM
PL 16363/0533	08/08/2018	MILPHARM LIMITED	RIVAROXABAN MILPHARM 15 MG FILM-COATED TABLETS / RIVAROXABAN MILPHARM 20 MG FILM-COATED	RIVAROXABAN	20.00	MILLIGRAMMES	POM
PL 17277/0378	08/08/2018	PHARMATHEN SA	PRAFSIA 5 MG FILM-COATED TABLETS	PRASUGREL BESILATE	7.120	MILLIGRAMMES	POM
PL 17277/0379	08/08/2018	PHARMATHEN SA	PRAFSIA 10 MG FILM-COATED TABLETS	PRASUGREL BESILATE	14.240	MILLIGRAMMES	POM
PL 36687/0387	08/08/2018	TORRENT PHARMA (UK) LIMITED	PRASUGREL TORRENT 5 MG FILM-COATED TABLETS	PRASUGREL BESILATE	7.12	MILLIGRAMMES	POM
PL 36687/0388	08/08/2018	TORRENT PHARMA (UK) LIMITED	PRASUGREL TORRENT 10 MG FILM-COATED TABLETS	PRASUGREL BESILATE	14.24	MILLIGRAMMES	POM
PL 40546/0047	08/08/2018	ARISTO PHARMA GMBH	PRASUGREL ARISTO 5 MG FILM-COATED TABLETS	PRASUGREL BESILATE	7.120	MILLIGRAMMES	POM
PL 40546/0048	08/08/2018	ARISTO PHARMA GMBH	PRASUGREL ARISTO 10 MG FILM-COATED TABLETS	PRASUGREL BESILATE	14.240	MILLIGRAMMES	POM
PL 48035/0012	08/08/2018	NEURAXPHARM ARZNEIMITTEL GMBH	ARIPIPIRAZOLE NEURAXPHARM 10 MG ORODISPERSIBLE TABLETS	ARIPIPIRAZOLE	10	MILLIGRAMMES	POM
PL 48035/0013	08/08/2018	NEURAXPHARM ARZNEIMITTEL GMBH	ARIPIPIRAZOLE NEURAXPHARM 15 MG ORODISPERSIBLE TABLETS	ARIPIPIRAZOLE	15	MILLIGRAMMES	POM
PL 48035/0014	08/08/2018	NEURAXPHARM ARZNEIMITTEL GMBH	ARIPIPIRAZOLE NEURAXPHARM 30 MG ORODISPERSIBLE TABLETS	ARIPIPIRAZOLE	30	MILLIGRAMMES	POM
PL 49445/0004	08/08/2018	AMAROX LIMITED	ENTECAVIR AMAROX 0.5 MG FILM-COATED TABLETS	ENTECAVIR MONOHYDRATE	0.5	MILLIGRAMMES	POM
PL 49445/0005	08/08/2018	AMAROX LIMITED	ENTECAVIR AMAROX 1 MG FILM-COATED TABLETS	ENTECAVIR MONOHYDRATE	1.00	MILLIGRAMMES	POM

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PL 20416/0513	09/08/2018	CRESCENT PHARMA LIMITED	DUTASTERIDE 0.5MG SOFT CAPSULES	DUTASTERIDE	0.500	MILLIGRAMMES	POM
PL 19907/0016	10/08/2018	BIOORGANICS BV	GEFITINIB 250 MG FILM-COATED TABLETS	GEFITINIB	250.00	MILLIGRAMMES	POM
PL 39307/0082	10/08/2018	SYRI LIMITED	CLONIDINE HYDROCHLORIDE 50MICROGRAMS/5ML ORAL SOLUTION	CLONIDINE HYDROCHLORIDE	0.05	MILLIGRAMMES	POM
PL 20416/0456	13/08/2018	CRESCENT PHARMA LIMITED	ROSUVASTATIN 5MG FILM-COATED TABLETS	ROSUVASTATIN CALCIUM	5.198	MILLIGRAMMES	POM
