

## Marketing authorisations granted in May 2016

PL Number	Grant Date	MA Holder	Licensed Name(s)	Active Ingredient	Quantity	Units	Legal Status
PL 16363/0479	04/05/2016	MILPHARM LIMITED	NAPROXEN 250 MG TABLETS	NAPROXEN	250	MILLIGRAMMES	POM
PL 16363/0480	04/05/2016	MILPHARM LIMITED	NAPROXEN 500 MG TABLETS	NAPROXEN	500	MILLIGRAMMES	POM
PL 17780/0758	05/05/2016	WINTHROP PHARMACEUTICALS UK LIMITED	DUTASTERIDE 0.5MG SOFT CAPSULES	DUTASTERIDE	0.5	MILLIGRAMMES	POM
PL 20075/0445	05/05/2016	ACCORD HEALTHCARE LIMITED	BUSULFAN 6 MG/ML CONCENTRATE FOR SOLUTION FOR INFUSION	BUSULFAN	6.00	MILLIGRAMMES	POM
PL 42357/0181	05/05/2016	AMNEAL PHARMA EUROPE LIMITED	DUTASTERIDE 0.5 MG SOFT CAPSULES	DUTASTERIDE	0.5	MILLIGRAMMES	POM
PL 42831/0005	05/05/2016	WARREN GENERICS SRO	LATANOPROST / TIMOLOL 50 MICROGRAMS / ML + 5 MG / ML EYE DROPS, SOLUTION	LATANOPROST	0.05	MILLIGRAMMES	POM
PL 42831/0005	05/05/2016	WARREN GENERICS SRO	LATANOPROST / TIMOLOL 50 MICROGRAMS / ML + 5 MG / ML EYE DROPS, SOLUTION	TIMOLOL MALEATE	6.8	MILLIGRAMMES	POM
PL 21880/0172	06/05/2016	MEDREICH PLC	PAROXETINE 10 MG FILM-COATED TABLETS	PAROXETINE HYDROCHLORIDE HEMIHYDRATE	11.38	MILLIGRAMMES	POM
PL 35507/0160	06/05/2016	LUPIN (EUROPE) LIMITED	EMTRICITABINE / TENOFOVIR DISOPROXIL LUPIN 200MG/245MG FILM-COATED TABLETS	EMTRICITABINE	200.00	MILLIGRAMMES	POM
PL 35507/0160	06/05/2016	LUPIN (EUROPE) LIMITED	EMTRICITABINE / TENOFOVIR DISOPROXIL LUPIN 200MG/245MG FILM-COATED TABLETS	TENOFOVIR DISOPROXIL FUMARATE	300.00	MILLIGRAMMES	POM
PL 00289/1989	10/05/2016	TEVA UK LIMITED	EZETIMIBE 10 MG TABLETS	EZETIMIBE	10.00	MILLIGRAMMES	POM
PL 36065/0001	10/05/2016	PHAGECON - SERVICOS E CONSULATORIA FARMACEUTICA LDA	ERYTHROMYCIN 1G POWDER FOR SOLUTION FOR INFUSION	ERYTHROMYCIN LACTOBIONATE	1.4882	GRAMMES	POM
PL 43362/0004	10/05/2016	CIPLA EUROPE NV	BIVALIRUDIN CIPLA 250 MG POWDER FOR CONCENTRATE FOR SOLUTION FOR INJECTION/INFUSION	BIVALIRUDIN	250.00	MILLIGRAMMES	POM
PL 17907/0392	11/05/2016	BRISTOL LABORATORIES LIMITED	TRAMADOL HYDROCHLORIDE/PARACETAMOL 37.5MG/325 MG FILM-COATED TABLETS	PARACETAMOL	325	MILLIGRAMMES	POM
PL 17907/0392	11/05/2016	BRISTOL LABORATORIES LIMITED	TRAMADOL HYDROCHLORIDE/PARACETAMOL 37.5MG/325 MG FILM-COATED TABLETS	TRAMADOL HYDROCHLORIDE	37.5	MILLIGRAMMES	POM
PL 24837/0080	11/05/2016	CONSILIENT HEALTH LIMITED	VIOLITE 100/20 MICROGRAMS FILM-COATED TABLETS	ETHINYLESTRADIOL	0.1	MILLIGRAMMES	POM
