

Marketing authorisations granted in December 2017

PL Number	Grant Date	MA Holder	Licensed Name(s)	Active Ingredient	Quantity	Units	Legal Status
PL 15190/0030	04/12/2017	LABORATOIRES SMB SA	HELIODREI 25.000 IU CAPSULE HARD	CHOLECALCIFEROL	25.000	INTERNATIONAL UNITS	POM
PL 36390/0227	04/12/2017	CIPLA (EU) LIMITED	PARACETAMOL 500MG EFFERVESCENT TABLETS	PARACETAMOL	500.000	MILLIGRAMMES	P
PL 00063/0754	05/12/2017	RECKITT BENCKISER HEALTHCARE (UK) LIMITED	GAVISCON DOUBLE ACTION PEPPERMINT FLAVOUR ORAL SUSPENSION SACHETS	CALCIUM CARBONATE	325.00	MILLIGRAMMES PER 10 MILLILITR	GSL
PL 00063/0754	05/12/2017	RECKITT BENCKISER HEALTHCARE (UK) LIMITED	GAVISCON DOUBLE ACTION PEPPERMINT FLAVOUR ORAL SUSPENSION SACHETS	SODIUM ALGINATE	500	MILLIGRAMMES PER 10 MILLILITR	GSL
PL 00063/0754	05/12/2017	RECKITT BENCKISER HEALTHCARE (UK) LIMITED	GAVISCON DOUBLE ACTION PEPPERMINT FLAVOUR ORAL SUSPENSION SACHETS	SODIUM HYDROGEN CARBONATE	213.00	MILLIGRAMMES PER 10 MILLILITR	GSL
PL 06831/0289	05/12/2017	GENUS PHARMACEUTICALS LIMITED	MOVELAT MUSCLE PAIN 2%/0.2% W/W CREAM	MUCOPOLYSACCHARIDE POLYSULPHATE	0.2	PERCENT WEIGHT IN WEIGHT	GSL
PL 06831/0289	05/12/2017	GENUS PHARMACEUTICALS LIMITED	MOVELAT MUSCLE PAIN 2%/0.2% W/W CREAM	SALICYLIC ACID	2	PERCENT WEIGHT IN WEIGHT	GSL
PL 40431/0028	05/12/2017	QDEM PHARMACEUTICALS LIMITED	ARMONEVE 2.5 MG/1.25 MG PROLONGED-RELEASE TABLETS	NALOXONE HYDROCHLORIDE DIHYDRATE	1.37	MILLIGRAMMES	POM
PL 40431/0028	05/12/2017	QDEM PHARMACEUTICALS LIMITED	ARMONEVE 2.5 MG/1.25 MG PROLONGED-RELEASE TABLETS	OXYCODONE HYDROCHLORIDE	2.63	MILLIGRAMMES	POM
PL 40431/0029	05/12/2017	QDEM PHARMACEUTICALS LIMITED	ARMONEVE 5 MG/2.5MG PROLONGED-RELEASE TABLETS	NALOXONE HYDROCHLORIDE DIHYDRATE	2.730	MILLIGRAMMES	POM
PL 40431/0029	05/12/2017	QDEM PHARMACEUTICALS LIMITED	ARMONEVE 5 MG/2.5MG PROLONGED-RELEASE TABLETS	OXYCODONE HYDROCHLORIDE	5.250	MILLIGRAMMES	POM
PL 40431/0030	05/12/2017	QDEM PHARMACEUTICALS LIMITED	ARMONEVE 10 MG/5 MG PROLONGED-RELEASE TABLETS	NALOXONE HYDROCHLORIDE DIHYDRATE	5.450	MILLIGRAMMES	POM
PL 40431/0030	05/12/2017	QDEM PHARMACEUTICALS LIMITED	ARMONEVE 10 MG/5 MG PROLONGED-RELEASE TABLETS	OXYCODONE HYDROCHLORIDE	10.500	MILLIGRAMMES	POM
PL 40431/0031	05/12/2017	QDEM PHARMACEUTICALS LIMITED	ARMONEVE 15 MG/7.5 MG PROLONGED-RELEASE TABLET	NALOXONE HYDROCHLORIDE DIHYDRATE	8.240	MILLIGRAMMES	POM