PL 20416/0457	13/08/2018	CRESCENT PHARMA LIMITED	ROSUVASTATIN 10MG FILM-COATED TABLETS	ROSUVASTATIN CALCIUM	10.395	MILLIGRAMMES	POM
PL 20416/0458	13/08/2018	CRESCENT PHARMA LIMITED	ROSUVASTATIN 20MG FILM-COATED TABLETS	ROSUVASTATIN CALCIUM	20.790	MILLIGRAMMES	POM
PL 20416/0459	13/08/2018	CRESCENT PHARMA LIMITED	ROSUVASTATIN 40MG FILM-COATED TABLETS	ROSUVASTATIN CALCIUM	41.580	MILLIGRAMMES	POM
PL 35104/0022	14/08/2018	PHOENIX LABS	BENZYDAMINE 0.15% W/V OROMUCOSAL SPRAY	BENZYDAMINE HYDROCHLORIDE	1.5	MILLIGRAMMES	P
PL 17780/0783	15/08/2018	ZENTIVA PHARMA UK LIMITED	FEBUXOSTAT 80MG FILM-COATED TABLETS	FEBUXOSTAT	80	MILLIGRAMMES	POM
PL 17780/0784	15/08/2018	ZENTIVA PHARMA UK LIMITED	FEBUXOSTAT 120 MG FILM-COATED TABLETS	FEBUXOSTAT	120	MILLIGRAMMES	POM
PL 40546/0044	15/08/2018	ARISTO PHARMA GMBH	ETHOSUXIMIDE ARISTO 250 MG SOFT CAPSULES	ETHOSUXIMIDE	250	MILLIGRAMMES	POM
PL 04416/1534	16/08/2018	SANDOZ LIMITED	GEFITINIB SANDOZ 250 MG FILM-COATED TABLETS	GEFITINIB	250	MILLIGRAMMES	POM
PL 35533/0086	16/08/2018	ASPIRE PHARMA LIMITED	DORZOLAMIDE/TIMOLOL 20 MG/ML + 5 MG/ML EYE DROPS, SOLUTION IN SINGLE DOSE CONTAINER	DORZOLAMIDE HYDROCHLORIDE	22.26	MILLIGRAMMES PER MILLILITRE	POM
PL 35533/0086	16/08/2018	ASPIRE PHARMA LIMITED	DORZOLAMIDE/TIMOLOL 20 MG/ML + 5 MG/ML EYE DROPS, SOLUTION IN SINGLE DOSE CONTAINER	TIMOLOL MALEATE	6.83	MILLIGRAMMES PER MILLILITRE	POM
PL 40546/0049	16/08/2018	ARISTO PHARMA GMBH	AGOMELATINE ARISTO 25 MG FILM-COATED TABLETS	AGOMELATINE / CITRIC ACID CO-CRYSTAL	44.739	MILLIGRAMMES	POM
PL 20094/0005	17/08/2018	DR KADE, PHARMAZEUTISCHE FABRIK GMBH	METHOCARBAMOL 750 MG TABLET	METHOCARBAMOL	750	MILLIGRAMMES	POM
PL 40546/0045	17/08/2018	ARISTO PHARMA GMBH	ETHOSUXIMIDE ARISTO 250 MG SOFT CAPSULES	ETHOSUXIMIDE	250	MILLIGRAMMES	POM
PL 20416/0492	20/08/2018	CRESCENT PHARMA LIMITED	OLANZAPINE 2.5MG FILM-COATED TABLETS	OLANZAPINE	2.500	MILLIGRAMMES	POM
PL 20416/0493	20/08/2018	CRESCENT PHARMA LIMITED	OLANZAPINE 5MG FILM-COATED TABLETS	OLANZAPINE	5.000	MILLIGRAMMES	POM
PL 20416/0494	20/08/2018	CRESCENT PHARMA LIMITED	OLANZAPINE 7.5MG FILM-COATED TABLETS	OLANZAPINE	7.500	MILLIGRAMMES	POM
PL 20416/0495	20/08/2018	CRESCENT PHARMA LIMITED	OLANZAPINE 10MG FILM-COATED TABLETS	OLANZAPINE	10.000	MILLIGRAMMES	POM
