

Marketing authorisations granted in September 2019

PL Number	Grant Date	MA Holder	Licensed Name(s)	Active Ingredient	Quantity	Units	Legal Status
PL 31750/0148	03/09/2019	SUN PHARMACEUTICAL INDUSTRIES EUROPE BV	SOLIFENACIN SUCCINATE 5 MG FILM-COATED TABLETS	SOLIFENACIN SUCCINATE	5	MILLIGRAMS	POM
PL 49565/0011	03/09/2019	NORTH STAR HEALTHCARE LIMITED	PAROXETINE 20 MG FILM-COATED TABLETS	PAROXETINE HYDROCHLORIDE HEMIHYDRATE	22.200	MILLIGRAMS	POM
PL 49565/0012	03/09/2019	NORTH STAR HEALTHCARE LIMITED	PAROXETINE 30 MG FILM-COATED TABLETS	PAROXETINE HYDROCHLORIDE HEMIHYDRATE	33.300	MILLIGRAMS	POM
PL 17780/0842	05/09/2019	ZENTIVA PHARMA UK LIMITED	DASATINIB ZENTIVA 20 MG FILM-COATED TABLETS	DASATINIB	20	MILLIGRAMS	POM
PL 17780/0843	05/09/2019	ZENTIVA PHARMA UK LIMITED	DASATINIB ZENTIVA 50 MG FILM-COATED TABLETS	DASATINIB	50	MILLIGRAMS	POM
PL 17780/0844	05/09/2019	ZENTIVA PHARMA UK LIMITED	DASATINIB ZENTIVA 70 MG FILM-COATED TABLETS	DASATINIB	70	MILLIGRAMS	POM
PL 17780/0845	05/09/2019	ZENTIVA PHARMA UK LIMITED	DASATINIB ZENTIVA 80 MG FILM-COATED TABLETS	DASATINIB	80	MILLIGRAMS	POM
PL 17780/0846	05/09/2019	ZENTIVA PHARMA UK LIMITED	DASATINIB ZENTIVA 100 MG FILM-COATED TABLETS	DASATINIB	100	MILLIGRAMS	POM
PL 17780/0847	05/09/2019	ZENTIVA PHARMA UK LIMITED	DASATINIB ZENTIVA 140 MG FILM-COATED TABLETS	DASATINIB	140	MILLIGRAMS	POM
PL 08553/0619	06/09/2019	DR REDDY'S LABORATORIES (UK) LIMITED	IBUPROFEN 400 MG SOLUTION FOR INFUSION	IBUPROFEN	400	MILLIGRAMS	POM
PL 08553/0632	06/09/2019	DR REDDY'S LABORATORIES (UK) LIMITED	IBUPROFEN 600 MG SOLUTION FOR INFUSION	IBUPROFEN	600	MILLIGRAMS	POM
PL 18945/0002	06/09/2019	FAES FARMA SA	SALCROZINE 500MG GASTRO-RESISTANT TABLETS	MESALAZINE	500	MILLIGRAMS	POM
PL 28278/0021	09/09/2019	IPCA LABORATORIES UK LIMITED	GABAPENTIN IPCA 600 MG FILM-COATED TABLETS	GABAPENTIN	600	MILLIGRAMS	POM
PL 28278/0022	09/09/2019	IPCA LABORATORIES UK LIMITED	GABAPENTIN IPCA 800 MG FILM-COATED TABLETS	GABAPENTIN	800	MILLIGRAMS	POM
PL 30684/0281	09/09/2019	DAWA LIMITED	AZITHROMYCIN 250 MG CAPSULES	AZITHROMYCIN DIHYDRATE	262.016	MILLIGRAMS	POM
PL 42765/0010	09/09/2019	RENATA (UK) LIMITED	AMANTADINE HYDROCHLORIDE 100 MG CAPSULES, HARD	AMANTADINE HYDROCHLORIDE	100	MILLIGRAMS	POM
PL 16866/0115	10/09/2019	YES PHARMACEUTICAL DEVELOPMENT SERVICES GMBH	DUTASTERIDE/TAMSULOSIN 0.5/0.4 MG HARD CAPSULES	DUTASTERIDE	0.5	MILLIGRAMS	POM
PL 16866/0115	10/09/2019	YES PHARMACEUTICAL DEVELOPMENT SERVICES GMBH	DUTASTERIDE/TAMSULOSIN 0.5/0.4 MG HARD CAPSULES	TAMSULOSIN HYDROCHLORIDE	0.4	MILLIGRAMS	POM
PL 16866/0117	10/09/2019	YES PHARMACEUTICAL DEVELOPMENT SERVICES GMBH	DUTASTERIDE/TAMSULOSIN 0.5/0.4 MG HARD CAPSULES	DUTASTERIDE	0.5	MILLIGRAMS	POM
