

Marketing authorisations granted in August 2017

PL Number	Grant Date	MA Holder	Licensed Name(s)	Active Ingredient	Quantity	Units	Legal Status
PL 20117/0277	01/08/2017	MORNINGSIDE HEALTHCARE LIMITED	METABET SR 750 MG PROLONGED RELEASE TABLETS	METFORMIN HYDROCHLORIDE	750.00	MILLIGRAMMES	POM
PL 42357/0233	01/08/2017	AMNEAL PHARMA EUROPE LIMITED	ENTECAVIR AMNEAL 0.5 MG FILM-COATED TABLETS	ENTECAVIR MONOHYDRATE	0.53	MILLIGRAMMES	POM
PL 42357/0234	01/08/2017	AMNEAL PHARMA EUROPE LIMITED	ENTECAVIR AMNEAL 1 MG FILM-COATED TABLETS	ENTECAVIR MONOHYDRATE	1.06	MILLIGRAMMES	POM
PL 46734/0001	01/08/2017	ECKERT & ZIEGLER RADIOPHARMA GMBH	GALLIAPHARM 0.74 - 1.85 GBQ RADIONUCLIDE GENERATOR	GALLIUM (GA 68) CHLORIDE	0.50	GIGA BECQUEREL UNITS	POM
PL 46734/0001	01/08/2017	ECKERT & ZIEGLER RADIOPHARMA GMBH	GALLIAPHARM 0.74 - 1.85 GBQ RADIONUCLIDE GENERATOR	GERMANIUM (68GE) CHLORIDE	0.74	GIGA BECQUEREL UNITS	POM
PL 44853/0001	02/08/2017	KENSINGTON PHARMA LIMITED	GANCICLOVIR 500 MG POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION	GANCICLOVIR SODIUM	546.00	MILLIGRAMMES	POM
PL 39307/0052	03/08/2017	SYRI LIMITED	CLONAZEPAM THAME 0.5MG/5ML ORAL SOLUTION	CLONAZEPAM	0.5	MILLIGRAMMES	POM
PL 39307/0053	03/08/2017	SYRI LIMITED	CLONAZEPAM THAME 2MG/5ML ORAL SOLUTION	CLONAZEPAM	2.0	MILLIGRAMMES	POM
PL 40546/0042	03/08/2017	ARISTO PHARMA GMBH	ENTECAVIR ARISTO 0.5 MG FILM-COATED TABLETS	ENTECAVIR MONOHYDRATE	0.53	MILLIGRAMMES	POM
PL 40546/0043	03/08/2017	ARISTO PHARMA GMBH	ENTECAVIR ARISTO 1 MG FILM-COATED TABLETS	ENTECAVIR MONOHYDRATE	1.06	MILLIGRAMMES	POM
PL 43008/0003	03/08/2017	UNIMEDIC AB	PHENYLEPHRINE UNIMEDIC 10 MG/ML, CONCENTRATE FOR SOLUTION FOR INJECTION/INFUSION	PHENYLEPHRINE HYDROCHLORIDE	10.000	MILLIGRAMMES	POM
PL 17780/0776	07/08/2017	WINTHROP PHARMACEUTICALS UK LIMITED	ABACAVIR/LAMIVUDINE ZENTIVA 600 MG/300 MG FILM-COATED TABLETS	ABACAVIR SULFATE	702.00	MILLIGRAMMES	POM
PL 17780/0776	07/08/2017	WINTHROP PHARMACEUTICALS UK LIMITED	ABACAVIR/LAMIVUDINE ZENTIVA 600 MG/300 MG FILM-COATED TABLETS	LAMIVUDINE	300.00	MILLIGRAMMES	POM
PL 39307/0071	07/08/2017	SYRI LIMITED	AMLODIPINE 5MG/5ML ORAL SOLUTION	AMLODIPINE BESILATE	6.935	MILLIGRAMMES PER 5 MILLILITRE	POM
PL 39307/0072	07/08/2017	SYRI LIMITED	AMLODIPINE 10MG/5ML ORAL SOLUTION	AMLODIPINE BESILATE	13.87	MILLIGRAMMES PER 5 MILLILITRE	POM
PL 04416/1512	08/08/2017	SANDOZ LIMITED	ATOMOXETINE SANDOZ 10 MG CAPSULES, HARD	ATOMOXETINE HYDROCHLORIDE	11.4278	MILLIGRAMMES	POM
