

Marketing authorisations granted in February 2019

PL Number	Grant Date	MA Holder	Licensed Name(s)	Active Ingredient	Quantity	Units	Legal Status
PL 17496/0034	01/02/2019	DALKEITH LABORATORIES LIMITED	CYANOCOBALAMIN 50 MICROGRAM FILM-COATED TABLETS	CYANOCOBALAMIN	50	MICROGRAMMES	P
PL 20395/0248	01/02/2019	RELONCHEM LIMITED	BELLS HEALTHCARE CHILDREN'S ALLERGY RELIEF 5MG/5ML ORAL SOLUTION	LORATADINE	1	MILLIGRAMMES PER MILLILITRE	P
PL 20395/0248	01/02/2019	RELONCHEM LIMITED	LORATADINE 5MG/5ML ORAL SOLUTION	LORATADINE	1	MILLIGRAMMES PER MILLILITRE	P
PL 25298/0082	01/02/2019	BROWN & BURK UK LIMITED	CARBOCISTEINE 250 MG/5 ML ADULT SYRUP	CARBOCISTEINE	250.00	MILLIGRAMMES PER 5 MILLILITRE	POM
PL 30684/0241	01/02/2019	DAWA LIMITED	DOXYCYCLINE 50MG CAPSULES	DOXYCYCLINE HYCLATE	57.71	MILLIGRAMMES	POM
PL 30684/0242	01/02/2019	DAWA LIMITED	DOXYCYCLINE 100MG CAPSULES	DOXYCYCLINE HYCLATE	115.41	MILLIGRAMMES	POM
PL 31103/0026	01/02/2019	BLUMONT 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 31103/0026	01/02/2019	BLUMONT 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 04416/1558	04/02/2019	SANDOZ LIMITED	EVEROLIMUS SANDOZ 2.5MG TABLETS	EVEROLIMUS	2.5	MILLIGRAMMES	POM
PL 04416/1559	04/02/2019	SANDOZ LIMITED	EVEROLIMUS SANDOZ 5MG TABLETS	EVEROLIMUS	5	MILLIGRAMMES	POM
PL 04416/1560	04/02/2019	SANDOZ LIMITED	EVEROLIMUS SANDOZ 10MG TABLETS	EVEROLIMUS	10	MILLIGRAMMES	POM
PL 42582/0015	06/02/2019	STIRLING ANGLIAN PHARMACEUTICALS LIMITED	ACEO 600 MG EFFERVESCENT TABLETS	ACETYLCYSTEINE	600	MILLIGRAMMES	POM
PL 00240/0443	07/02/2019	THORNTON & ROSS LIMITED	TENOFOVIR STADA 245 MG FILM-COATED TABLETS	TENOFOVIR DISOPROXIL SUCCINATE	300.6	MILLIGRAMMES	POM
PL 00427/0247	07/02/2019	ROSEMONT PHARMACEUTICALS LIMITED	PREGABALIN ROSEMONT 20MG/ML ORAL SOLUTION	PREGABALIN	20.00	MILLIGRAMMES PER MILLILITRE	POM
PL 36722/0112	07/02/2019	SPECIAL CONCEPT DEVELOPMENT (UK) LIMITED	PARACETAMOL 500 MG TABLETS	PARACETAMOL	500.000	MILLIGRAMMES	GSL
PL 36722/0113	07/02/2019	SPECIAL CONCEPT DEVELOPMENT (UK) LIMITED	PARACETAMOL 1000 MG TABLETS	PARACETAMOL	1000.000	MILLIGRAMMES	GSL
PL 17780/0815	08/02/2019	ZENTIVA PHARMA UK LIMITED	VILDAGLIPTIN ZENTIVA 50MG TABLETS	VILDAGLIPTIN	50.0	MILLIGRAMMES	POM