PL 40431/0031	05/12/2017	QDEM PHARMACEUTICALS LIMITED	ARMONEVE 15 MG/7.5 MG PROLONGED-RELEASE TABLET	OXYCODONE HYDROCHLORIDE	15.75	MILLIGRAMMES	POM
PL 40431/0032	05/12/2017	QDEM PHARMACEUTICALS LIMITED	ARMONEVE 20MG/10 MG PROLONGED-RELEASE TABLETS	NALOXONE HYDROCHLORIDE DIHYDRATE	10.900	MILLIGRAMMES	POM
PL 40431/0032	05/12/2017	QDEM PHARMACEUTICALS LIMITED	ARMONEVE 20MG/10 MG PROLONGED-RELEASE TABLETS	OXYCODONE HYDROCHLORIDE	21.000	MILLIGRAMMES	POM
PL 40431/0033	05/12/2017	QDEM PHARMACEUTICALS LIMITED	ARMONEVE 30MG/15MG PROLONGED-RELEASE TABLETS	NALOXONE HYDROCHLORIDE DIHYDRATE	16.480	MILLIGRAMMES	POM
PL 40431/0033	05/12/2017	QDEM PHARMACEUTICALS LIMITED	ARMONEVE 30MG/15MG PROLONGED-RELEASE TABLETS	OXYCODONE HYDROCHLORIDE	31.500	MILLIGRAMMES	POM
PL 40431/0034	05/12/2017	QDEM PHARMACEUTICALS LIMITED	ARMONEVE 40MG/20MG PROLONGED-RELEASE TABLETS	NALOXONE HYDROCHLORIDE DIHYDRATE	21.800	MILLIGRAMMES	POM
PL 40431/0034	05/12/2017	QDEM PHARMACEUTICALS LIMITED	ARMONEVE 40MG/20MG PROLONGED-RELEASE TABLETS	OXYCODONE HYDROCHLORIDE	42.000	MILLIGRAMMES	POM
PL 20075/0533	06/12/2017	ACCORD HEALTHCARE LIMITED	OLMESARTAN MEDOXOMIL/AMLODIPINE 20/5 MG FILM-COATED TABLETS	AMLODIPINE BESILATE	6.950	MILLIGRAMMES	POM
PL 20075/0533	06/12/2017	ACCORD HEALTHCARE LIMITED	OLMESARTAN MEDOXOMIL/AMLODIPINE 20/5 MG FILM-COATED TABLETS	OLMESARTAN MEDOXOMIL	20.000	MILLIGRAMMES	POM
PL 20075/0534	06/12/2017	ACCORD HEALTHCARE LIMITED	OLMESARTAN MEDOXOMIL/AMLODIPINE 40/5 MG FILM-COATED TABLETS	AMLODIPINE BESILATE	6.950	MILLIGRAMMES	POM
PL 20075/0534	06/12/2017	ACCORD HEALTHCARE LIMITED	OLMESARTAN MEDOXOMIL/AMLODIPINE 40/5 MG FILM-COATED TABLETS	OLMESARTAN MEDOXOMIL	40.000	MILLIGRAMMES	POM
PL 20075/0535	06/12/2017	ACCORD HEALTHCARE LIMITED	OLMESARTAN MEDOXOMIL/AMLODIPINE 40/10 MG FILM-COATED TABLETS	AMLODIPINE BESILATE	13.900	MILLIGRAMMES	POM
PL 20075/0535	06/12/2017	ACCORD HEALTHCARE LIMITED	OLMESARTAN MEDOXOMIL/AMLODIPINE 40/10 MG FILM-COATED TABLETS	OLMESARTAN MEDOXOMIL	40.000	MILLIGRAMMES	POM
PL 36687/0201	06/12/2017	TORRENT PHARMA (UK) LIMITED	ZONISAMIDE TORRENT 25 MG HARD CAPSULES	ZONISAMIDE	25.00	MILLIGRAMMES	POM
PL 36687/0202	06/12/2017	TORRENT PHARMA (UK) LIMITED	ZONISAMIDE TORRENT 50 MG HARD CAPSULES	ZONISAMIDE	50.000	MILLIGRAMMES	POM