PL 20416/0496	20/08/2018	CRESCENT PHARMA LIMITED	OLANZAPINE 15MG FILM-COATED TABLETS	OLANZAPINE	15.000	MILLIGRAMMES	POM
PL 20416/0497	20/08/2018	CRESCENT PHARMA LIMITED	OLANZAPINE 20MG FILM-COATED TABLETS	OLANZAPINE	20.000	MILLIGRAMMES	POM
PL 20416/0551	20/08/2018	CRESCENT PHARMA LIMITED	ZOPICLONE 7.5 MG FILM-COATED TABLETS	ZOPICLONE	7.500	MILLIGRAMMES	POM
PL 20075/1241	21/08/2018	ACCORD HEALTHCARE LIMITED	AGOMELATINE ACCORD 25 MG FILM-COATED TABLETS	AGOMELATINE / CITRIC ACID CO-CRYSTAL	44.739	MILLIGRAMMES	POM
PL 39280/0013	21/08/2018	SYNCHRONY PHARMA LIMITED	BORTEZOMIB 3.5 MG POWDER FOR SOLUTION FOR INJECTION	BORTEZOMIB	3.5	MILLIGRAMMES	POM
PL 43801/0001	21/08/2018	SCIECURE PHARMA LIMITED	ONDANSETRON 2 MG/ML SOLUTION FOR INJECTION	ONDANSETRON HYDROCHLORIDE DIHYDRATE	2.494	MILLIGRAMMES PER MILLILITRE	POM
PL 48035/0015	21/08/2018	NEURAXPHARM ARZNEIMITTEL GMBH	AGOMELATINE NEURAXPHARM 25 MG FILM-COATED TABLETS	AGOMELATINE / CITRIC ACID CO-CRYSTAL	44.739	MILLIGRAMMES	POM
PL 30652/0013	23/08/2018	LABORATOIRES BIOGARAN	AGOMELATINE BIOGARAN 25 MG FILM-COATED TABLETS	AGOMELATINE	25.00	MILLIGRAMMES	POM
PL 48035/0004	23/08/2018	NEURAXPHARM ARZNEIMITTEL GMBH	ATOMOXETINE NEURAXPHARM 10 MG HARD CAPSULES	ATOMOXETINE HYDROCHLORIDE	11.4278	MILLIGRAMMES	POM
PL 48035/0005	23/08/2018	NEURAXPHARM ARZNEIMITTEL GMBH	ATOMOXETINE NEURAXPHARM 18 MG HARD CAPSULES	ATOMOXETINE HYDROCHLORIDE	20.5700	MILLIGRAMMES	POM

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PL 48035/0006	23/08/2018	NEURAXPHARM ARZNEIMITTEL GMBH	ATOMOXETINE NEURAXPHARM 25 MG HARD CAPSULES	ATOMOXETINE HYDROCHLORIDE	28.5695	MILLIGRAMMES	POM
PL 48035/0007	23/08/2018	NEURAXPHARM ARZNEIMITTEL GMBH	ATOMOXETINE NEURAXPHARM 40 MG HARD CAPSULES	ATOMOXETINE HYDROCHLORIDE	45.711	MILLIGRAMMES	POM
PL 48035/0008	23/08/2018	NEURAXPHARM ARZNEIMITTEL GMBH	ATOMOXETINE NEURAXPHARM 60 MG HARD CAPSULES	ATOMOXETINE HYDROCHLORIDE	68.5667	MILLIGRAMMES	POM
PL 48035/0009	23/08/2018	NEURAXPHARM ARZNEIMITTEL GMBH	ATOMOXETINE NEURAXPHARM 80 MG HARD CAPSULES	ATOMOXETINE HYDROCHLORIDE	91.4223	MILLIGRAMMES	POM
PL 48035/0010	23/08/2018	NEURAXPHARM ARZNEIMITTEL GMBH	ATOMOXETINE NEURAXPHARM 100 MG HARD CAPSULES	ATOMOXETINE HYDROCHLORIDE	114.2779	MILLIGRAMMES	POM