PL 20416/0563	08/02/2019	CRESCENT PHARMA LIMITED	ZOLMITRIPTAN 2.5MG ORODISPERSIBLE TABLETS	ZOLMITRIPTAN	2.5	MILLIGRAMMES	POM
PL 20416/0564	08/02/2019	CRESCENT PHARMA LIMITED	ZOLMITRIPTAN 5MG ORODISPERSIBLE TABLETS	ZOLMITRIPTAN	5	MILLIGRAMMES	POM
PL 24598/0062	08/02/2019	NORIDEM ENTERPRISES LIMITED	CLARITHROMYCIN 500 MG POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION	CLARITHROMYCIN LACTOBIONATE	739.5	MILLIGRAMMES	POM
PL 25258/0284	08/02/2019	GLENMARK PHARMACEUTICALS EUROPE LIMITED	DIPYRIDAMOLE 200 MG MODIFIED RELEASE CAPSULES, HARD	DIPYRIDAMOLE	200	MILLIGRAMMES	POM
PL 36390/0241	08/02/2019	CIPLA (EU) LIMITED	ERLOTINIB 25MG FILM-COATED TABLETS	ERLOTINIB HYDROCHLORIDE	27.317	MILLIGRAMMES	POM
PL 36390/0242	08/02/2019	CIPLA (EU) LIMITED	ERLOTINIB 100MG FILM-COATED TABLETS	ERLOTINIB HYDROCHLORIDE	109.267	MILLIGRAMMES	POM
PL 36390/0243	08/02/2019	CIPLA (EU) LIMITED	ERLOTINIB 150MG FILM-COATED TABLETS	ERLOTINIB HYDROCHLORIDE	163.90	MILLIGRAMMES	POM
PL 36659/0005	08/02/2019	RHODES PHARMA LIMITED	CYNRIL 200 MICROGRAMS COMPRESSED LOZENGES WITH INTEGRAL OROMUCOSAL APPLICATOR	FENTANYL CITRATE	0.3142	MILLIGRAMMES	POM
PL 36659/0006	08/02/2019	RHODES PHARMA LIMITED	CYNRIL 400 MICROGRAMS COMPRESSED LOZENGES WITH INTEGRAL OROMUCOSAL APPLICATOR	FENTANYL CITRATE	0.6285	MILLIGRAMMES	POM
PL 36659/0007	08/02/2019	RHODES PHARMA LIMITED	CYNRIL 600 MICROGRAMS COMPRESSED LOZENGES WITH INTEGRAL OROMUCOSAL APPLICATOR	FENTANYL CITRATE	0.9425	MILLIGRAMMES	POM
PL 36659/0008	08/02/2019	RHODES PHARMA LIMITED	CYNRIL 800 MICROGRAMS COMPRESSED LOZENGES WITH INTEGRAL OROMUCOSAL APPLICATOR	FENTANYL CITRATE	1.2567	MILLIGRAMMES	POM
PL 36659/0009	08/02/2019	RHODES PHARMA LIMITED	CYNRIL 1200 MICROGRAMS COMPRESSED LOZENGES WITH INTEGRAL OROMUCOSAL APPLICATOR	FENTANYL CITRATE	1.8851	MILLIGRAMMES	POM
PL 36659/0010	08/02/2019	RHODES PHARMA LIMITED	CYNRIL 1600 MICROGRAMS COMPRESSED LOZENGES WITH INTEGRAL OROMUCOSAL APPLICATOR	FENTANYL CITRATE	2.5134	MILLIGRAMMES	POM

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PL 43808/0015	08/02/2019	ENDO VENTURES LIMITED	MORPHINE HYDROCHLORIDE TABLETS 10MG	MORPHINE HYDROCHLORIDE	10	MILLIGRAMMES	POM
PL 43808/0016	08/02/2019	ENDO VENTURES LIMITED	MORPHINE HYDROCHLORIDE 20MG TABLETS	MORPHINE HYDROCHLORIDE	20.00	MILLIGRAMMES	POM