PL 36687/0203	06/12/2017	TORRENT PHARMA (UK) LIMITED	ZONISAMIDE TORRENT 100 MG HARD CAPSULES	ZONISAMIDE	100.000	MILLIGRAMMES	POM
PL 47015/0001	06/12/2017	GRINDEKS AS	ATRACURIUM BESILATE 10 MG/ML SOLUTION FOR INJECTION/INFUSION	ATRACURIUM BESILATE	25	MILLIGRAMMES	POM

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PL 00289/2095	07/12/2017	TEVA UK LIMITED	ANAGRELIDE 0.5 MG HARD CAPSULES	ANAGRELIDE HYDROCHLORIDE MONOHYDRATE	0.61	MILLIGRAMMES	POM
PL 00289/2096	07/12/2017	TEVA UK LIMITED	ANAGRELIDE 1 MG HARD CAPSULES	ANAGRELIDE HYDROCHLORIDE MONOHYDRATE	1.22	MILLIGRAMMES	POM
PL 00289/2097	07/12/2017	TEVA UK LIMITED	ANAGRELIDE 0.5 MG HARD CAPSULES	ANAGRELIDE HYDROCHLORIDE MONOHYDRATE	0.61	MILLIGRAMMES	POM
PL 00289/2098	07/12/2017	TEVA UK LIMITED	ANAGRELIDE 1 MG HARD CAPSULES	ANAGRELIDE HYDROCHLORIDE MONOHYDRATE	1.22	MILLIGRAMMES	POM
PL 04569/1700	07/12/2017	GENERICS (UK) LIMITED	ATOMOXETINE 10 MG CAPSULES, HARD	ATOMOXETINE HYDROCHLORIDE	11.43	MILLIGRAMMES	POM
PL 04569/1701	07/12/2017	GENERICS (UK) LIMITED	ATOMOXETINE 18 MG CAPSULES, HARD	ATOMOXETINE HYDROCHLORIDE	20.57	MILLIGRAMMES	POM
PL 04569/1702	07/12/2017	GENERICS (UK) LIMITED	ATOMOXETINE 25 MG CAPSULES, HARD	ATOMOXETINE HYDROCHLORIDE	28.58	MILLIGRAMMES	POM
PL 04569/1703	07/12/2017	GENERICS (UK) LIMITED	ATOMOXETINE 40 MG CAPSULES, HARD	ATOMOXETINE HYDROCHLORIDE	45.72	MILLIGRAMMES	POM
PL 04569/1704	07/12/2017	GENERICS (UK) LIMITED	ATOMOXETINE 60 MG CAPSULES, HARD	ATOMOXETINE HYDROCHLORIDE	68.58	MILLIGRAMMES	POM
PL 04569/1705	07/12/2017	GENERICS (UK) LIMITED	ATOMOXETINE 80 MG CAPSULES, HARD	ATOMOXETINE HYDROCHLORIDE	91.44	MILLIGRAMMES	POM
PL 04569/1706	07/12/2017	GENERICS (UK) LIMITED	ATOMOXETINE 100 MG CAPSULES, HARD	ATOMOXETINE HYDROCHLORIDE	114.30	MILLIGRAMMES	POM
PL 15413/0085	08/12/2017	HIKMA FARMACEUTICA (PORTUGAL) SA	PEMETREXED 25 MG/ML CONCENTRATE FOR SOLUTION FOR INFUSION	PEMETREXED	25	MILLIGRAMMES PER MILLILITRE	POM
PL 15919/0037	08/12/2017	GENTHON BV	PEMETREXED GENTHON 25 MG/ML, CONCENTRATE FOR SOLUTION FOR INFUSION	PEMETREXED	25	MILLIGRAMMES PER MILLILITRE	POM
PL 17780/0807	08/12/2017	WINTHROP PHARMACEUTICALS UK LIMITED	PEMETREXED ZENTIVA 25MG/ML CONCENTRATE FOR SOLUTION FOR INFUSION	PEMETREXED	25	MILLIGRAMMES PER MILLILITRE	POM