PL 24837/0080	11/05/2016	CONSILIENT HEALTH LIMITED	VIOLITE 100/20 MICROGRAMS FILM-COATED TABLETS	LEVONORGESTREL	0.02	MILLIGRAMMES	POM
PL 33831/0028	11/05/2016	BLUE BIO PHARMACEUTICALS LIMITED	CALCIUM CARBONATE / COLECALCIFEROL 1250MG / 400IU CHEWABLE TABLETS	CALCIUM CARBONATE	1250.00	MILLIGRAMMES	P
PL 33831/0028	11/05/2016	BLUE BIO PHARMACEUTICALS LIMITED	CALCIUM CARBONATE / COLECALCIFEROL 1250MG / 400IU CHEWABLE TABLETS	COLECALCIFEROL CONCENTRATE (POWDER FORM)	400.00	INTERNATIONAL UNITS	P
PL 36780/0003	11/05/2016	INFOMED FLUIDS SRL	LEVOFLOXACIN 5 MG/ML SOLUTION FOR INFUSION	LEVOFLOXACIN HEMIHYDRATE	5.12	MILLIGRAMMES PER MILLILITRE	POM
PL 43362/0016	11/05/2016	CIPLA (EU) LIMITED	VALGANCICLOVIR 450 MG FILM-COATED TABLETS	VALGANCICLOVIR HYDROCHLORIDE	496.30	MILLIGRAMMES	POM
PL 19611/0193	13/05/2016	NICHE GENERICS LIMITED	ARIPIRAZOLE NICHE 5 MG TABLETS	ARIPIRAZOLE	5.00	MILLIGRAMMES	POM
PL 19611/0194	13/05/2016	NICHE GENERICS LIMITED	ARIPIRAZOLE NICHE 10 MG TABLETS	ARIPIRAZOLE	10.00	MILLIGRAMMES	POM
PL 19611/0195	13/05/2016	NICHE GENERICS LIMITED	ARIPIRAZOLE NICHE 15 MG TABLETS	ARIPIRAZOLE	15.00	MILLIGRAMMES	POM
PL 19611/0196	13/05/2016	NICHE GENERICS LIMITED	ARIPIRAZOLE NICHE 30 MG TABLETS	ARIPIRAZOLE	30.00	MILLIGRAMMES	POM

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PL 23218/0135	13/05/2016	LABORATORIOS LICONSA SA	DUTASTERIDE 0.5 MG SOFT CAPSULES	DUTASTERIDE	0.5	MILLIGRAMMES	POM
PL 30306/0649	13/05/2016	ACTAVIS GROUP PTC EHF	TADALAFIL ACTAVIS 2.5 MG FILM-COATED TABLETS	TADALAFIL	2.50	MILLIGRAMMES	POM
PL 30306/0650	13/05/2016	ACTAVIS GROUP PTC EHF	TADALAFIL ACTAVIS 5 MG FILM-COATED TABLETS	TADALAFIL	5.00	MILLIGRAMMES	POM
PL 30306/0651	13/05/2016	ACTAVIS GROUP PTC EHF	TADALAFIL ACTAVIS 10 MG FILM-COATED TABLETS	TADALAFIL	10.00	MILLIGRAMMES	POM
PL 30306/0652	13/05/2016	ACTAVIS GROUP PTC EHF	TADALAFIL ACTAVIS 20 MG FILM-COATED TABLETS	TADALAFIL	20.00	MILLIGRAMMES	POM
PL 39307/0034	13/05/2016	SYRI LIMITED	ACICLOVIR 200MG/5ML ORAL SUSPENSION	ACICLOVIR	200	MILLIGRAMMES PER 5 MILLILITR	POM
PL 39307/0035	13/05/2016	SYRI LIMITED	ACICLOVIR 400MG/5ML ORAL SUSPENSION	ACICLOVIR	400.00	MILLIGRAMMES PER 5 MILLILITR	POM
PL 42357/0216	17/05/2016	AMNEAL PHARMA EUROPE LIMITED	SEVELAMER CARBONATE AMNEAL 800 MG FILM-COATED TABLETS	SEVELAMER CARBONATE	800.00	MILLIGRAMMES	POM
PL 03194/0118	18/05/2016	FERRING PHARMACEUTICALS LIMITED	NOQDIRNA 25 MICROGRAM ORAL LYOPHILISATE	DESMOPRESSIN ACETATE	0.025	MILLIGRAMMES	POM
