

**Marketing authorisations granted in April 2017**

PL Number	Grant Date	MA Holder	Licensed Name(s)	Active Ingredient	Quantity	Units	Legal Status
PL 04416/1477	03/04/2017	SANDOZ LIMITED	EMTRICITABINE/ TENOFOVIR DISOPROXIL 200MG/245MG FILM-COATED TABLETS	EMTRICITABINE	200	MILLIGRAMMES	POM
PL 04416/1477	03/04/2017	SANDOZ LIMITED	EMTRICITABINE/ TENOFOVIR DISOPROXIL 200MG/245MG FILM-COATED TABLETS	TENOFOVIR DISOPROXIL	245	MILLIGRAMMES	POM
PL 41386/0001	03/04/2017	KLINGE PHARMA GMBH	TENOFOVIR DISOPROXIL KLINGE 245 MG FILM-COATED TABLETS	TENOFOVIR DISOPROXIL PHOSPHATE	291.000	MILLIGRAMMES	POM
PL 42357/0185	03/04/2017	AMNEAL PHARMA EUROPE LIMITED	LIDOCAINE 10 MG/ML SOLUTION FOR INJECTION	LIDOCAINE HYDROCHLORIDE	10	MILLIGRAMMES	POM
PL 42357/0186	03/04/2017	AMNEAL PHARMA EUROPE LIMITED	LIDOCAINE 20 MG/ML SOLUTION FOR INJECTION	LIDOCAINE HYDROCHLORIDE	20	MILLIGRAMMES	POM
PL 16239/0046	04/04/2017	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S A	ENANTYUM 25 MG ORAL SOLUTION	DEXKETOPROFEN TROMETAMOL	36.90	MILLIGRAMMES	POM
PL 20075/0493	04/04/2017	ACCORD HEALTHCARE LIMITED	METHOFILL 7.5 MG SOLUTION FOR INJECTION IN PRE-FILLED INJECTOR	METHOTREXATE	50.00	MILLIGRAMMES PER MILLILITRE	POM
PL 20075/0505	04/04/2017	ACCORD HEALTHCARE LIMITED	METHOFILL 10 MG SOLUTION FOR INJECTION IN PRE-FILLED INJECTOR	METHOTREXATE	50.00	MILLIGRAMMES PER MILLILITRE	POM
PL 20075/0506	04/04/2017	ACCORD HEALTHCARE LIMITED	METHOFILL 12.5 MG SOLUTION FOR INJECTION IN PRE-FILLED INJECTOR	METHOTREXATE	50.00	MILLIGRAMMES PER MILLILITRE	POM
PL 20075/0507	04/04/2017	ACCORD HEALTHCARE LIMITED	METHOFILL 15 MG SOLUTION FOR INJECTION IN PRE-FILLED INJECTOR	METHOTREXATE	50.00	MILLIGRAMMES PER MILLILITRE	POM
PL 20075/0508	04/04/2017	ACCORD HEALTHCARE LIMITED	METHOFILL 17.5 MG SOLUTION FOR INJECTION IN PRE-FILLED INJECTOR	METHOTREXATE	50.00	MILLIGRAMMES PER MILLILITRE	POM
PL 20075/0509	04/04/2017	ACCORD HEALTHCARE LIMITED	METHOFILL 20 MG SOLUTION FOR INJECTION IN PRE-FILLED INJECTOR	METHOTREXATE	50	MILLIGRAMMES PER MILLILITRE	POM
PL 20075/0510	04/04/2017	ACCORD HEALTHCARE LIMITED	METHOFILL 22.5 MG SOLUTION FOR INJECTION IN PRE-FILLED INJECTOR	METHOTREXATE	50.00	MILLIGRAMMES PER MILLILITRE	POM
PL 20075/0511	04/04/2017	ACCORD HEALTHCARE LIMITED	METHOFILL 25 MG SOLUTION FOR INJECTION IN PRE-FILLED INJECTOR	METHOTREXATE	50	MILLIGRAMMES PER MILLILITRE	POM
PL 20075/0512	04/04/2017	ACCORD HEALTHCARE LIMITED	METHOFILL 27.5 MG SOLUTION FOR INJECTION IN PRE-FILLED INJECTOR	METHOTREXATE	50.00	MILLIGRAMMES PER MILLILITRE	POM