PL 04416/1513	08/08/2017	SANDOZ LIMITED	ATOMOXETINE SANDOZ 18 MG CAPSULES, HARD	ATOMOXETINE HYDROCHLORIDE	20.5700	MILLIGRAMMES	POM
PL 04416/1514	08/08/2017	SANDOZ LIMITED	ATOMOXETINE SANDOZ 25 MG CAPSULES, HARD	ATOMOXETINE HYDROCHLORIDE	28.5695	MILLIGRAMMES	POM
PL 04416/1515	08/08/2017	SANDOZ LIMITED	ATOMOXETINE SANDOZ 40 MG CAPSULES, HARD	ATOMOXETINE HYDROCHLORIDE	45.7111	MILLIGRAMMES	POM
PL 04416/1516	08/08/2017	SANDOZ LIMITED	ATOMOXETINE SANDOZ 60 MG CAPSULES, HARD	ATOMOXETINE HYDROCHLORIDE	68.5667	MILLIGRAMMES	POM
PL 04416/1517	08/08/2017	SANDOZ LIMITED	ATOMOXETINE SANDOZ 80 MG CAPSULES, HARD	ATOMOXETINE HYDROCHLORIDE	91.4223	MILLIGRAMMES	POM
PL 04416/1518	08/08/2017	SANDOZ LIMITED	ATOMOXETINE SANDOZ 100 MG CAPSULES, HARD	ATOMOXETINE HYDROCHLORIDE	114.2779	MILLIGRAMMES	POM
PL 06464/3086	08/08/2017	WAYMADE PLC	ZONISAMIDE WAYMADE 25 MG HARD CAPSULES	ZONISAMIDE	25.000	MILLIGRAMMES	POM
PL 06464/3087	08/08/2017	WAYMADE PLC	ZONISAMIDE WAYMADE 50 MG HARD CAPSULES	ZONISAMIDE	50.000	MILLIGRAMMES	POM
PL 06464/3088	08/08/2017	WAYMADE PLC	ZONISAMIDE WAYMADE 100 MG HARD CAPSULES	ZONISAMIDE	100.000	MILLIGRAMMES	POM
PL 31103/0024	09/08/2017	BLUMONT PHARMA LIMITED	ACETAZOLAMIDE 250MG TABLETS	ACETAZOLAMIDE	250	MILLIGRAMMES	POM
PL 31103/0024	09/08/2017	BLUMONT PHARMA LIMITED	CETAMOKS 250 MG TABLETS	ACETAZOLAMIDE	250	MILLIGRAMMES	POM
PL 46752/0001	09/08/2017	SEQIRUS SRL	FLUAD, SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	INFLUENZA VIRUS STRAINS -	15	MICROGRAMMES	POM
PL 42357/0252	10/08/2017	AMNEAL PHARMA EUROPE LIMITED	MYLOXIFIN 5 MG/2.5 MG PROLONGED-RELEASE TABLETS	NALOXONE HYDROCHLORIDE DIHYDRATE	2.74	MILLIGRAMMES	POM
PL 42357/0252	10/08/2017	AMNEAL PHARMA EUROPE LIMITED	MYLOXIFIN 5 MG/2.5 MG PROLONGED-RELEASE TABLETS	OXYCODONE HYDROCHLORIDE	5.00	MILLIGRAMMES	POM
PL 42357/0253	10/08/2017	AMNEAL PHARMA EUROPE LIMITED	MYLOXIFIN 10MG/5 MG PROLONGED-RELEASE TABLETS	NALOXONE HYDROCHLORIDE DIHYDRATE	5.45	MILLIGRAMMES	POM

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PL 42357/0253	10/08/2017	AMNEAL PHARMA EUROPE LIMITED	MYLOXIFIN 10MG/5 MG PROLONGED-RELEASE TABLETS	OXYCODONE HYDROCHLORIDE	10.00	MILLIGRAMMES	POM
PL 42357/0254	10/08/2017	AMNEAL PHARMA EUROPE LIMITED	MYLOXIFIN 20MG/10 MG PROLONGED-RELEASE TABLETS	NALOXONE HYDROCHLORIDE DIHYDRATE	10.90	MILLIGRAMMES	POM
PL 42357/0254	10/08/2017	AMNEAL PHARMA EUROPE LIMITED	MYLOXIFIN 20MG/10 MG PROLONGED-RELEASE TABLETS	OXYCODONE HYDROCHLORIDE	20.00	MILLIGRAMMES	POM