PL 03194/0119	18/05/2016	FERRING PHARMACEUTICALS LIMITED	NOQDIRNA 50 MICROGRAM ORAL LYOPHILISATE	DESMOPRESSIN ACETATE	0.050	MILLIGRAMMES	POM
PL 13621/0070	18/05/2016	FLYNN PHARMA LIMITED	RASAGILINE FLYNN 1 MG TABLETS	RASAGILINE TARTRATE	1.44	MILLIGRAMMES	POM
PL 17907/0539	18/05/2016	BRISTOL LABORATORIES LIMITED	TELMISARTAN BRISTOL LABORATORIES 20 MG TABLETS	TELMISARTAN	20.00	MILLIGRAMMES	POM
PL 17907/0540	18/05/2016	BRISTOL LABORATORIES LIMITED	TELMISARTAN BRISTOL LABORATORIES 40 MG TABLETS	TELMISARTAN	40.00	MILLIGRAMMES	POM
PL 17907/0541	18/05/2016	BRISTOL LABORATORIES LIMITED	TELMISARTAN BRISTOL LABORATORIES 80MG TABLETS	TELMISARTAN	80.00	MILLIGRAMMES	POM
PL 30464/0170	18/05/2016	ATHLONE PHARMACEUTICALS LIMITED	TRAMADOL HYDROCHLORIDE/PARACETAMOL 37.5 MG/325 MG FILM-COATED TABLETS	PARACETAMOL	325	MILLIGRAMMES	POM
PL 30464/0170	18/05/2016	ATHLONE PHARMACEUTICALS LIMITED	TRAMADOL HYDROCHLORIDE/PARACETAMOL 37.5 MG/325 MG FILM-COATED TABLETS	TRAMADOL HYDROCHLORIDE	37.5	MILLIGRAMMES	POM
PL 42751/0003	18/05/2016	TERIX LABS LIMITED	NULBIA 5% CREAM	LIDOCAINE	25.00	MILLIGRAMMES	P
PL 42751/0003	18/05/2016	TERIX LABS LIMITED	NULBIA 5% CREAM	PRILOCAINE	25.00	MILLIGRAMMES	P
PL 20142/0019	20/05/2016	NORGINE B.V	MOVICOL READY TO TAKE ORAL SOLUTION IN SACHET	MACROGOL 3350	13.125	GRAMMES	P
PL 20142/0019	20/05/2016	NORGINE B.V	MOVICOL READY TO TAKE ORAL SOLUTION IN SACHET	POTASSIUM CHLORIDE	0.0502	GRAMMES	P
PL 20142/0019	20/05/2016	NORGINE B.V	MOVICOL READY TO TAKE ORAL SOLUTION IN SACHET	SODIUM CHLORIDE	0.3508	GRAMMES	P
PL 20142/0019	20/05/2016	NORGINE B.V	MOVICOL READY TO TAKE ORAL SOLUTION IN SACHET	SODIUM HYDROGEN CARBONATE	0.1786	GRAMMES	P
PL 29831/0593	20/05/2016	WOCKHARDT UK LIMITED	PARACETAMOL 500MG/5ML ORAL SOLUTION	PARACETAMOL	100.00	MILLIGRAMMES PER MILLILITRE	POM
PL 42357/0195	20/05/2016	AMNEAL PHARMA EUROPE LIMITED	GABAPENTINE AMNEAL 100 MG CAPSULES	GABAPENTIN	100.00	MILLIGRAMMES	POM
PL 42357/0196	20/05/2016	AMNEAL PHARMA EUROPE LIMITED	GABAPENTINE AMNEAL 300 MG CAPSULES	GABAPENTIN	300.00	MILLIGRAMMES	POM

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PL 42357/0197	20/05/2016	AMNEAL PHARMA EUROPE LIMITED	GABAPENTINE AMNEAL 400 MG CAPSULES	GABAPENTIN	400.00	MILLIGRAMMES	POM
PL 17907/0547	23/05/2016	BRISTOL LABORATORIES LIMITED	ATORVASTATIN 10 MG FILM-COATED TABLETS	ATORVASTATIN CALCIUM TRIHYDRATE	10.85	MILLIGRAMMES	POM