PL 16866/0117	10/09/2019	YES PHARMACEUTICAL DEVELOPMENT SERVICES GMBH	DUTASTERIDE/TAMSULOSIN 0.5/0.4 MG HARD CAPSULES	TAMSULOSIN HYDROCHLORIDE	0.4	MILLIGRAMS	POM
PL 00142/0913	11/09/2019	ACCORD-UK LIMITED	THALIDOMIDE 50 MG HARD CAPSULES	THALIDOMIDE	50	MILLIGRAMS	POM
PL 06464/3111	11/09/2019	WAYMADE PLC	SEVELAMER HYDROCHLORIDE 400 MG FILM-COATED TABLETS	SEVELAMER HYDROCHLORIDE	400	MILLIGRAMS	POM
PL 06464/3112	11/09/2019	WAYMADE PLC	SEVELAMER HYDROCHLORIDE 800 MG FILM-COATED TABLETS	SEVELAMER HYDROCHLORIDE	800	MILLIGRAMS	POM
PL 20243/0003	11/09/2019	PHARMA NORD APS	MELATONIN PHARMA NORD 3 MG FILM-COATED TABLETS	MELATONIN	3	MILLIGRAMS	POM
PL 40739/0081	11/09/2019	ENNOGEN HEALTHCARE LIMITED	ACETYLCYSTEINE 600MG TABLETS	ACETYLCYSTEINE	600.00	MILLIGRAMS	POM
PL 40739/0081	11/09/2019	ENNOGEN HEALTHCARE LIMITED	MUCOLIGHT 600MG TABLETS	ACETYLCYSTEINE	600.00	MILLIGRAMS	POM
PL 10590/0069	12/09/2019	GALDERMA (UK) LIMITED	ACNECID FACE 5% W/W GEL	BENZOYL PEROXIDE, HYDROUS	5	PERCENTAGE WEIGHT IN WEIGHT	GSL
PL 10590/0070	12/09/2019	GALDERMA (UK) LIMITED	ACNECID FACE WASH	BENZOYL PEROXIDE, HYDROUS	5	PERCENTAGE WEIGHT IN WEIGHT	GSL
PL 15413/0092	13/09/2019	HIKMA FARMACEUTICA (PORTUGAL) SA	BENDAMUSTINE 2.5 MG/ML POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION	BENDAMUSTINE HYDROCHLORIDE	100	MILLIGRAMS	POM
PL 15413/0092	13/09/2019	HIKMA FARMACEUTICA (PORTUGAL) SA	BENDAMUSTINE 2.5 MG/ML POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION	BENDAMUSTINE HYDROCHLORIDE	25	MILLIGRAMS	POM
PL 25258/0301	13/09/2019	GLENMARK PHARMACEUTICALS EUROPE LIMITED	DUTASTERIDE/TAMSULOSIN HYDROCHLORIDE GLENMARK 0.5 MG/0.4 MG HARD CAPSULES	DUTASTERIDE	0.5	MILLIGRAMS	POM
PL 25258/0301	13/09/2019	GLENMARK PHARMACEUTICALS EUROPE LIMITED	DUTASTERIDE/TAMSULOSIN HYDROCHLORIDE GLENMARK 0.5 MG/0.4 MG HARD CAPSULES	TAMSULOSIN HYDROCHLORIDE	0.4	MILLIGRAMS	POM

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PL 40739/0181	13/09/2019	ENNOGEN HEALTHCARE LIMITED	ACETYLCYSTEINE 600MG CAPSULES	ACETYLCYSTEINE	600	MILLIGRAMS	POM
PL 40739/0181	13/09/2019	ENNOGEN HEALTHCARE LIMITED	MUCOLIGHT 600MG CAPSULES	ACETYLCYSTEINE	600	MILLIGRAMS	POM
PL 48604/0002	13/09/2019	NEO HEALTH UK LIMITED	PYRIXIP 40 MG POWDER FOR SOLUTION FOR INJECTION	PARECOXIB SODIUM	42.36	MILLIGRAMS	POM
PL 48604/0003	13/09/2019	NEO HEALTH UK LIMITED	PYRIXIP 40 MG POWDER AND SOLVENT FOR SOLUTION FOR INJECTION	PARECOXIB SODIUM	42.36	MILLIGRAMS	POM
PL 15190/0032	17/09/2019	LABORATOIRES SMB SA	LIBROXAR 2 MG/0.5 MG SUBLINGUAL TABLETS	BUPRENORPHINE HYDROCHLORIDE	2.16	MILLIGRAMS	POM