PL 35533/0084	08/12/2017	ASPIRE PHARMA LIMITED	SODIUM CROMOGLICATE 2% W/V EYE DROPS, SOLUTION (EYE DROPS)	SODIUM CROMOGLICATE	20.0	MILLIGRAMMES PER MILLILITRE	P
PL 44696/0001	08/12/2017	RENASCENCE PHARMA LIMITED	RENAPIME 1G POWDER FOR SOLUTION FOR INJECTION OR INFUSION	CEFEPIME DIHYDROCHLORIDE MONOHYDRATE	1189.14	MILLIGRAMMES	POM
PL 44696/0002	08/12/2017	RENASCENCE PHARMA LIMITED	RENAPIME 2G POWDER FOR SOLUTION FOR INJECTION OR INFUSION	CEFEPIME DIHYDROCHLORIDE MONOHYDRATE	2378.28	MILLIGRAMMES	POM
PL 17277/0371	13/12/2017	PHARMATHEN SA	DAVARINO 75 MG FILM-COATED TABLETS	DARUNAVIR PROPYLENE GLYCOLATE	85.42	MILLIGRAMMES	POM
PL 17277/0372	13/12/2017	PHARMATHEN SA	DAVARINO 150 MG FILM-COATED TABLETS	DARUNAVIR PROPYLENE GLYCOLATE	170.84	MILLIGRAMMES	POM
PL 17277/0373	13/12/2017	PHARMATHEN SA	DAVARINO 300 MG FILM-COATED TABLETS	DARUNAVIR PROPYLENE GLYCOLATE	341.66	MILLIGRAMMES	POM
PL 17277/0374	13/12/2017	PHARMATHEN SA	DAVARINO 400 MG FILM-COATED TABLETS	DARUNAVIR PROPYLENE GLYCOLATE	455.55	MILLIGRAMMES	POM
PL 17277/0375	13/12/2017	PHARMATHEN SA	DAVARINO 600 MG FILM-COATED TABLETS	DARUNAVIR PROPYLENE GLYCOLATE	683.33	MILLIGRAMMES	POM
PL 17277/0376	13/12/2017	PHARMATHEN SA	DAVARINO 800 MG FILM-COATED TABLETS	DARUNAVIR PROPYLENE GLYCOLATE	911.10	MILLIGRAMMES	POM
PL 30306/0763	13/12/2017	ACTAVIS GROUP PTC EHF	DEFERIPRONE 500MG FILM-COATED TABLETS	DEFERIPRONE	500	MILLIGRAMMES	POM
PL 30306/0764	13/12/2017	ACTAVIS GROUP PTC EHF	DEFERIPRONE 1000MG FILM-COATED TABLETS	DEFERIPRONE	1000	MILLIGRAMMES	POM
PL 25258/0244	14/12/2017	GLENMARK PHARMACEUTICALS EUROPE LIMITED	IOHEXOL 140MG I/ML SOLUTION FOR INJECTION	IODINE	140.00	MILLIGRAMMES	POM
PL 25258/0244	14/12/2017	GLENMARK PHARMACEUTICALS EUROPE LIMITED	IOHEXOL 140MG I/ML SOLUTION FOR INJECTION	IOHEXOL	302.00	MILLIGRAMMES	POM
PL 25258/0245	14/12/2017	GLENMARK PHARMACEUTICALS EUROPE LIMITED	IOHEXOL 240MG I/ML SOLUTION FOR INJECTION	IODINE	240.00	MILLIGRAMMES	POM
PL 25258/0245	14/12/2017	GLENMARK PHARMACEUTICALS EUROPE LIMITED	IOHEXOL 240MG I/ML SOLUTION FOR INJECTION	IOHEXOL	518.00	MILLIGRAMMES	POM
PL 25258/0246	14/12/2017	GLENMARK PHARMACEUTICALS EUROPE LIMITED	IOHEXOL 300MG I/ML SOLUTION FOR INJECTION	IODINE	300.00	MILLIGRAMMES	POM
PL 25258/0246	14/12/2017	GLENMARK PHARMACEUTICALS EUROPE LIMITED	IOHEXOL 300MG I/ML SOLUTION FOR INJECTION	IOHEXOL	647.00	MILLIGRAMMES	POM