PL 20075/0513	04/04/2017	ACCORD HEALTHCARE LIMITED	METHOFILL 30 MG SOLUTION FOR INJECTION IN PRE-FILLED INJECTOR	METHOTREXATE	50.00	MILLIGRAMMES PER MILLILITRE	POM
PL 40546/0009	04/04/2017	ARISTO PHARMA GMBH	TENOFOVIR DISOPROXIL ARISTO 245 MG FILM-COATED TABLETS	TENOFOVIR DISOPROXIL PHOSPHATE	291.000	MILLIGRAMMES	POM
PL 20117/0271	05/04/2017	MORNINGSIDE HEALTHCARE LIMITED	NEVIRAPINE MORNINGSIDE 400 MG PROLONGED-RELEASE TABLETS	NEVIRAPINE ANHYDROUS	400.000	MILLIGRAMMES	POM
PL 08553/0571	06/04/2017	DR REDDY'S LABORATORIES (UK) LIMITED	BENDAMUSTINE HYDROCHLORIDE 180 MG/4 ML CONCENTRATE FOR SOLUTION FOR INFUSION	BENDAMUSTINE HYDROCHLORIDE	180	MILLIGRAMMES	POM
PL 16239/0047	06/04/2017	MENARINI INTERNATIONAL OPERATIONS LUXEMBOURG S A	KERAL 25 MG ORAL SOLUTION IN SACHET	DEXKETOPROFEN TROMETAMOL	36.90	MILLIGRAMMES	POM
PL 18956/0021	06/04/2017	MEDICOM HEALTHCARE LIMITED	LATANOPROST 0.005% W/V EYE DROPS, SOLUTION	LATANOPROST	0.05	MILLIGRAMMES PER MILLILITRE	POM
PL 16786/0003	07/04/2017	SPECIAL PRODUCTS LIMITED	EPISTATUS 10MG OROMUCOSAL SOLUTION	MIDAZOLAM MALEATE	13.60	MILLIGRAMMES PER MILLILITRE	POM
PL 30684/0243	10/04/2017	DAWA LIMITED	CYANOCOBALAMIN 50 MICROGRAM FILM-COATED TABLETS	CYANOCOBALAMIN	50.00	MICROGRAMMES	P
PL 20117/0260	11/04/2017	MORNINGSIDE HEALTHCARE LIMITED	DAPSONE 50 MG TABLETS	DAPSONE	50.00	MILLIGRAMMES	POM
PL 20117/0261	11/04/2017	MORNINGSIDE HEALTHCARE LIMITED	DAPSONE 100 MG TABLETS	DAPSONE	100.00	MILLIGRAMMES	POM
PL 31750/0102	11/04/2017	SUN PHARMACEUTICAL INDUSTRIES EUROPE BV	SOLIFENACIN SUCCINATE 10 MG FILM-COATED TABLETS	SOLIFENACIN SUCCINATE	10	MILLIGRAMMES	POM
PL 44673/0003	11/04/2017	GLAXOSMITHKLINE CONSUMER HEALTHCARE (UK) TRADING LIMITED	PARACETAMOL, ASCORBIC ACID, PHENYLEPHRINE HYDROCHLORIDE 750MG/60MG/10MG POWDER FOR ORAL SOLUTION	ASCORBIC ACID	60.0	MILLIGRAMMES	GSL
PL 44673/0003	11/04/2017	GLAXOSMITHKLINE CONSUMER HEALTHCARE (UK) TRADING LIMITED	PARACETAMOL, ASCORBIC ACID, PHENYLEPHRINE HYDROCHLORIDE 750MG/60MG/10MG POWDER FOR ORAL SOLUTION	PARACETAMOL	750.0	MILLIGRAMMES	GSL
PL 44673/0003	11/04/2017	GLAXOSMITHKLINE CONSUMER HEALTHCARE (UK) TRADING LIMITED	PARACETAMOL, ASCORBIC ACID, PHENYLEPHRINE HYDROCHLORIDE 750MG/60MG/10MG POWDER FOR ORAL SOLUTION	PHENYLEPHRINE HYDROCHLORIDE	10.0	MILLIGRAMMES	GSL
PL 44673/0005	11/04/2017	GLAXOSMITHKLINE CONSUMER HEALTHCARE (UK) TRADING LIMITED	PARACETAMOL AND PHENYLEPHRINE HYDROCHLORIDE 750/10 MG POWDER FOR ORAL SOLUTION	PARACETAMOL	750	MILLIGRAMMES	GSL
PL 44673/0005	11/04/2017	GLAXOSMITHKLINE CONSUMER HEALTHCARE (UK) TRADING LIMITED	PARACETAMOL AND PHENYLEPHRINE HYDROCHLORIDE 750/10 MG POWDER FOR ORAL SOLUTION	PHENYLEPHRINE HYDROCHLORIDE	10	MILLIGRAMMES	GSL