PL 17907/0548	23/05/2016	BRISTOL LABORATORIES LIMITED	ATORVASTATIN 20 MG FILM-COATED TABLETS	ATORVASTATIN CALCIUM TRIHYDRATE	21.70	MILLIGRAMMES	POM
PL 17907/0549	23/05/2016	BRISTOL LABORATORIES LIMITED	ATORVASTATIN 40 MG FILM-COATED TABLETS	ATORVASTATIN CALCIUM TRIHYDRATE	43.40	MILLIGRAMMES	POM
PL 17907/0550	23/05/2016	BRISTOL LABORATORIES LIMITED	ATORVASTATIN 80 MG FILM-COATED TABLETS	ATORVASTATIN CALCIUM TRIHYDRATE	86.80	MILLIGRAMMES	POM
PL 20075/0438	23/05/2016	ACCORD HEALTHCARE LIMITED	BIVALIRUDIN 250 MG POWDER FOR CONCENTRATE FOR SOLUTION FOR INJECTION OR INFUSIO	BIVALIRUDIN	250.000	MILLIGRAMMES	POM
PL 00289/1927	24/05/2016	TEVA UK LIMITED	CASPOFUNGIN TEVA 50 MG POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION	CASPOFUNGIN ACETATE	60.60	MILLIGRAMMES	POM
PL 00289/1928	24/05/2016	TEVA UK LIMITED	CASPOFUNGIN TEVA 70 MG POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION	CASPOFUNGIN ACETATE	83.90	MILLIGRAMMES	POM
PL 00289/2007	25/05/2016	TEVA UK LIMITED	OLMESARTAN MEDOXOMIL / HYDROCHLOROTHIAZIDE 20MG/12.5MG FILM COATED TABLETS	HYDROCHLOROTHIAZIDE	12.5	MILLIGRAMMES	POM
PL 00289/2007	25/05/2016	TEVA UK LIMITED	OLMESARTAN MEDOXOMIL / HYDROCHLOROTHIAZIDE 20MG/12.5MG FILM COATED TABLETS	OLMESARTAN MEDOXOMIL	20.00	MILLIGRAMMES	POM
PL 00289/2008	25/05/2016	TEVA UK LIMITED	OLMESARTAN MEDOXOMIL / HYDROCHLOROTHIAZIDE 20MG/25MG FILM COATED TABLETS	HYDROCHLOROTHIAZIDE	25.00	MILLIGRAMMES	POM
PL 00289/2008	25/05/2016	TEVA UK LIMITED	OLMESARTAN MEDOXOMIL / HYDROCHLOROTHIAZIDE 20MG/25MG FILM COATED TABLETS	OLMESARTAN MEDOXOMIL	20.00	MILLIGRAMMES	POM
PL 00289/2009	25/05/2016	TEVA UK LIMITED	OLMESARTAN MEDOXOMIL / HYDROCHLOROTHIAZIDE 40MG/12.5MG FILM COATED TABLETS	HYDROCHLOROTHIAZIDE	12.5	MILLIGRAMMES	POM
PL 00289/2009	25/05/2016	TEVA UK LIMITED	OLMESARTAN MEDOXOMIL / HYDROCHLOROTHIAZIDE 40MG/12.5MG FILM COATED TABLETS	OLMESARTAN MEDOXOMIL	40.00	MILLIGRAMMES	POM
PL 00289/2010	25/05/2016	TEVA UK LIMITED	OLMESARTAN MEDOXOMIL / HYDROCHLOROTHIAZIDE 40MG/25MG FILM COATED TABLETS	HYDROCHLOROTHIAZIDE	25.00	MILLIGRAMMES	POM
PL 00289/2010	25/05/2016	TEVA UK LIMITED	OLMESARTAN MEDOXOMIL / HYDROCHLOROTHIAZIDE 40MG/25MG FILM COATED TABLETS	OLMESARTAN MEDOXOMIL	40.00	MILLIGRAMMES	POM
PL 17780/0760	25/05/2016	WINTHROP PHARMACEUTICALS UK LIMITED	BRANCICO XL 50 MG PROLONGED-RELEASE TABLETS	QUETIAPINE FUMARATE	57.560	MILLIGRAMMES	POM
