

Marketing authorisations granted in January 2019

PL Number	Grant Date	MA Holder	Licensed Name(s)	Active Ingredient	Quantity	Units	Legal Status
PL 44041/0091	02/01/2019	NOUMED LIFE SCIENCES LIMITED	DICYCLOVERINE HYDROCHLORIDE 10MG/5ML ORAL SOLUTION	DICYCLOVERINE HYDROCHLORIDE	10	MILLIGRAMMES PER 5 MILLILITRE	POM
PL 48819/0001	02/01/2019	MCCROWLEY & HUGHES SL	PREGABALIN MCCROWLEY AND HUGHES 25MG TABLETS	PREGABALIN	25	MILLIGRAMMES	POM
PL 48819/0002	02/01/2019	MCCROWLEY & HUGHES SL	PREGABALIN MCCROWLEY AND HUGHES 50MG TABLETS	PREGABALIN	50	MILLIGRAMMES	POM
PL 48819/0003	02/01/2019	MCCROWLEY & HUGHES SL	PREGABALIN MCCROWLEY AND HUGHES 75MG TABLETS	PREGABALIN	75	MILLIGRAMMES	POM
PL 48819/0004	02/01/2019	MCCROWLEY & HUGHES SL	PREGABALIN MCCROWLEY AND HUGHES 100MG TABLETS	PREGABALIN	100	MILLIGRAMMES	POM
PL 48819/0005	02/01/2019	MCCROWLEY & HUGHES SL	PREGABALIN MCCROWLEY AND HUGHES 150MG TABLETS	PREGABALIN	150	MILLIGRAMMES	POM
PL 48819/0006	02/01/2019	MCCROWLEY & HUGHES SL	PREGABALIN MCCROWLEY AND HUGHES 200MG TABLETS	PREGABALIN	200	MILLIGRAMMES	POM
PL 48819/0007	02/01/2019	MCCROWLEY & HUGHES SL	PREGABALIN MCCROWLEY AND HUGHES 225MG TABLETS	PREGABALIN	225	MILLIGRAMMES	POM
PL 48819/0008	02/01/2019	MCCROWLEY & HUGHES SL	PREGABALIN MCCROWLEY AND HUGHES 300MG TABLETS	PREGABALIN	300	MILLIGRAMMES	POM
PL 17907/0616	03/01/2019	BRISTOL LABORATORIES LIMITED	IBUPROFEN 200 MG SOFT CAPSULES	IBUPROFEN	200.00	MILLIGRAMMES	GSL
PL 20075/1186	03/01/2019	ACCORD HEALTHCARE LIMITED	GEFITINIB ACCORD 250 MG FILM-COATED TABLETS	GEFITINIB	250	MILLIGRAMMES	POM
PL 29831/0588	03/01/2019	WOCKHARDT UK LIMITED	CO-CODAMOL 15/500MG TABLETS	CODEINE PHOSPHATE HEMIHYDRATE	15	MILLIGRAMMES	POM
PL 29831/0588	03/01/2019	WOCKHARDT UK LIMITED	CO-CODAMOL 15/500MG TABLETS	PARACETAMOL	500	MILLIGRAMMES	POM
PL 47015/0006	04/01/2019	AS KALCEKS	ROCURONIUM BROMIDE 10 MG/ML SOLUTION FOR INJECTION/INFUSION	ROCURONIUM BROMIDE	10	MILLIGRAMMES	POM
PL 00289/2159	08/01/2019	TEVA UK LIMITED	METFORMIN TEVA SR 500 MG PROLONGED-RELEASE TABLETS	METFORMIN HYDROCHLORIDE	500.00	MILLIGRAMMES	POM
PL 00289/2160	08/01/2019	TEVA UK LIMITED	METFORMIN TEVA SR 750 MG PROLONGED-RELEASE TABLETS	METFORMIN HYDROCHLORIDE	750.00	MILLIGRAMMES	POM
PL 00289/2161	08/01/2019	TEVA UK LIMITED	METFORMIN TEVA SR 1000 MG PROLONGED-RELEASE TABLETS	METFORMIN HYDROCHLORIDE	1000.00	MILLIGRAMMES	POM