PL 11311/0614	11/02/2019	TILLOMED LABORATORIES LIMITED	CARBIMAZOLE 5 MG TABLETS	CARBIMAZOLE	5	MILLIGRAMMES	POM
PL 11311/0615	11/02/2019	TILLOMED LABORATORIES LIMITED	CARBIMAZOLE 20 MG TABLETS	CARBIMAZOLE	20	MILLIGRAMMES	POM
PL 16058/0026	11/02/2019	SANTEN OY	SAFLUTAN 15 MICROGRAMS/ML EYE DROPS, SOLUTION	TAFLUPROST	0.015	MILLIGRAMMES PER MILLILITRE	POM
PL 39352/0434	11/02/2019	KOSEI PHARMA UK LIMITED	SOLIFENACIN SUCCINATE 5 MG FILM-COATED TABLET	SOLIFENACIN SUCCINATE	5	MILLIGRAMMES	POM
PL 39352/0435	11/02/2019	KOSEI PHARMA UK LIMITED	SOLIFENACIN SUCCINATE 10 MG FILM-COATED TABLET	SOLIFENACIN SUCCINATE	10	MILLIGRAMMES	POM
PL 48278/0002	11/02/2019	ZISTA PHARMA LIMITED	ACETAZOLAMIDE 250 MG TABLETS	ACETAZOLAMIDE	250	MILLIGRAMMES	POM
PL 11311/0573	12/02/2019	TILLOMED LABORATORIES LIMITED	NITROFURANTOIN 50MG CAPSULES, HARD	NITROFURANTOIN MACROCRYSTALS	50	MILLIGRAMMES	POM
PL 11311/0574	12/02/2019	TILLOMED LABORATORIES LIMITED	NITROFURANTOIN 100MG CAPSULES, HARD	NITROFURANTOIN MACROCRYSTALS	100	MILLIGRAMMES	POM
PL 34771/0246	12/02/2019	MACLEODS PHARMA UK LIMITED	LACOSAMIDE MACLEODS 50 MG FILM-COATED TABLETS	LACOSAMIDE	50.00	MILLIGRAMMES	POM
PL 34771/0247	12/02/2019	MACLEODS PHARMA UK LIMITED	LACOSAMIDE MACLEODS 100 MG FILM-COATED TABLETS	LACOSAMIDE	100.00	MILLIGRAMMES	POM
PL 34771/0248	12/02/2019	MACLEODS PHARMA UK LIMITED	LACOSAMIDE MACLEODS 150 MG FILM-COATED TABLETS	LACOSAMIDE	150.00	MILLIGRAMMES	POM
PL 34771/0249	12/02/2019	MACLEODS PHARMA UK LIMITED	LACOSAMIDE MACLEODS 200 MG FILM-COATED TABLETS	LACOSAMIDE	200.00	MILLIGRAMMES	POM
PL 00068/0412	13/02/2019	3M HEALTH CARE LIMITED	SOLUPREP 2% W/V / 70% V/V CUTANEOUS SOLUTION	CHLORHEXIDINE DIGLUCONATE SOLUTION	20.00	MILLIGRAMMES PER MILLILITRE	GSL
PL 00068/0412	13/02/2019	3M HEALTH CARE LIMITED	SOLUPREP 2% W/V / 70% V/V CUTANEOUS SOLUTION	ISOPROPYL ALCOHOL	0.70	MILLILITRES	GSL
PL 00068/0413	13/02/2019	3M HEALTH CARE LIMITED	SOLUPREP WITH TINT 2% W/V / 70% V/V CUTANEOUS SOLUTION	CHLORHEXIDINE DIGLUCONATE SOLUTION	20	MILLIGRAMMES PER MILLILITRE	GSL
PL 00068/0413	13/02/2019	3M HEALTH CARE LIMITED	SOLUPREP WITH TINT 2% W/V / 70% V/V CUTANEOUS SOLUTION	ISOPROPYL ALCOHOL	0.70	MILLILITRES	GSL