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PL 25258/0247	14/12/2017	GLENMARK PHARMACEUTICALS EUROPE LIMITED	IOHEXOL 350MG I/ML SOLUTION FOR INJECTION	IODINE	350.00	MILLIGRAMMES	POM
PL 25258/0247	14/12/2017	GLENMARK PHARMACEUTICALS EUROPE LIMITED	IOHEXOL 350MG I/ML SOLUTION FOR INJECTION	IOHEXOL	755.00	MILLIGRAMMES	POM
PL 35646/0062	14/12/2017	ALKEM PHARMA GMBH	IBUPROFEN 200 MG FILM-COATED TABLETS	IBUPROFEN	200	MILLIGRAMMES	P
PL 35646/0063	14/12/2017	ALKEM PHARMA GMBH	IBUPROFEN 400 MG FILM-COATED TABLETS	IBUPROFEN	400	MILLIGRAMMES	P
PL 35646/0064	14/12/2017	ALKEM PHARMA GMBH	IBUPROFEN 600 MG FILM-COATED TABLETS	IBUPROFEN	600	MILLIGRAMMES	P
PL 34771/0194	15/12/2017	MACLEODS PHARMA UK LIMITED	NEBIVOLOL 2.5MG TABLETS	NEBIVOLOL HYDROCHLORIDE	2.725	MILLIGRAMMES	POM
PL 34771/0195	15/12/2017	MACLEODS PHARMA UK LIMITED	NEBIVOLOL 5MG TABLETS	NEBIVOLOL HYDROCHLORIDE	5	MILLIGRAMMES	POM
PL 34771/0196	15/12/2017	MACLEODS PHARMA UK LIMITED	NEBIVOLOL 10MG TABLETS	NEBIVOLOL HYDROCHLORIDE	10	MILLIGRAMMES	POM
PL 35533/0103	18/12/2017	ASPIRE PHARMA LIMITED	EYZEETAN 0.3 MG/ML + 5 MG/ML EYE DROPS, SOLUTION	BIMATOPROST	0.300	MILLIGRAMMES PER MILLILITRE	POM
PL 35533/0103	18/12/2017	ASPIRE PHARMA LIMITED	EYZEETAN 0.3 MG/ML + 5 MG/ML EYE DROPS, SOLUTION	TIMOLOL MALEATE	6.830	MILLIGRAMMES PER MILLILITRE	POM
PL 35533/0107	18/12/2017	ASPIRE PHARMA LIMITED	EYREIDA 0.3MG/ML EYE DROPS, SOLUTION	BIMATOPROST	0.3	MILLIGRAMMES	POM
PL 04416/1520	19/12/2017	SANDOZ LIMITED	CINACALCET SANDOZ 30 MG FILM-COATED TABLETS	CINACALCET HYDROCHLORIDE	33.06	MILLIGRAMMES	POM
PL 04416/1521	19/12/2017	SANDOZ LIMITED	CINACALCET SANDOZ 60 MG FILM-COATED TABLETS	CINACALCET HYDROCHLORIDE	66.12	MILLIGRAMMES	POM
PL 04416/1522	19/12/2017	SANDOZ LIMITED	CINACALCET SANDOZ 90 MG FILM-COATED TABLETS	CINACALCET HYDROCHLORIDE	99.18	MILLIGRAMMES	POM
PL 30139/0039	19/12/2017	INTAS PHARMACEUTICALS LIMITED	DIAZEPAM 5MG TABLETS	DIAZEPAM	5.000	MILLIGRAMMES	POM
PL 30139/0040	19/12/2017	INTAS PHARMACEUTICALS LIMITED	DIAZEPAM 10MG TABLETS	DIAZEPAM	10.000	MILLIGRAMMES	POM
PL 40739/0110	19/12/2017	ENNOGEN HEALTHCARE LIMITED	DUTASTERIDE 0.5 MG SOFT CAPSULES, ZEPRON 0.5 MG SOFT CAPSULES	DUTASTERIDE	0.5	MILLIGRAMMES	POM