PL 37090/0001	08/01/2019	AMOMED PHARMA GMBH	ARGIPRESSIN AMOMED 20 IU/ ML SOLUTION FOR INJECTION	ARGIPRESSIN	20.000	INTERNATIONAL UNITS PER ML	POM
PL 44570/0013	08/01/2019	QILU PHARMA SPAIN SL	TADALAFIL 5 MG FILM-COATED TABLETS	TADALAFIL	5	MILLIGRAMMES	POM
PL 44570/0014	08/01/2019	QILU PHARMA SPAIN SL	TADALAFIL 10 MG FILM-COATED TABLETS	TADALAFIL	10	MILLIGRAMMES	POM
PL 44570/0015	08/01/2019	QILU PHARMA SPAIN SL	TADALAFIL 20 MG FILM-COATED TABLETS	TADALAFIL	20	MILLIGRAMMES	POM
PL 44570/0018	08/01/2019	QILU PHARMA SPAIN SL	GEFITINIB 250 MG FILM-COATED TABLETS	GEFITINIB	250	MILLIGRAMMES	POM
PL 04854/0161	09/01/2019	GEDEON RICHTER PLC	SAWIS 2 MG TABLETS	DIENOGEST	2.00	MILLIGRAMMES	POM
PL 32870/0050	09/01/2019	USV EUROPE LIMITED	ROSUVASTATIN USV 5 MG FILM-COATED TABLETS	ROSUVASTATIN CALCIUM	5.208	MILLIGRAMMES	POM
PL 32870/0051	09/01/2019	USV EUROPE LIMITED	ROSUVASTATIN USV 10 MG FILM-COATED TABLETS	ROSUVASTATIN CALCIUM	10.416	MILLIGRAMMES	POM
PL 32870/0052	09/01/2019	USV EUROPE LIMITED	ROSUVASTATIN USV 20 MG FILM-COATED TABLETS	ROSUVASTATIN CALCIUM	20.832	MILLIGRAMMES	POM
PL 32870/0053	09/01/2019	USV EUROPE LIMITED	ROSUVASTATIN USV 40 MG FILM-COATED TABLETS	ROSUVASTATIN CALCIUM	41.664	MILLIGRAMMES	POM
PL 17277/0382	10/01/2019	PHARMATHEN SA	ATANTO 80MG HARD CAPSULES	APREPITANT	80.00	MILLIGRAMMES	POM
PL 17277/0383	10/01/2019	PHARMATHEN SA	ATANTO 125MG HARD CAPSULES	APREPITANT	125.00	MILLIGRAMMES	POM
PL 17277/0384	10/01/2019	PHARMATHEN SA	ATANTO 80MG/125 MG HARD CAPSULES	APREPITANT	125.00	MILLIGRAMMES	POM
PL 17277/0384	10/01/2019	PHARMATHEN SA	ATANTO 80MG/125 MG HARD CAPSULES	APREPITANT	80.00	MILLIGRAMMES	POM

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PL 21562/0028	10/01/2019	DISTRQUIIMICA S.A.	DABIGATRAN ETEXILATE 75 MG HARD CAPSULES	DABIGATRAN ETEXILATE MESILATE	86.48	MILLIGRAMMES	POM
PL 21562/0029	10/01/2019	DISTRQUIIMICA S.A.	DABIGATRAN ETEXILATE 110 MG HARD CAPSULES	DABIGATRAN ETEXILATE MESILATE	126.83	MILLIGRAMMES	POM
PL 21562/0030	10/01/2019	DISTRQUIIMICA S.A.	DABIGATRAN ETEXILATE 150 MG HARD CAPSULES	DABIGATRAN ETEXILATE MESILATE	172.95	MILLIGRAMMES	POM
PL 35646/0071	10/01/2019	ALKEM PHARMA GMBH	DEFERASIROX ALKEM 125 MG DISPERSIBLE TABLETS	DEFERASIROX	125.000	MILLIGRAMMES	POM
PL 35646/0072	10/01/2019	ALKEM PHARMA GMBH	DEFERASIROX ALKEM 250 MG DISPERSIBLE TABLETS	DEFERASIROX	250.000	MILLIGRAMMES	POM