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PL 15413/0070	12/04/2017	HIKMA FARMACEUTICA (PORTUGAL) SA	CALCIUM FOLINATE 10 MG/ML SOLUTION FOR INJECTION OR INFUSION	CALCIUM FOLINATE	10.8	MILLIGRAMMES	POM
PL 16363/0511	12/04/2017	MILPHARM LIMITED	DUTASTERIDE 0.5 MG SOFT CAPSULES	DUTASTERIDE	0.500	MILLIGRAMMES	POM
PL 20075/0461	12/04/2017	ACCORD HEALTHCARE LIMITED	NEVIRAPINE 200 MG TABLETS	NEVIRAPINE ANHYDROUS	200.00	MILLIGRAMMES	POM
PL 20075/0492	12/04/2017	ACCORD HEALTHCARE LIMITED	EMTRICITABINE/TENOFOVIR DISOPROXIL 200 MG/245 MG FILM-COATED TABLETS	EMTRICITABINE	200.00	MILLIGRAMMES	POM
PL 20075/0492	12/04/2017	ACCORD HEALTHCARE LIMITED	EMTRICITABINE/TENOFOVIR DISOPROXIL 200 MG/245 MG FILM-COATED TABLETS	TENOFOVIR DISOPROXIL	245.00	MILLIGRAMMES	POM
PL 11311/0552	13/04/2017	TILLOMED LABORATORIES LIMITED	MELPHALAN 50 MG POWDER AND SOLVENT FOR SOLUTION FOR INJECTION/INFUSION	MELPHALAN	50	MILLIGRAMMES	POM
PL 40496/0007	13/04/2017	BRILLPHARMA LIMITED	ESOMEPRAZOLE 20 MG GASTRO RESISTANT TABLETS	ESOMEPRAZOLE MAGNESIUM DIHYDRATE	21.753	MILLIGRAMMES	POM
PL 42357/0228	13/04/2017	AMNEAL PHARMA EUROPE LIMITED	NICORANDIL 10 MG TABLETS	NICORANDIL	10	MILLIGRAMMES	POM
PL 42357/0229	13/04/2017	AMNEAL PHARMA EUROPE LIMITED	NICORANDIL 20 MG TABLETS	NICORANDIL	20	MILLIGRAMMES	POM
PL 44887/0001	13/04/2017	MIMER MEDICAL AB	NICASSIST 1MG/SPRAY MOUTH SPRAY	NICOTINE	1.00	MILLIGRAMMES	GSL
PL 25174/0033	18/04/2017	LABORATORIO REIG JOFRE SA	GANCICLOVIR 500 MG POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION	GANCICLOVIR SODIUM	543	MILLIGRAMMES	POM
PL 35507/0169	18/04/2017	LUPIN (EUROPE) LIMITED	TENOFOVIR DISOPROXIL LUPIN 245 MG FILM-COATED TABLETS	TENOFOVIR DISOPROXIL PHOSPHATE	291.00	MILLIGRAMMES	POM
PL 35507/0174	18/04/2017	LUPIN (EUROPE) LIMITED	EMTRICITABINE/TENOFOVIR DISOPROXIL LUPIN 200 MG/245 MG FILM-COATED TABLETS	EMTRICITABINE	200.00	MILLIGRAMMES	POM
PL 35507/0174	18/04/2017	LUPIN (EUROPE) LIMITED	EMTRICITABINE/TENOFOVIR DISOPROXIL LUPIN 200 MG/245 MG FILM-COATED TABLETS	TENOFOVIR DISOPROXIL PHOSPHATE	291.00	MILLIGRAMMES	POM
PL 35507/0189	18/04/2017	LUPIN (EUROPE) LIMITED	EMTRICITABINE/TENOFOVIR DISOPROXIL LUPIN 200 MG/245 MG FILM-COATED TABLETS	EMTRICITABINE	200	MILLIGRAMMES	POM
PL 35507/0189	18/04/2017	LUPIN (EUROPE) LIMITED	EMTRICITABINE/TENOFOVIR DISOPROXIL LUPIN 200 MG/245 MG FILM-COATED TABLETS	TENOFOVIR DISOPROXIL PHOSPHATE	291	MILLIGRAMMES	POM
PL 08828/0266	19/04/2017	FRESENIUS KABI LIMITED	ERTAPENEM 1G POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION	ERTAPENEM SODIUM	1.046	GRAMMES	POM