PL 15011/0023	14/02/2019	INFECTOPHARM ARZNEIMITTEL UND CONSILIUM GMBH	MUPIROCIN 20 MG/G NASAL OINTMENT	MUPIROCIN CALCIUM	2.15	GRAMMES	POM
PL 21844/0037	14/02/2019	STRAGEN UK LIMITED	DIENOGEST 2 MG FILM-COATED TABLETS	DIENOGEST	2.00	MILLIGRAMMES	POM
PL 31750/0132	14/02/2019	SUN PHARMACEUTICAL INDUSTRIES EUROPE BV	ERLOTINIB SUN 25 MG FILM-COATED TABLETS	ERLOTINIB HYDROCHLORIDE	27.317	MILLIGRAMMES	POM
PL 31750/0133	14/02/2019	SUN PHARMACEUTICAL INDUSTRIES EUROPE BV	ERLOTINIB SUN 100 MG FILM-COATED TABLETS	ERLOTINIB HYDROCHLORIDE	109.267	MILLIGRAMMES	POM
PL 31750/0144	14/02/2019	SUN PHARMACEUTICAL INDUSTRIES EUROPE BV	ERLOTINIB SUN 150 MG FILM-COATED TABLETS	ERLOTINIB HYDROCHLORIDE	163.900	MILLIGRAMMES	POM
PL 00289/2246	15/02/2019	TEVA UK LIMITED	DRONEDARONE TEVA 400 MG FILM-COATED TABLETS	DRONEDARONE HYDROCHLORIDE	426.20	MILLIGRAMMES	POM
PL 16363/0562	15/02/2019	MILPHARM LIMITED	MACROGOL 10 G POWDER FOR ORAL SOLUTION	MACROGOL 4000	10000	MILLIGRAMMES	P
PL 28176/0188	15/02/2019	STRIDES ARCOLAB INTERNATIONAL LIMITED	STRIVIT-D3 3200 IU CAPSULES, SOFT	COLECALCIFEROL	0.088	MILLIGRAMMES	POM
PL 28176/0189	15/02/2019	STRIDES ARCOLAB INTERNATIONAL LIMITED	STRIVIT-D3 20,000 IU CAPSULES, SOFT	COLECALCIFEROL	0.55	MILLIGRAMMES	POM
PL 34771/0245	15/02/2019	MACLEODS PHARMA UK LIMITED	MEMANTINE MACLEODS 5 MG/PUMP ACTUATION ORAL SOLUTION	MEMANTINE HYDROCHLORIDE	5	MILLIGRAMMES	POM
PL 36687/0390	15/02/2019	TORRENT PHARMA (UK) LIMITED	RIVAROXABAN 10 MG FILM-COATED TABLETS	RIVAROXABAN	10.000	MILLIGRAMMES	POM
PL 36687/0391	15/02/2019	TORRENT PHARMA (UK) LIMITED	RIVAROXABAN 15 MG FILM-COATED TABLETS	RIVAROXABAN	15.000	MILLIGRAMMES	POM

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PL 36687/0392	15/02/2019	TORRENT PHARMA (UK) LIMITED	RIVAROXABAN 20 MG FILM-COATED TABLETS	RIVAROXABAN	20	MILLIGRAMMES	POM
PL 36722/0114	15/02/2019	SPECIAL CONCEPT DEVELOPMENT (UK) LIMITED	PARACETAMOL 500 MG TABLETS	PARACETAMOL	500.000	MILLIGRAMMES	P
PL 36722/0115	15/02/2019	SPECIAL CONCEPT DEVELOPMENT (UK) LIMITED	PARACETAMOL 1000 MG TABLETS	PARACETAMOL	1000.000	MILLIGRAMMES	POM
PL 42623/0063	15/02/2019	ETHYPHARM UK LIMITED	VENLALIC XL 300 MG PROLONGED-RELEASE TABLET	VENLAFAXINE HYDROCHLORIDE	300	MILLIGRAMMES	POM