PL 35646/0073	10/01/2019	ALKEM PHARMA GMBH	DEFERASIROX ALKEM 500 MG DISPERSIBLE TABLETS	DEFERASIROX	500.000	MILLIGRAMMES	POM
PL 06464/3099	11/01/2019	WAYMADE PLC	PRASUGREL WAYMADE 5 MG FILM-COATED TABLETS	PRASUGREL	5.000	MILLIGRAMMES	POM
PL 06464/3100	11/01/2019	WAYMADE PLC	PRASUGREL WAYMADE 10 MG FILM-COATED TABLETS	PRASUGREL	10.00	MILLIGRAMMES	POM
PL 17780/0822	11/01/2019	ZENTIVA PHARMA UK LIMITED	APREPITANT ZENTIVA 80MG HARD CAPSULES	APREPITANT	80.00	MILLIGRAMMES	POM
PL 17780/0823	11/01/2019	ZENTIVA PHARMA UK LIMITED	APREPITANT ZENTIVA 125 MG HARD CAPSULES	APREPITANT	125.00	MILLIGRAMMES	POM
PL 17780/0824	11/01/2019	ZENTIVA PHARMA UK LIMITED	APREPITANT ZENTIVA 125MG/80MG HARD CAPSULES	APREPITANT	125.0	MILLIGRAMMES	POM
PL 17780/0824	11/01/2019	ZENTIVA PHARMA UK LIMITED	APREPITANT ZENTIVA 125MG/80MG HARD CAPSULES	APREPITANT	80.00	MILLIGRAMMES	POM
PL 17907/0595	11/01/2019	BRISTOL LABORATORIES LIMITED	FLUCLOXACILLIN 125MG/5ML POWDER FOR ORAL SOLUTION, SUGAR-FREE	FLUCLOXACILLIN SODIUM	136.00	MILLIGRAMMES	POM
PL 17907/0596	11/01/2019	BRISTOL LABORATORIES LIMITED	FLUCLOXACILLIN 250MG/5ML POWDER FOR ORAL SOLUTION, SUGAR-FREE	FLUCLOXACILLIN SODIUM	272.00	MILLIGRAMMES	POM
PL 20075/1237	11/01/2019	ACCORD HEALTHCARE LIMITED	TOPOTECAN ACCORD HEALTHCARE 1MG POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION	TOPOTECAN HYDROCHLORIDE	1.09	MILLIGRAMMES PER MILLILITRE	POM
PL 20075/1238	11/01/2019	ACCORD HEALTHCARE LIMITED	TOPOTECAN ACCORD HEALTHCARE 4MG POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION	TOPOTECAN HYDROCHLORIDE	4.35	MILLIGRAMMES PER MILLILITRE	POM
PL 42765/0007	11/01/2019	RENATA (UK) LIMITED	CLINDAMYCIN 75MG CAPSULES, HARD	CLINDAMYCIN HYDROCHLORIDE	86.21	MILLIGRAMMES	POM
PL 42765/0008	11/01/2019	RENATA (UK) LIMITED	CLINDAMYCIN 150MG CAPSULES, HARD	CLINDAMYCIN HYDROCHLORIDE	172.41	MILLIGRAMMES	POM
PL 42765/0009	11/01/2019	RENATA (UK) LIMITED	CLINDAMYCIN 300MG CAPSULES, HARD	CLINDAMYCIN HYDROCHLORIDE	344.82	MILLIGRAMMES	POM
PL 45043/0001	11/01/2019	NEON HEALTHCARE LIMITED	ITRACONAZOLE 10 MG/ML CONCENTRATE AND SOLVENT FOR SOLUTION FOR INFUSION	ITRACONAZOLE	257	MILLIGRAMMES	POM
PL 45043/0001	11/01/2019	NEON HEALTHCARE LIMITED	ITRACONAZOLE 10 MG/ML CONCENTRATE AND SOLVENT FOR SOLUTION FOR INFUSION	SODIUM CHLORIDE	450	MILLIGRAMMES	POM