PL 00101/0973	20/12/2017	NOVARTIS PHARMACEUTICALS UK LIMITED	RITALIN XL 10 MG MODIFIED-RELEASE HARD CAPSULES	METHYLPHENIDATE HYDROCHLORIDE	10	MILLIGRAMMES	POM
PL 00101/0974	20/12/2017	NOVARTIS PHARMACEUTICALS UK LIMITED	RITALIN XL 20 MG MODIFIED-RELEASE HARD CAPSULES	METHYLPHENIDATE HYDROCHLORIDE	20	MILLIGRAMMES	POM
PL 00101/0975	20/12/2017	NOVARTIS PHARMACEUTICALS UK LIMITED	RITALIN XL 30 MG MODIFIED-RELEASE HARD CAPSULES	METHYLPHENIDATE HYDROCHLORIDE	30	MILLIGRAMMES	POM
PL 00101/0976	20/12/2017	NOVARTIS PHARMACEUTICALS UK LIMITED	RITALIN XL 40 MG MODIFIED-RELEASE HARD CAPSULES	METHYLPHENIDATE HYDROCHLORIDE	40	MILLIGRAMMES	POM
PL 00101/0977	20/12/2017	NOVARTIS PHARMACEUTICALS UK LIMITED	RITALIN XL 60 MG MODIFIED-RELEASE HARD CAPSULES	METHYLPHENIDATE HYDROCHLORIDE	60	MILLIGRAMMES	POM
PL 34771/0197	20/12/2017	MACLEODS PHARMA UK LIMITED	CARBIMAZOLE 5 MG TABLETS	CARBIMAZOLE	5	MILLIGRAMMES	POM
PL 34771/0198	20/12/2017	MACLEODS PHARMA UK LIMITED	CARBIMAZOLE 10 MG TABLETS	CARBIMAZOLE	10	MILLIGRAMMES	POM
PL 34771/0199	20/12/2017	MACLEODS PHARMA UK LIMITED	CARBIMAZOLE 15 MG TABLETS	CARBIMAZOLE	15	MILLIGRAMMES	POM
PL 34771/0200	20/12/2017	MACLEODS PHARMA UK LIMITED	CARBIMAZOLE 20 MG TABLETS	CARBIMAZOLE	20	MILLIGRAMMES	POM
PL 16363/0518	21/12/2017	MILPHARM LIMITED	ZOLEDRONIC ACID MILPHARM 5 MG/ 100 ML SOLUTION FOR INFUSION	ZOLEDRONIC ACID MONOHYDRATE	0.05	MILLIGRAMMES PER MILLILITRE	POM
PL 25298/0062	21/12/2017	BROWN & BURK UK LIMITED	CLARITHROMYCIN 250 MG FILM COATED TABLETS	CLARITHROMYCIN	250.000	MILLIGRAMMES	POM
PL 25298/0053	21/12/2017	BROWN & BURK UK LIMITED	CLARITHROMYCIN 500 MG FILM COATED TABLETS	CLARITHROMYCIN	500.000	MILLIGRAMMES	POM
PL 35533/0056	21/12/2017	ASPIRE PHARMA LIMITED	IBUPROFEN 200MG/SML ORAL SUSPENSION	IBUPROFEN	40.00	MILLIGRAMMES	POM
PL 08553/0585	22/12/2017	DR REDDY'S LABORATORIES (UK) LIMITED	ABACA VIR 300 MG FILM-COATED TABLETS	ABACA VIR	300.00	MILLIGRAMMES	POM

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PL 36282/0012	22/12/2017	RIA GENERICS LIMITED	NORTRIPTYLINE 10MG TABLET	NORTRIPTYLINE HYDROCHLORIDE	11.40	MILLIGRAMMES	POM
PL 36282/0013	22/12/2017	RIA GENERICS LIMITED	NORTRIPTYLINE 25MG TABLET	NORTRIPTYLINE HYDROCHLORIDE	28.50	MILLIGRAMMES	POM
PL 14338/0010	27/12/2017	PATHEON SOFTGELS BV	PARACETAMOL 500 MG, CAPSULES, SOFT	PARACETAMOL	500.000	MILLIGRAMMES	GSL