PL 04569/1766	18/02/2019	GENERICS (UK) LIMITED	NORTRIPTYLINE 50 MG FILM-COATED TABLETS	NORTRIPTYLINE HYDROCHLORIDE	57.00	MILLIGRAMMES	POM
PL 46130/0001	18/02/2019	RAFARM UK LIMITED	DEXAMETHASONE RAFARM UK 1MG/ML EYE DROPS SOLUTION	DEXAMETHASONE SODIUM PHOSPHATE	1.093	MILLIGRAMMES	POM
PL 34771/0228	19/02/2019	MACLEODS PHARMA UK LIMITED	EMTRICITABINE/TENOFOVIR DISOPROXIL MACLEODS 200 MG/245 MG FILM-COATED TABLETS	EMTRICITABINE	200.000	MILLIGRAMMES	POM
PL 34771/0228	19/02/2019	MACLEODS PHARMA UK LIMITED	EMTRICITABINE/TENOFOVIR DISOPROXIL MACLEODS 200 MG/245 MG FILM-COATED TABLETS	TENOFOVIR DISOPROXIL FUMARATE	300.000	MILLIGRAMMES	POM
PL 06831/0310	20/02/2019	GENUS PHARMACEUTICALS LIMITED	CINACALCET STADA 30 MG FILM-COATED TABLETS	CINACALCET HYDROCHLORIDE	33.067	MILLIGRAMMES	POM
PL 06831/0311	20/02/2019	GENUS PHARMACEUTICALS LIMITED	CINACALCET STADA 60 MG FILM-COATED TABLETS	CINACALCET HYDROCHLORIDE	66.133	MILLIGRAMMES	POM
PL 06831/0312	20/02/2019	GENUS PHARMACEUTICALS LIMITED	CINACALCET STADA 90 MG FILM-COATED TABLETS	CINACALCET HYDROCHLORIDE	99.2	MILLIGRAMMES	POM
PL 16002/0090	20/02/2019	PHARMAFILE LIMITED	SODIUM FLUORIDE 5000 PPM TOOTHPASTE	SODIUM FLUORIDE	0.011	GRAMMES	POM
PL 41947/0037	20/02/2019	ELC GROUP SRO	COLESTYRAMINE LIGHT 4G POWDER FOR ORAL SUSPENSION	COLESTYRAMINE	4	GRAMMES	POM
PL 48037/0003	20/02/2019	PASSAUER PHARMA GMBH	LEVETIRACETAM PASSAUER 250 MG FILM-COATED TABLETS	LEVETIRACETAM	250	MILLIGRAMMES	POM
PL 48037/0004	20/02/2019	PASSAUER PHARMA GMBH	LEVETIRACETAM PASSAUER 500 MG FILM-COATED TABLETS	LEVETIRACETAM	500	MILLIGRAMMES	POM
PL 48037/0005	20/02/2019	PASSAUER PHARMA GMBH	LEVETIRACETAM PASSAUER 750 MG FILM-COATED TABLETS	LEVETIRACETAM	750	MILLIGRAMMES	POM
PL 48037/0006	20/02/2019	PASSAUER PHARMA GMBH	LEVETIRACETAM PASSAUER 1000 MG FILM-COATED TABLETS	LEVETIRACETAM	1000	MILLIGRAMMES	POM
PL 48037/0007	20/02/2019	PASSAUER PHARMA GMBH	LEVETIRACETAM PASSAUER 100 MG/ML ORAL SOLUTION	LEVETIRACETAM	100	MILLIGRAMMES PER MILLILITRE	POM
PL 08553/0638	21/02/2019	DR REDDY'S LABORATORIES (UK) LIMITED	POSACONAZOLE DR. REDDY'S 40 MG/ML ORAL SUSPENSION	POSACONAZOLE	40	MILLIGRAMMES PER MILLILITRE	POM