PL 42357/0255	10/08/2017	AMNEAL PHARMA EUROPE LIMITED	MYLOXIFIN 30MG/15 MG PROLONGED-RELEASE TABLETS	NALOXONE HYDROCHLORIDE DIHYDRATE	16.35	MILLIGRAMMES	POM
PL 42357/0255	10/08/2017	AMNEAL PHARMA EUROPE LIMITED	MYLOXIFIN 30MG/15 MG PROLONGED-RELEASE TABLETS	OXYCODONE HYDROCHLORIDE	30.00	MILLIGRAMMES	POM
PL 42357/0256	10/08/2017	AMNEAL PHARMA EUROPE LIMITED	MYLOXIFIN 40MG/20MG PROLONGED-RELEASE TABLETS	NALOXONE HYDROCHLORIDE DIHYDRATE	21.80	MILLIGRAMMES	POM
PL 42357/0256	10/08/2017	AMNEAL PHARMA EUROPE LIMITED	MYLOXIFIN 40MG/20MG PROLONGED-RELEASE TABLETS	OXYCODONE HYDROCHLORIDE	40.00	MILLIGRAMMES	POM
PL 04416/1511	11/08/2017	SANDOZ LIMITED	BORTEZOMIB EBEWE 3.5 MG POWDER FOR SOLUTION FOR INJECTION	BORTEZOMIB	3.5	MILLIGRAMMES	POM
PL 16363/0489	11/08/2017	MILPHARM LIMITED	LINEZOLID 2 MG/ML SOLUTION FOR INFUSION	LINEZOLID	2.0	MILLIGRAMMES PER MILLILITRE	POM
PL 00289/2116	14/08/2017	TEVA UK LIMITED	LIOTHYRONINE SODIUM 20 MICROGRAM TABLETS	LIOTHYRONINE SODIUM	20	MICROGRAMMES	POM
PL 41188/0013	14/08/2017	JENSONR PLUS LIMITED	ENTECAVIR 0.5 MG FILM-COATED TABLETS	ENTECAVIR	0.50	MILLIGRAMMES	POM
PL 41188/0014	14/08/2017	JENSONR PLUS LIMITED	ENTECAVIR 1 MG FILM-COATED TABLETS	ENTECAVIR	1	MILLIGRAMMES	POM
PL 42765/0003	14/08/2017	RENATA (UK) LIMITED	HYDROCORTISONE 10 MG TABLETS	HYDROCORTISONE	10.00	MILLIGRAMMES	POM
PL 42765/0004	14/08/2017	RENATA (UK) LIMITED	HYDROCORTISONE 20 MG TABLETS	HYDROCORTISONE	20.00	MILLIGRAMMES	POM
PL 08553/0580	15/08/2017	DR REDDY'S LABORATORIES (UK) LIMITED	DAPTOMYCIN DR. REDDY'S 350 MG POWDER FOR SOLUTION FOR INJECTION/INFUSION	DAPTOMYCIN	350.00	MILLIGRAMMES	POM
PL 08553/0581	15/08/2017	DR REDDY'S LABORATORIES (UK) LIMITED	DAPTOMYCIN DR. REDDY'S 500 MG POWDER FOR SOLUTION FOR INJECTION/INFUSION	DAPTOMYCIN	500.00	MILLIGRAMMES	POM
PL 39307/0077	15/08/2017	SYRI LIMITED	CITALOPRAM 40MG/ML ORAL DROPS, SOLUTION	CITALOPRAM HYDROCHLORIDE	44.48	MILLIGRAMMES PER MILLILITRE	POM
PL 00043/0219	17/08/2017	LEO LABORATORIES LIMITED	DOVONEX PSORIASIS 50 MICROGRAM PER G OINTMENT	CALCIPOTRIOL ANHYDROUS	50	MICROGRAMMES PER GRAM	P
PL 00289/2091	18/08/2017	TEVA UK LIMITED	ANAGRELIDE 0.5 MG HARD CAPSULES	ANAGRELIDE HYDROCHLORIDE MONOHYDRATE	0.61	MILLIGRAMMES	POM
PL 20416/0376	18/08/2017	CRESCENT PHARMA LIMITED	NARATRIPTAN 2.5 MG FILM-COATED TABLETS	NARATRIPTAN HYDROCHLORIDE	2.78	MILLIGRAMMES	POM
PL 43801/0052	18/08/2017	SCIECURE PHARMA LIMITED	CLOPIDOGREL SCIECURE 75MG FILM-COATED TABLETS	CLOPIDOGREL BISULFATE	75.000	MILLIGRAMMES	POM
PL 44202/0001	18/08/2017	CONVENTIA MEDICAL LLP	DICLOALGAN 12.5 MG SOFT CAPSULES	DICLOFENAC EPOLAMINE	15.38	MILLIGRAMMES	POM