PL 00289/2214	14/01/2019	TEVA UK LIMITED	DASATINIB TEVA 20 MG FILM-COATED TABLETS	DASATINIB MONOHYDRATE	20.739	MILLIGRAMMES	POM
PL 00289/2215	14/01/2019	TEVA UK LIMITED	DASATINIB TEVA 50 MG FILM-COATED TABLETS	DASATINIB MONOHYDRATE	51.847	MILLIGRAMMES	POM
PL 00289/2216	14/01/2019	TEVA UK LIMITED	DASATINIB TEVA 70 MG FILM-COATED TABLETS	DASATINIB MONOHYDRATE	72.585	MILLIGRAMMES	POM
PL 00289/2217	14/01/2019	TEVA UK LIMITED	DASATINIB TEVA 80 MG FILM-COATED TABLETS	DASATINIB MONOHYDRATE	82.954	MILLIGRAMMES	POM
PL 00289/2218	14/01/2019	TEVA UK LIMITED	DASATINIB TEVA 100 MG FILM-COATED TABLETS	DASATINIB MONOHYDRATE	103.683	MILLIGRAMMES	POM
PL 00289/2231	14/01/2019	TEVA UK LIMITED	SORAFENIB TEVA 200 MG FILM-COATED TABLETS	SORAFENIB TOSYLATE	200	MILLIGRAMMES	POM
PL 17683/0139	14/01/2019	ALFRED E TIEFENBACHER GMBH & CO KG	PRUCALOPRIDE TIEFENBACHER 1 MG FILM-COATED TABLETS	PRUCALOPRIDE SUCCINATE	1321	UNITS PER GRAMME	POM
PL 17683/0140	14/01/2019	ALFRED E TIEFENBACHER GMBH & CO KG	PRUCALOPRIDE TIEFENBACHER 2 MG FILM-COATED TABLETS	PRUCALOPRIDE SUCCINATE	2.642	MILLIGRAMMES	POM
PL 40739/0091	14/01/2019	ENNOGEN HEALTHCARE LIMITED	BIDEX 84MG/ML ORAL SOLUTION	SODIUM BICARBONATE	420	MILLIGRAMMES PER 5 MILLILITRE P	
PL 40739/0091	14/01/2019	ENNOGEN HEALTHCARE LIMITED	SODIUM BICARBONATE 84MG/ML ORAL SOLUTION	SODIUM BICARBONATE	420	MILLIGRAMMES PER 5 MILLILITRE P	

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PL 44400/0007	14/01/2019	L M MANUFACTURING LIMITED	PREGABALIN LIQMEDS 20MG/ML ORAL SOLUTION	PREGABALIN	20.00	MILLIGRAMMES PER MILLILITRE	POM
PL 46788/0021	14/01/2019	ALTAN PHARMA LIMITED	ROPIVACAINE ALTAN 10 MG/ML SOLUTION FOR INJECTION	ROPIVACAINE HYDROCHLORIDE MONOHYDRATE	105.80	MILLIGRAMMES	POM
PL 46788/0022	14/01/2019	ALTAN PHARMA LIMITED	ROPIVACAINE 7.5 MG/ML SOLUTION FOR INJECTION	ROPIVACAINE HYDROCHLORIDE MONOHYDRATE	7.5	GRAMMES	POM
PL 46788/0023	14/01/2019	ALTAN PHARMA LIMITED	ROPIVACAINE 2 MG/ML SOLUTION FOR INJECTION	ROPIVACAINE HYDROCHLORIDE MONOHYDRATE	2	MILLIGRAMMES	POM
PL 20897/0109	15/01/2019	HELM AG	ULIPRISTAL HELM 30MG FILM-COATED TABLETS	ULIPRISTAL ACETATE	30.0	MILLIGRAMMES	P
PL 40546/0073	15/01/2019	ARISTO PHARMA GMBH	ULIPRISTAL ARISTO 30 MG FILM-COATED TABLET	ULIPRISTAL ACETATE	30	MILLIGRAMMES	P
PL 41344/0046	15/01/2019	COLONIS PHARMA LIMITED	ILOPROST 100 MICROGRAMS/ML CONCENTRATE FOR SOLUTION FOR INFUSION	ILOPROST	0.1	MILLIGRAMMES	POM