PL 10673/0045	21/02/2019	OCTAPHARMA LIMITED	CUTAQUIG, 165 MG/ML, SOLUTION FOR INJECTION	HUMAN NORMAL IMMUNOGLOBULIN	165	MILLIGRAMMES PER MILLILITRE	POM
PL 05448/0001	26/02/2019	ISTITUTO BIOCHIMICO ITALIANO GIOVANNI LORENZINI SPA	VORICONAZOLE IBISQUS 200 MG POWDER FOR SOLUTION FOR INFUSION	VORICONAZOLE	200.00	MILLIGRAMMES	POM
PL 35646/0070	26/02/2019	ALKEM PHARMA GMBH	SODIUM OXYBATE 500 MG/ML ORAL SOLUTION	SODIUM OXYBATE	500	MILLIGRAMMES PER MILLILITRE	POM
PL 17589/0015	27/02/2019	DEMO SA PHARMACEUTICAL INDUSTRY	BRODILATEN 1.25 MG / 2.5 ML NEBULISER SOLUTION	SALBUTAMOL SULFATE	0.60	MILLIGRAMMES PER MILLILITRE	POM
PL 17589/0016	27/02/2019	DEMO SA PHARMACEUTICAL INDUSTRY	BRODILATEN 2.5 MG / 2.5 ML NEBULISER SOLUTION	SALBUTAMOL SULFATE	1.2	MILLIGRAMMES PER MILLILITRE	POM
PL 17589/0017	27/02/2019	DEMO SA PHARMACEUTICAL INDUSTRY	BRODILATEN 5.0 MG / 2.5 ML NEBULISER SOLUTION	SALBUTAMOL SULFATE	2.4	MILLIGRAMMES PER MILLILITRE	POM
PL 35533/0135	27/02/2019	ASPIRE PHARMA LIMITED	SEVODYNE 15 MICROGRAMS/HOUR TRANSDERMAL PATCH	BUPRENORPHINE	15	MILLIGRAMMES	POM
PL 44570/0012	27/02/2019	QILU PHARMA SPAIN SL	TENOFOVIR DISOPROXIL QILU 245 MG FILM-COATED TABLETS	TENOFOVIR DISOPROXIL FUMARATE	300	MILLIGRAMMES	POM
PL 00289/2174	28/02/2019	TEVA UK LIMITED	VILDAGLIPTIN/METFORMIN 50MG/850 MG FILM-COATED TABLETS	METFORMIN HYDROCHLORIDE	850	MILLIGRAMMES	POM
PL 00289/2174	28/02/2019	TEVA UK LIMITED	VILDAGLIPTIN/METFORMIN 50MG/850 MG FILM-COATED TABLETS	VILDAGLIPTIN	50	MILLIGRAMMES	POM
PL 00289/2174	28/02/2019	TEVA UK LIMITED	VILDAGLIPTIN/METFORMIN 50MG/850MG FILM-COATED TABLETS	METFORMIN HYDROCHLORIDE	850	MILLIGRAMMES	POM

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PL 00289/2174	28/02/2019	TEVA UK LIMITED	VILDAGLIPTIN/METFORMIN 50MG/850MG FILM-COATED TABLETS	VILDAGLIPTIN	50	MILLIGRAMMES	POM
PL 00289/2175	28/02/2019	TEVA UK LIMITED	VILDAGLIPTIN/METFORMIN 50MG/1000MG FILM-COATED TABLETS	METFORMIN HYDROCHLORIDE	1000	MILLIGRAMMES	POM
PL 00289/2175	28/02/2019	TEVA UK LIMITED	VILDAGLIPTIN/METFORMIN 50MG/1000MG FILM-COATED TABLETS	VILDAGLIPTIN	50	MILLIGRAMMES	POM
PL 00289/2176	28/02/2019	TEVA UK LIMITED	VILDAGLIPTIN 50 MG TABLETS	VILDAGLIPTIN	50	MILLIGRAMMES	POM
PL 00289/2176	28/02/2019	TEVA UK LIMITED	VILDAGLIPTIN 50MG TABLETS	VILDAGLIPTIN	50	MILLIGRAMMES	POM