PL 17780/0761	25/05/2016	WINTHROP PHARMACEUTICALS UK LIMITED	BRANCICO XL 150 MG PROLONGED-RELEASE TABLETS	QUETIAPINE FUMARATE	172.68	MILLIGRAMMES	POM
PL 17780/0762	25/05/2016	WINTHROP PHARMACEUTICALS UK LIMITED	BRANCICO XL 200 MG PROLONGED-RELEASE TABLETS	QUETIAPINE FUMARATE	230.24	MILLIGRAMMES	POM
PL 17780/0763	25/05/2016	WINTHROP PHARMACEUTICALS UK LIMITED	BRANCICO XL 300 MG PROLONGED-RELEASE TABLETS	QUETIAPINE FUMARATE	345.36	MILLIGRAMMES	POM
PL 17780/0764	25/05/2016	WINTHROP PHARMACEUTICALS UK LIMITED	BRANCICO XL 400 MG PROLONGED-RELEASE TABLETS	QUETIAPINE FUMARATE	460.48	MILLIGRAMMES	POM
PL 17907/0538	25/05/2016	BRISTOL LABORATORIES LIMITED	RASAGILINE BRISTOL 1 MG TABLETS	RASAGILINE HEMITARTRATE	1.438	MILLIGRAMMES	POM
PL 30139/0041	26/05/2016	INTAS PHARMACEUTICALS LIMITED	NITRAZEPAM 5 MG TABLETS	NITRAZEPAM	5.000	MILLIGRAMMES	POM
PL 41947/0017	26/05/2016	ELC GROUP SRO	FLUMAZENIL 0.1 MG/ML SOLUTION FOR INJECTION / INFUSION	FLUMAZENIL	0.1	MILLIGRAMMES	POM
PL 43945/0003	26/05/2016	LAMDA LABORATORIES SA	PREGABALIN FOCUS 20 MG/ML ORAL SOLUTION	PREGABALIN	20.0	MILLIGRAMMES	POM

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PL 44041/0015	26/05/2016	NOUMED LIFE SCIENCES LIMITED	ERYTHROMYCIN 250MG GASTRO-RESISTANT TABLETS	ERYTHROMYCIN	250.00	MILLIGRAMMES	POM
PL 34328/0010	27/05/2016	PANMEDICA	CASPOFUNGIN PANPHARMA 50 MG POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION	CASPOFUNGIN ACETATE	55.449	MILLIGRAMMES	POM
PL 34328/0011	27/05/2016	PANMEDICA	CASPOFUNGIN PANPHARMA 70 MG POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION	CASPOFUNGIN ACETATE	77.630	MILLIGRAMMES	POM
PL 39307/0057	27/05/2016	SYRI LIMITED	FLUOXETINE 20MG/5ML ORAL SOLUTION	FLUOXETINE HYDROCHLORIDE	0.0224	GRAMMES	POM
PL 41947/0016	27/05/2016	ELC GROUP SRO	HEPARIN 5,000 I.U./ML, SOLUTION FOR INJECTION	HEPARIN SODIUM	5000	INTERNATIONAL UNITS	POM
PL 30322/0002	31/05/2016	ALISSA HEALTHCARE RESEARCH LIMITED	VITAMIN D3 20,000 IU CAPSULES, SOFT	COLECALCIFEROL	0.500	MILLIGRAMMES	POM
PL 30322/0016	31/05/2016	ALISSA HEALTHCARE RESEARCH LIMITED	TRANZILEVE 5 MICROGRAM/HOUR TRANSDERMAL PATCH	BUPRENORPHINE	5	MILLIGRAMMES	POM
PL 30322/0017	31/05/2016	ALISSA HEALTHCARE RESEARCH LIMITED	TRANZILEVE 10 MICROGRAM/HOUR TRANSDERMAL PATCH	BUPRENORPHINE	10	MILLIGRAMMES	POM
PL 30322/0018	31/05/2016	ALISSA HEALTHCARE RESEARCH LIMITED	TRANZILEVE 20 MICROGRAM/HOUR TRANSDERMAL PATCH	BUPRENORPHINE	20	MILLIGRAMMES	POM