PL 44202/0002	18/08/2017	CONVENTIA MEDICAL LLP	DICLOALGAN 25 MG SOFT CAPSULES	DICLOFENAC EPOLAMINE	30.76	MILLIGRAMMES	POM
PL 44278/0003	22/08/2017	NOVELGENIX THERAPEUTICS LIMITED	HYDROCORTISONE 10MG TABLETS	HYDROCORTISONE	10.00	MILLIGRAMMES	POM
PL 44278/0004	22/08/2017	NOVELGENIX THERAPEUTICS LIMITED	HYDROCORTISONE 20MG TABLETS	HYDROCORTISONE	20	MILLIGRAMMES	POM
PL 00015/0375	23/08/2017	BOEHRINGER INGELHEIM LIMITED	SODIUM PICOSULFATE 5 MG / 5 ML ORAL SOLUTION	SODIUM PICOSULFATE	100	MILLIGRAMMES	GSL
PL 17589/0010	23/08/2017	DEMO SA PHARMACEUTICAL INDUSTRY	MAGNESIUM SULFATE 10% W/V SOLUTION FOR INJECTION OR INFUSION	MAGNESIUM SULFATE HEPTAHYDRATE	100.0	MILLIGRAMMES PER MILLILITRE	POM
PL 17589/0011	23/08/2017	DEMO SA PHARMACEUTICAL INDUSTRY	MAGNESIUM SULFATE 50% W/V SOLUTION FOR INJECTION OR CONCENTRATE FOR SOLUTION FOR INJECTION OR INFUSION	MAGNESIUM SULFATE HEPTAHYDRATE	500.0	MILLIGRAMMES PER MILLILITRE	POM
PL 21880/0199	24/08/2017	MEDREICH PLC	METFORMIN 500MG FILM-COATED TABLETS	METFORMIN HYDROCHLORIDE	500	MILLIGRAMMES	POM
PL 21880/0200	24/08/2017	MEDREICH PLC	METFORMIN 850MG FILM-COATED TABLETS	METFORMIN HYDROCHLORIDE	850	MILLIGRAMMES	POM
PL 11311/0547	25/08/2017	TILLOMED LABORATORIES LIMITED	RIZATRIPTAN 5 MG ORODISPERSIBLE TABLETS	RIZATRIPTAN BENZOATE	7.265	MILLIGRAMMES	POM

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PL 11311/0548	25/08/2017	TILLOMED LABORATORIES LIMITED	RIZATRIPTAN 10 MG ORODISPERSIBLE TABLETS	RIZATRIPTAN BENZOATE	14.530	MILLIGRAMMES	POM
PL 20416/0532	25/08/2017	CRESCENT PHARMA LIMITED	VARDENAFIL CRESCENT 5MG FILM-COATED TABLETS	VARDENAFIL HYDROCHLORIDE TRIHYDRATE	5.928	MILLIGRAMMES	POM
PL 20416/0533	25/08/2017	CRESCENT PHARMA LIMITED	VARDENAFIL CRESCENT 10MG FILM-COATED TABLETS	VARDENAFIL HYDROCHLORIDE TRIHYDRATE	11.855	MILLIGRAMMES	POM
PL 20416/0534	25/08/2017	CRESCENT PHARMA LIMITED	VARDENAFIL CRESCENT 20MG FILM-COATED TABLETS	VARDENAFIL HYDROCHLORIDE TRIHYDRATE	23.710	MILLIGRAMMES	POM
PL 21597/0027	25/08/2017	G L PHARMA GMBH	OXSORALEN 20 MICROGRAMS/ML SOLUTION FOR BLOOD FRACTION MODIFICATION	METHOXSALEN	0.020	MILLIGRAMMES PER MILLILITRE	POM
PL 30322/0005	25/08/2017	ALISSA HEALTHCARE RESEARCH LIMITED	VITAMIN D3 10,000 IU CAPSULES, SOFT	COLECALCIFEROL	0.275	MILLIGRAMMES	POM
PL 30322/0020	25/08/2017	ALISSA HEALTHCARE RESEARCH LIMITED	VITAMIN D3 400 IU CAPSULES, SOFT	COLECALCIFEROL	0.0110	MILLIGRAMMES	POM
PL 30322/0022	25/08/2017	ALISSA HEALTHCARE RESEARCH LIMITED	VITAMIN D3 1,000 IU CAPSULES, SOFT	COLECALCIFEROL	0.0275	MILLIGRAMMES	POM