PL 46379/0004	15/01/2019	VIVANTA GENERICS SRO	ROSUVASTATIN 5 MG FILM-COATED TABLETS	ROSUVASTATIN CALCIUM	5.20	MILLIGRAMMES	POM
PL 46379/0005	15/01/2019	VIVANTA GENERICS SRO	ROSUVASTATIN 10 MG FILM-COATED TABLETS	ROSUVASTATIN CALCIUM	10.40	MILLIGRAMMES	POM
PL 46379/0006	15/01/2019	VIVANTA GENERICS SRO	ROSUVASTATIN 20 MG FILM-COATED TABLETS	ROSUVASTATIN CALCIUM	20.80	MILLIGRAMMES	POM
PL 46379/0007	15/01/2019	VIVANTA GENERICS SRO	ROSUVASTATIN 40 MG FILM-COATED TABLETS	ROSUVASTATIN CALCIUM	41.60	MILLIGRAMMES	POM
PL 20373/0055	16/01/2019	REGIOMEDICA GMBH	ALITRETINOIN 10 MG CAPSULES, SOFT	ALITRETINOIN	10.00	MILLIGRAMMES	POM
PL 20373/0056	16/01/2019	REGIOMEDICA GMBH	ALITRETINOIN 30 MG CAPSULES, SOFT	ALITRETINOIN	30.00	MILLIGRAMMES	POM
PL 40546/0068	16/01/2019	ARISTO PHARMA GMBH	MUNUZA 300 MG/5 ML NEBULISER SOLUTION	TOBRAMYCIN	300	MILLIGRAMMES PER 5 MILLILITRE	POM
PL 24837/0094	17/01/2019	CONSILIENT HEALTH LIMITED	VINORELBINE 20 MG SOFT CAPSULES	VINORELBINE TARTRATE	27.70	MILLIGRAMMES	POM
PL 24837/0095	17/01/2019	CONSILIENT HEALTH LIMITED	VINORELBINE 30 MG SOFT CAPSULES	VINORELBINE TARTRATE	41.55	MILLIGRAMMES	POM
PL 24837/0096	17/01/2019	CONSILIENT HEALTH LIMITED	VINORELBINE 80 MG SOFT CAPSULES	VINORELBINE TARTRATE	110.80	MILLIGRAMMES	POM
PL 30306/0765	17/01/2019	ACTAVIS GROUP PTC EHF	PERLIRING 0.015MG/0.12MG/ 24 HOURS VAGINAL DELIVERY SYSTEM	ETHINYLESTRADIOL	2.700	MILLIGRAMMES	POM
PL 30306/0765	17/01/2019	ACTAVIS GROUP PTC EHF	PERLIRING 0.015MG/0.12MG/ 24 HOURS VAGINAL DELIVERY SYSTEM	ETONOGESTREL	11.70	MILLIGRAMMES	POM
PL 04425/0756	18/01/2019	AVENTIS PHARMA LIMITED	TRIVALENT INFLUENZA VACCINE (SPLIT VIRION, INACTIVATED) HIGH DOSE, SUSPENSION FOR INJECTION	A/HONG KONG/4801/2014 (H3N2) - LIKE STRAIN (A/HONG KONG/4801/2014, NYMC X-263B)	60	MICROGRAMMES	POM
PL 04425/0756	18/01/2019	AVENTIS PHARMA LIMITED	TRIVALENT INFLUENZA VACCINE (SPLIT VIRION, INACTIVATED) HIGH DOSE, SUSPENSION FOR INJECTION	A/MICHIGAN/45/2015 (H1N1)PDM09 - LIKE STRAIN (A/MICHIGAN/45/2015, NYMC X-275)	60	MICROGRAMMES	POM
PL 04425/0756	18/01/2019	AVENTIS PHARMA LIMITED	TRIVALENT INFLUENZA VACCINE (SPLIT VIRION, INACTIVATED) HIGH DOSE, SUSPENSION FOR INJECTION	B/BRISBANE/60/2008 (VICTORIA LINEAGE)-LIKE VIRUS	60	MICROGRAMMES	POM