PL 15413/0068	24/08/2018	HIKMA FARMACEUTICA (PORTUGAL) SA	CARBOPLATIN 10 MG/ML SOLUTION FOR INFUSION	CARBOPLATIN	10	MILLIGRAMMES PER MILLILITRE	POM
PL 16363/0522	24/08/2018	MILPHARM LIMITED	IBUPROFEN 200 MG FILM-COATED TABLETS	IBUPROFEN	200	MILLIGRAMMES	POM
PL 16363/0523	24/08/2018	MILPHARM LIMITED	IBUPROFEN 400 MG FILM-COATED TABLETS	IBUPROFEN	400.00	MILLIGRAMMES	POM
PL 16363/0524	24/08/2018	MILPHARM LIMITED	IBUPROFEN 600 MG FILM-COATED TABLETS	IBUPROFEN	600.00	MILLIGRAMMES	POM
PL 17780/0816	24/08/2018	ZENTIVA PHARMA UK LIMITED	SOLIFENACIN SUCCINATE 5MG FILM COATED TABLETS	SOLIFENACIN SUCCINATE	5.00	MILLIGRAMMES	POM
PL 17780/0817	24/08/2018	ZENTIVA PHARMA UK LIMITED	SOLIFENACIN SUCCINATE 10MG FILM COATED TABLETS	SOLIFENACIN SUCCINATE	10.00	MILLIGRAMMES	POM
PL 23022/0132	24/08/2018	PHAROS - PHARMACEUTICAL ORIENTED SERVICES LIMITED	DASATINIB PHAROS 20 MG FILM-COATED TABLETS	DASATINIB	20	MILLIGRAMMES	POM
PL 23022/0133	24/08/2018	PHAROS - PHARMACEUTICAL ORIENTED SERVICES LIMITED	DASATINIB PHAROS 50 MG FILM-COATED TABLETS	DASATINIB	50	MILLIGRAMMES	POM
PL 23022/0134	24/08/2018	PHAROS - PHARMACEUTICAL ORIENTED SERVICES LIMITED	DASATINIB PHAROS 70 MG FILM-COATED TABLETS	DASATINIB	70	MILLIGRAMMES	POM
PL 23022/0135	24/08/2018	PHAROS - PHARMACEUTICAL ORIENTED SERVICES LIMITED	DASATINIB PHAROS 80 MG FILM-COATED TABLETS	DASATINIB	80	MILLIGRAMMES	POM
PL 23022/0136	24/08/2018	PHAROS - PHARMACEUTICAL ORIENTED SERVICES LIMITED	DASATINIB PHAROS 100 MG FILM-COATED TABLETS	DASATINIB	100	MILLIGRAMMES	POM
PL 23022/0137	24/08/2018	PHAROS - PHARMACEUTICAL ORIENTED SERVICES LIMITED	DASATINIB PHAROS 140 MG FILM-COATED TABLETS	DASATINIB	140	MILLIGRAMMES	POM
PL 35501/0015	24/08/2018	HCS BVBA	PRASUGREL HCS 5 MG FILM-COATED TABLETS	PRASUGREL	5.00	MILLIGRAMMES	POM
PL 35501/0016	24/08/2018	HCS BVBA	PRASUGREL HCS 10 MG FILM-COATED TABLETS	PRASUGREL	10.00	MILLIGRAMMES	POM
PL 11311/0583	31/08/2018	TILLOMED LABORATORIES LIMITED	MOXIFLOXACIN 400MG FILM-COATED TABLETS	MOXIFLOXACIN HYDROCHLORIDE	400	MILLIGRAMMES	POM
PL 16363/0525	31/08/2018	MILPHARM LIMITED	IBUPROFEN 200 MG FILM-COATED TABLETS	IBUPROFEN	200	MILLIGRAMMES	P
PL 16363/0526	31/08/2018	MILPHARM LIMITED	IBUPROFEN 400 MG FILM-COATED TABLETS	IBUPROFEN	400	MILLIGRAMMES	P