PL 35507/0190	19/04/2017	LUPIN (EUROPE) LIMITED	TENOFOVIR DISOPROXIL LUPIN 245 MG FILM-COATED TABLETS	TENOFOVIR DISOPROXIL PHOSPHATE	291.00	MILLIGRAMMES	POM
PL 36687/0199	19/04/2017	TORRENT PHARMA (UK) LIMITED	FENOFIBRATE 160 MG FILM-COATED TABLETS	FENOFIBRATE	160.00	MILLIGRAMMES	POM
PL 35667/0009	20/04/2017	FARMALIDER SA	IBUPROFEN 400 MG SOLUTION FOR INFUSION	IBUPROFEN	400	MILLIGRAMMES PER MILLILITRE	POM
PL 35667/0010	20/04/2017	FARMALIDER SA	IBUPROFEN 600 MG SOLUTION FOR INFUSION	IBUPROFEN	600	MILLIGRAMMES PER MILLILITRE	POM
PL 16363/0512	21/04/2017	MILPHARM LIMITED	ATORVASTATIN 30 MG FILM-COATED TABLETS	ATORVASTATIN CALCIUM TRIHYDRATE	32.472	MILLIGRAMMES	POM
PL 16363/0513	21/04/2017	MILPHARM LIMITED	ATORVASTATIN 60 MG FILM-COATED TABLETS	ATORVASTATIN CALCIUM TRIHYDRATE	64.944	MILLIGRAMMES	POM
PL 35501/0009	21/04/2017	HCS BVBA	OXYCODONE HYDROCHLORIDE/NALOXONE HYDROCHLORIDE HCS BVBA 10MG/5MG PROLONGED-RELEASE TABLETS	NALOXONE HYDROCHLORIDE DIHYDRATE	5.45	MILLIGRAMMES	POM
PL 35501/0009	21/04/2017	HCS BVBA	OXYCODONE HYDROCHLORIDE/NALOXONE HYDROCHLORIDE HCS BVBA 10MG/5MG PROLONGED-RELEASE TABLETS	OXYCODONE HYDROCHLORIDE	10.00	MILLIGRAMMES	POM
PL 35501/0010	21/04/2017	HCS BVBA	OXYCODONE HYDROCHLORIDE/NALOXONE HYDROCHLORIDE HCS BVBA 20MG/10MG PROLONGED-RELEASE TABLETS	NALOXONE HYDROCHLORIDE DIHYDRATE	10.90	MILLIGRAMMES	POM
PL 35501/0010	21/04/2017	HCS BVBA	OXYCODONE HYDROCHLORIDE/NALOXONE HYDROCHLORIDE HCS BVBA 20MG/10MG PROLONGED-RELEASE TABLETS	OXYCODONE HYDROCHLORIDE	20.00	MILLIGRAMMES	POM
PL 35501/0011	21/04/2017	HCS BVBA	OXYCODONE HYDROCHLORIDE/NALOXONE HYDROCHLORIDE HCS BVBA 40MG/20MG PROLONGED-RELEASE TABLETS	NALOXONE HYDROCHLORIDE DIHYDRATE	21.80	MILLIGRAMMES	POM
PL 35501/0011	21/04/2017	HCS BVBA	OXYCODONE HYDROCHLORIDE/NALOXONE HYDROCHLORIDE HCS BVBA 40MG/20MG PROLONGED-RELEASE TABLETS	OXYCODONE HYDROCHLORIDE	40.00	MILLIGRAMMES	POM
PL 21039/0046	24/04/2017	IBSA FARMACEUTICI ITALIA S.R.L.	MERIOFERT 75 IU POWDER AND SOLVENT FOR SOLUTION FOR INJECTION	MENOTROPHIN	75	INTERNATIONAL UNITS	POM
PL 21039/0047	24/04/2017	IBSA FARMACEUTICI ITALIA S.R.L.	MERIOFERT 150 IU POWDER AND SOLVENT FOR SOLUTION FOR INJECTION	MENOTROPHIN	150	INTERNATIONAL UNITS	POM

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PL 41386/0002	24/04/2017	KLINGE PHARMA GMBH	EMTRICITABINE/TENOFOVIR DISOPROXIL KLINGE 200 MG/245 MG FILM-COATED TABLETS	EMTRICITABINE	200.00	MILLIGRAMMES	POM
PL 41386/0002	24/04/2017	KLINGE PHARMA GMBH	EMTRICITABINE/TENOFOVIR DISOPROXIL KLINGE 200 MG/245 MG FILM-COATED TABLETS	TENOFOVIR DISOPROXIL PHOSPHATE	291.00	MILLIGRAMMES	POM