PL 04425/0756	18/01/2019	AVENTIS PHARMA LIMITED	TRIVALENT INFLUENZA VACCINE (SPLIT VIRION, INACTIVATED) HIGH DOSE, SUSPENSION FOR INJECTION	INFLUENZA VIRUS STRAINS INACTIVATED	0.0	THOUSAND TABLETS	POM
PL 22363/0026	18/01/2019	KAPPLER PHARMA CONSULT GMBH	SILDENAFIL 50MG FILM-COATED TABLETS	SILDENAFIL CITRATE	70.243	MILLIGRAMMES	POM
PL 35646/0076	21/01/2019	ALKEM PHARMA GMBH	CINACALCET 30 MG FILM-COATED TABLETS	CINACALCET HYDROCHLORIDE	33.00	MILLIGRAMMES	POM
PL 35646/0077	21/01/2019	ALKEM PHARMA GMBH	CINACALCET 60 MG FILM-COATED TABLETS	CINACALCET HYDROCHLORIDE	66.0	MILLIGRAMMES	POM
PL 35646/0078	21/01/2019	ALKEM PHARMA GMBH	CINACALCET 90 MG FILM-COATED TABLETS	CINACALCET HYDROCHLORIDE	99	MILLIGRAMMES	POM
PL 19863/0002	22/01/2019	SELSDON HEALTHCARE LIMITED	FLUORITOP LF 2800 PPM FLUORIDE TOOTHPASTE	SODIUM FLUORIDE	0.619	PERCENT WEIGHT IN WEIGHT	P
PL 19863/0003	22/01/2019	SELSDON HEALTHCARE LIMITED	FLUORITOP HF 5000 PPM FLUORIDE TOOTHPASTE	SODIUM FLUORIDE	1.105	PERCENT WEIGHT IN WEIGHT	P
PL 01883/0270	23/01/2019	MACARTHYS LABORATORIES LIMITED	CYCLIZINE LACTATE 50 MG/ML SOLUTION FOR INJECTION	CYCLIZINE LACTATE	50	MILLIGRAMMES PER MILLILITRE	POM
PL 28176/0186	23/01/2019	STRIDES ARCOLAB INTERNATIONAL LIMITED	TRAZODONE HYDROCHLORIDE 50MG CAPSULE, HARD	TRAZODONE HYDROCHLORIDE	50	MILLIGRAMMES	POM

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PL 28176/0187	23/01/2019	STRIDES ARCOLAB INTERNATIONAL LIMITED	TRAZODONE HYDROCHLORIDE 100MG CAPSULE, HARD	TRAZODONE HYDROCHLORIDE	100	MILLIGRAMMES	POM
PL 36390/0232	23/01/2019	CIPLA (EU) LIMITED	LENALIDOMIDE 5 MG CAPSULES HARD	LENALIDOMIDE	5	MILLIGRAMMES	POM
PL 36390/0233	23/01/2019	CIPLA (EU) LIMITED	LENALIDOMIDE 10 MG CAPSULES HARD	LENALIDOMIDE	10	MILLIGRAMMES	POM
PL 36390/0234	23/01/2019	CIPLA (EU) LIMITED	LENALIDOMIDE 15 MG CAPSULES HARD	LENALIDOMIDE	15	MILLIGRAMMES	POM
PL 36390/0235	23/01/2019	CIPLA (EU) LIMITED	LENALIDOMIDE 20 MG CAPSULES HARD	LENALIDOMIDE	20	MILLIGRAMMES	POM
PL 36390/0236	23/01/2019	CIPLA (EU) LIMITED	LENALIDOMIDE 25 MG CAPSULES HARD	LENALIDOMIDE	25	MILLIGRAMMES	POM
PL 39352/0395	23/01/2019	KOSEI PHARMA UK LIMITED	VILDAGLIPTIN 50MG TABLETS	VILDAGLIPTIN	50	MILLIGRAMMES	POM
PL 46788/0020	24/01/2019	ALTAN PHARMA LIMITED	ROPIVACAINE ALTAN 2 MG/ML SOLUTION FOR INFUSION	ROPIVACAINE HYDROCHLORIDE MONOHYDRATE	2	GRAMMES	POM
PL 20075/1165	25/01/2019	ACCORD HEALTHCARE LIMITED	APREPITANT ACCORD 80 MG HARD CAPSULES	APREPITANT	80	MILLIGRAMMES	POM