PL 43801/0010	25/08/2017	SCIECURE PHARMA LIMITED	IRBESARTAN HYDROCHLOROTHIAZIDE 150 MG/12.5 MG FILM-COATED TABLETS	HYDROCHLOROTHIAZIDE	12.5	MILLIGRAMMES	POM
PL 43801/0010	25/08/2017	SCIECURE PHARMA LIMITED	IRBESARTAN HYDROCHLOROTHIAZIDE 150 MG/12.5 MG FILM-COATED TABLETS	IRBESARTAN	150.0	MILLIGRAMMES	POM
PL 43801/0011	25/08/2017	SCIECURE PHARMA LIMITED	IRBESARTAN HYDROCHLOROTHIAZIDE 300 MG/12.5 MG FILM-COATED TABLETS	HYDROCHLOROTHIAZIDE	12.5	MILLIGRAMMES	POM
PL 43801/0011	25/08/2017	SCIECURE PHARMA LIMITED	IRBESARTAN HYDROCHLOROTHIAZIDE 300 MG/12.5 MG FILM-COATED TABLETS	IRBESARTAN	300	MILLIGRAMMES	POM
PL 43801/0012	25/08/2017	SCIECURE PHARMA LIMITED	IRBESARTAN HYDROCHLOROTHIAZIDE 300 MG/25 MG FILM-COATED TABLETS.	HYDROCHLOROTHIAZIDE	25	MILLIGRAMMES	POM
PL 43801/0012	25/08/2017	SCIECURE PHARMA LIMITED	IRBESARTAN HYDROCHLOROTHIAZIDE 300 MG/25 MG FILM-COATED TABLETS.	IRBESARTAN	300	MILLIGRAMMES	POM
PL 36390/0224	29/08/2017	CIPLA (EU) LIMITED	ENTECAVIR CIPLA 0.5 MG FILM COATED TABLETS	ENTECAVIR	0.500	MILLIGRAMMES	POM
PL 36390/0225	29/08/2017	CIPLA (EU) LIMITED	ENTECAVIR CIPLA 1.0 MG FILM COATED TABLETS	ENTECAVIR	1.000	MILLIGRAMMES	POM
PL 46180/0001	29/08/2017	AFDOS PHARMACEUTICALS LIMITED	MOXIFLOXACIN 400 MG FILM-COATED TABLETS	MOXIFLOXACIN HYDROCHLORIDE	436.80	MILLIGRAMMES	POM
PL 21597/0016	30/08/2017	G L PHARMA GMBH	OXYCODONE HYDROCHLORIDE/NALOXONE HYDROCHLORIDE G.L. PHARMA 5 MG/2.5 MG PROLONGED-RELEASE TABLET	NALOXONE HYDROCHLORIDE DIHYDRATE	2.75	MILLIGRAMMES	POM
PL 21597/0016	30/08/2017	G L PHARMA GMBH	OXYCODONE HYDROCHLORIDE/NALOXONE HYDROCHLORIDE G.L. PHARMA 5 MG/2.5 MG PROLONGED-RELEASE TABLET	OXYCODONE HYDROCHLORIDE	5	MILLIGRAMMES	POM
PL 25298/0083	30/08/2017	BROWN & BURK UK LIMITED	ETORICOXIB 30MG FILM-COATED TABLETS	ETORICOXIB	30	MILLIGRAMMES	POM
PL 25298/0084	30/08/2017	BROWN & BURK UK LIMITED	ETORICOXIB 60MG FILM-COATED TABLETS	ETORICOXIB	60	MILLIGRAMMES	POM
PL 25298/0085	30/08/2017	BROWN & BURK UK LIMITED	ETORICOXIB 90MG FILM-COATED TABLETS	ETORICOXIB	90	MILLIGRAMMES	POM
PL 25298/0086	30/08/2017	BROWN & BURK UK LIMITED	ETORICOXIB 120MG FILM-COATED TABLETS	ETORICOXIB	120	MILLIGRAMMES	POM
PL 42357/0244	30/08/2017	AMNEAL PHARMA EUROPE LIMITED	ABACAVIR/LAMIVUDINE 600MG/300MG FILM-COATED TABLETS	ABACAVIR HYDROCHLORIDE	676.401	MILLIGRAMMES	POM
PL 42357/0244	30/08/2017	AMNEAL PHARMA EUROPE LIMITED	ABACAVIR/LAMIVUDINE 600MG/300MG FILM-COATED TABLETS	LAMIVUDINE	300	MILLIGRAMMES	POM