PL 20075/0498	25/04/2017	ACCORD HEALTHCARE LIMITED	METUXTAN SR 500 MG PROLONGED RELEASE TABLETS	METFORMIN HYDROCHLORIDE	500	MILLIGRAMMES	POM
PL 20117/0263	25/04/2017	MORNINGSIDE HEALTHCARE LIMITED	PROCHLORPERAZINE MALEATE 3MG BUCCAL TABLETS	PROCHLORPERAZINE MALEATE	3	MILLIGRAMMES	P
PL 20117/0264	25/04/2017	MORNINGSIDE HEALTHCARE LIMITED	PROCHLORPERAZINE MALEATE 3MG BUCCAL TABLETS	PROCHLORPERAZINE MALEATE	3	MILLIGRAMMES	POM
PL 00063/0749	26/04/2017	RECKITT BENCKISER HEALTHCARE (UK) LIMITED	GAVISCON ADVANCE ANISEED FLAVOUR ORAL SUSPENSION	POTASSIUM HYDROGEN CARBONATE	20	MILLIGRAMMES PER MILLILITRE	GSL
PL 00063/0749	26/04/2017	RECKITT BENCKISER HEALTHCARE (UK) LIMITED	GAVISCON ADVANCE ANISEED FLAVOUR ORAL SUSPENSION	SODIUM ALGINATE	100	MILLIGRAMMES PER MILLILITRE	GSL
PL 27583/0236	26/04/2017	APOTEX EUROPE BV	EMTRICITABINE/ TENOFOVIR DISOPROXIL APOTEX EUROPE BV 200 MG/245 MG FILM-COATED TABLETS	EMTRICITABINE	200.0	MILLIGRAMMES	POM
PL 27583/0236	26/04/2017	APOTEX EUROPE BV	EMTRICITABINE/ TENOFOVIR DISOPROXIL APOTEX EUROPE BV 200 MG/245 MG FILM-COATED TABLETS	TENOFOVIR DISOPROXIL	245.0	MILLIGRAMMES	POM
PL 44254/0001	26/04/2017	PAR LABORATORIES EUROPE LIMITED	ATRANSIPAR 200MG/25MG MODIFIED-RELEASE CAPSULE, HARD	ACETYSALICYLIC ACID	25.00	MILLIGRAMMES	POM
PL 44254/0001	26/04/2017	PAR LABORATORIES EUROPE LIMITED	ATRANSIPAR 200MG/25MG MODIFIED-RELEASE CAPSULE, HARD	DIPYRIDAMOLE	200.00	MILLIGRAMMES	POM
PL 40546/0008	27/04/2017	ARISTO PHARMA GMBH	EMTRICITABINE/TENOFOVIR DISOPROXIL ARISTO 200 MG/245 MG FILM-COATED TABLETS	EMTRICITABINE	200.00	MILLIGRAMMES	POM
PL 40546/0008	27/04/2017	ARISTO PHARMA GMBH	EMTRICITABINE/TENOFOVIR DISOPROXIL ARISTO 200 MG/245 MG FILM-COATED TABLETS	TENOFOVIR DISOPROXIL PHOSPHATE	291.00	MILLIGRAMMES	POM
PL 16363/0492	28/04/2017	MILPHARM LIMITED	AUROBEVERINE MR 200 MG MODIFIED-RELEASE CAPSULES, HARD	MEBEVERINE HYDROCHLORIDE	200	MILLIGRAMMES	POM
PL 17780/0792	28/04/2017	WINTHROP PHARMACEUTICALS UK LIMITED	ENTECAVIR ZENTIVA 0.5 MG FILM-COATED TABLETS	ENTECAVIR	0.5	MILLIGRAMMES	POM
PL 17780/0793	28/04/2017	WINTHROP PHARMACEUTICALS UK LIMITED	ENTECAVIR ZENTIVA 1.0 MG FILM-COATED TABLETS	ENTECAVIR	1.000	MILLIGRAMMES	POM
PL 25258/0233	28/04/2017	GLENMARK PHARMACEUTICALS EUROPE LIMITED	ENTECAVIR 0.5 MG FILM-COATED TABLETS	ENTECAVIR	0.500	MILLIGRAMMES	POM
PL 25258/0234	28/04/2017	GLENMARK PHARMACEUTICALS EUROPE LIMITED	ENTECAVIR 1 MG FILM-COATED TABLETS	ENTECAVIR	1.000	MILLIGRAMMES	POM
PL 30306/0721	28/04/2017	ACTAVIS GROUP PTC EHF	AUDAVATE 0.1% W/W CREAM	BETAMETHASONE VALERATE	0.122	GRAMMES	POM