PL 20075/1166	25/01/2019	ACCORD HEALTHCARE LIMITED	APREPITANT ACCORD 125 MG HARD CAPSULES	APREPITANT	125	MILLIGRAMMES	POM
PL 20075/1181	25/01/2019	ACCORD HEALTHCARE LIMITED	APREPITANT ACCORD 80/125 MG HARD CAPSULES	APREPITANT	125	MILLIGRAMMES	POM
PL 20075/1181	25/01/2019	ACCORD HEALTHCARE LIMITED	APREPITANT ACCORD 80/125 MG HARD CAPSULES	APREPITANT	80	MILLIGRAMMES	POM
PL 42357/0261	25/01/2019	AMNEAL PHARMA EUROPE LIMITED	IOHEXOL 300 MG I/ML SOLUTION FOR INJECTION	IOHEXOL	300.00	MILLIGRAMMES PER MILLILITRE	POM
PL 42357/0262	25/01/2019	AMNEAL PHARMA EUROPE LIMITED	IOHEXOL 350 MG I/ML SOLUTION FOR INJECTION	IOHEXOL	350.00	MILLIGRAMMES PER MILLILITRE	POM
PL 49038/0001	25/01/2019	S.F. GROUP SRL	RINOFF 50 MICROGRAMS/ACTUATION NASAL SPRAY, SUSPENSION	MOMETASONE FUROATE MONOHYDRATE	0.052	MG PER ACTUATION	POM
PL 49039/0001	25/01/2019	FARTO SRL- FARMACO BIOCHIMICO TOSCANO	MOMECORT 50 MICROGRAMS/ACTUATION NASAL SPRAY, SUSPENSION	MOMETASONE FUROATE MONOHYDRATE	0.052	MG PER ACTUATION	POM
PL 50181/0001	25/01/2019	DRUGS MINERALS AND GENERICS ITALIA SRL	MOMETASONE FUROATE 50 MICROGRAMS/ACTUATION NASAL SPRAY, SUSPENSION	MOMETASONE FUROATE MONOHYDRATE	0.052	MG PER ACTUATION	POM
PL 50182/0001	25/01/2019	LABORATORIO CHIMICO DECA DR. CAPUANI SRL	MOMETASONE FUROATE 50 MICROGRAMS/ACTUATION NASAL SPRAY, SUSPENSION	MOMETASONE FUROATE MONOHYDRATE	0.052	MG PER ACTUATION	POM
PL 04569/1754	28/01/2019	GENERICS (UK) LIMITED	NORTRIPTYLINE 10 MG FILM-COATED TABLETS	NORTRIPTYLINE HYDROCHLORIDE	11.40	MILLIGRAMMES	POM
PL 04569/1755	28/01/2019	GENERICS (UK) LIMITED	NORTRIPTYLINE 25MG FILM-COATED TABLETS	NORTRIPTYLINE HYDROCHLORIDE	28.50	MILLIGRAMMES	POM
PL 20416/0482	28/01/2019	CRESCENT PHARMA LIMITED	AZITHROMYCIN 250MG FILM-COATED TABLETS	AZITHROMYCIN DIHYDRATE	262.02	MILLIGRAMMES	POM
PL 20416/0483	28/01/2019	CRESCENT PHARMA LIMITED	AZITHROMYCIN 500MG FILM-COATED TABLETS	AZITHROMYCIN DIHYDRATE	524.40	MILLIGRAMMES	POM
PL 49718/0017	28/01/2019	NEURAXPHARM UK LIMITED	OXYCODONE HYDROCHLORIDE/NALOXONE HYDROCHLORIDE 5 MG/2.5 MG PROLONGED-RELEASE TABLETS	NALOXONE HYDROCHLORIDE DIHYDRATE	2.74	MILLIGRAMMES	POM
PL 49718/0017	28/01/2019	NEURAXPHARM UK LIMITED	OXYCODONE HYDROCHLORIDE/NALOXONE HYDROCHLORIDE 5 MG/2.5 MG PROLONGED-RELEASE TABLETS	OXYCODONE HYDROCHLORIDE	5.00	MILLIGRAMMES	POM
PL 49718/0018	28/01/2019	NEURAXPHARM UK LIMITED	OXYCODONE HYDROCHLORIDE/NALOXONE HYDROCHLORIDE 10MG/5MG PROLONGED-RELEASE TABLETS	NALOXONE HYDROCHLORIDE DIHYDRATE	5.45	MILLIGRAMMES	POM
PL 49718/0018	28/01/2019	NEURAXPHARM UK LIMITED	OXYCODONE HYDROCHLORIDE/NALOXONE HYDROCHLORIDE 10MG/5MG PROLONGED-RELEASE TABLETS	OXYCODONE HYDROCHLORIDE	10.0	MILLIGRAMMES	POM
PL 49718/0019	28/01/2019	NEURAXPHARM UK LIMITED	OXYCODONE HYDROCHLORIDE/NALOXONE HYDROCHLORIDE 20MG/10M GPROLONGED-RELEASE TABLETS	NALOXONE HYDROCHLORIDE DIHYDRATE	10.9	MILLIGRAMMES	POM
PL 49718/0019	28/01/2019	NEURAXPHARM UK LIMITED	OXYCODONE HYDROCHLORIDE/NALOXONE HYDROCHLORIDE 20MG/10M GPROLONGED-RELEASE TABLETS	OXYCODONE HYDROCHLORIDE	20	MILLIGRAMMES	POM
PL 49718/0020	28/01/2019	NEURAXPHARM UK LIMITED	OXYCODONE HYDROCHLORIDE/NALOXONE HYDROCHLORIDE 30MG/15MG PROLONGED-RELEASE TABLETS	NALOXONE HYDROCHLORIDE DIHYDRATE	16.35	MILLIGRAMMES	POM
PL 49718/0020	28/01/2019	NEURAXPHARM UK LIMITED	OXYCODONE HYDROCHLORIDE/NALOXONE HYDROCHLORIDE 30MG/15MG PROLONGED-RELEASE TABLETS	OXYCODONE HYDROCHLORIDE	30	MILLIGRAMMES	POM
PL 49718/0021	28/01/2019	NEURAXPHARM UK LIMITED	OXYCODONE HYDROCHLORIDE/NALOXONE HYDROCHLORIDE 40MG/20MG PROLONGED-RELEASE TABLETS	NALOXONE HYDROCHLORIDE DIHYDRATE	21.8	MILLIGRAMMES	POM

Marketing authorisations granted in January 2019

PL Number	Grant Date	MA Holder	Licensed Name(s)	Active Ingredient	Quantity	Units	Legal Status
PL 49718/0021	28/01/2019	NEURAXPHARM UK LIMITED	OXYCODONE HYDROCHLORIDE/NALOXONE HYDROCHLORIDE 40MG/20MG PROLONGED-RELEASE TABLETS	OXYCODONE HYDROCHLORIDE	40	MILLIGRAMMES	POM
PL 17907/0674	29/01/2019	BRISTOL LABORATORIES LIMITED	CARBOCISTEINE 375 MG CAPSULES, HARD	CARBOCISTEINE	375	MILLIGRAMMES	POM
PL 17907/0686	29/01/2019	BRISTOL LABORATORIES LIMITED	BETAHISTINE DIHYDROCHLORIDE 8MG TABLETS	BETAHISTINE DIHYDROCHLORIDE	8	MILLIGRAMMES	POM
PL 17907/0687	29/01/2019	BRISTOL LABORATORIES LIMITED	BETAHISTINE DIHYDROCHLORIDE 16MG TABLETS	BETAHISTINE DIHYDROCHLORIDE	16	MILLIGRAMMES	POM
PL 43659/0023	29/01/2019	PRIMEGEN LIMITED	TEMAZEPAM 10MG/5ML ORAL SOLUTION	TEMAZEPAM	0.01	GRAMMES PER 5 MILLILITRES	POM
PL 02855/0305	31/01/2019	OMEGA PHARMA LIMITED	KETOPROFEN 25MG FILM-COATED TABLETS	KETOPROFEN LYSINATE	40.00	MILLIGRAMMES	POM
PL 02855/0310	31/01/2019	OMEGA PHARMA LIMITED	KETOPROFEN 25MG GRANULES	KETOPROFEN LYSINATE	40.01	MILLIGRAMMES	POM