PL 15190/0032	17/09/2019	LABORATOIRES SMB SA	LIBROXAR 2 MG/0.5 MG SUBLINGUAL TABLETS	NALOXONE HYDROCHLORIDE DIHYDRATE	0.5	MILLIGRAMS	POM
PL 15190/0033	17/09/2019	LABORATOIRES SMB SA	LIBROXAR 8 MG/2 MG SUBLINGUAL TABLETS	BUPRENORPHINE HYDROCHLORIDE	8.64	MILLIGRAMS	POM
PL 15190/0033	17/09/2019	LABORATOIRES SMB SA	LIBROXAR 8 MG/2 MG SUBLINGUAL TABLETS	NALOXONE HYDROCHLORIDE DIHYDRATE	2.44	MILLIGRAMS	POM
PL 12762/0548	18/09/2019	MERCURY PHARMACEUTICALS LIMITED	TADALAFIL 10MG FILM-COATED TABLETS	TADALAFIL	10	MILLIGRAMS	POM
PL 12762/0549	18/09/2019	MERCURY PHARMACEUTICALS LIMITED	TADALAFIL 20MG FILM-COATED TABLETS	TADALAFIL	20	MILLIGRAMS	POM
PL 20075/1244	18/09/2019	ACCORD HEALTHCARE LIMITED	AMBRISENTAN ACCORD 5MG FILM-COATED TABLETS	AMBRISENTAN	5	MILLIGRAMS	POM
PL 20075/1245	18/09/2019	ACCORD HEALTHCARE LIMITED	AMBRISENTAN ACCORD 10MG FILM-COATED TABLETS	AMBRISENTAN	10	MILLIGRAMS	POM
PL 11587/0098	19/09/2019	MEDAC GESELLSCHAFT FUR KLINISCHE SPEZIALPRAPARATE MB	MELPHALAN 50 MG POWDER AND SOLVENT FOR SOLUTION FOR INJECTION/INFUSION	MELPHALAN HYDROCHLORIDE	55.975	MILLIGRAMS	POM
PL 11587/0098	19/09/2019	MEDAC GESELLSCHAFT FUR KLINISCHE SPEZIALPRAPARATE MB	MELPHALAN 50 MG POWDER AND SOLVENT FOR SOLUTION FOR INJECTION/INFUSION	SODIUM CITRATE ANHYDROUS	200	MILLIGRAMS	POM
PL 15764/0126	19/09/2019	STRANDHAVEN LIMITED	CLINDAMYCIN HYDROCHLORIDE 300MG CAPSULES, HARD	CLINDAMYCIN HYDROCHLORIDE	326	MILLIGRAMS	POM
PL 16028/0165	19/09/2019	GALPHARM HEALTHCARE LIMITED	SILDENAFIL 50MG FILM-COATED TABLET	SILDENAFIL CITRATE	50	MILLIGRAMS	P
PL 28278/0003	19/09/2019	IPCA LABORATORIES UK LIMITED	METFORMIN IPCA 500 MG FILM COATED TABLETS	METFORMIN HYDROCHLORIDE	500	MILLIGRAMS	POM
PL 28278/0004	19/09/2019	IPCA LABORATORIES UK LIMITED	METFORMIN IPCA 850 MG FILM COATED TABLETS	METFORMIN HYDROCHLORIDE	850	MILLIGRAMS	POM
PL 28278/0005	19/09/2019	IPCA LABORATORIES UK LIMITED	METFORMIN IPCA 1000 MG FILM COATED TABLETS	METFORMIN HYDROCHLORIDE	1000	MILLIGRAMS	POM
PL 48259/0032	19/09/2019	NORTHUMBRIA PHARMA LIMITED	SILDENAFIL 25 MG FILM-COATED TABLETS	SILDENAFIL CITRATE	35.120	MILLIGRAMS	POM
PL 48259/0033	19/09/2019	NORTHUMBRIA PHARMA LIMITED	SILDENAFIL 50 MG FILM-COATED TABLETS	SILDENAFIL CITRATE	70.240	MILLIGRAMS	POM
PL 48259/0034	19/09/2019	NORTHUMBRIA PHARMA LIMITED	SILDENAFIL 100 MG FILM-COATED TABLETS	SILDENAFIL CITRATE	140.480	MILLIGRAMS	POM
PL 13606/0202	20/09/2019	STRIDES PHARMA UK LIMITED	CARBIMAZOLE 5 MG TABLETS	CARBIMAZOLE	5	MILLIGRAMS	POM
PL 13606/0203	20/09/2019	STRIDES PHARMA UK LIMITED	CARBIMAZOLE 20 MG TABLETS	CARBIMAZOLE	20	MILLIGRAMS	POM
PL 14251/0073	20/09/2019	MANX HEALTHCARE LIMITED	AZITHROMYCIN 250MG CAPSULES	AZITHROMYCIN DIHYDRATE	262.016	MILLIGRAMS	POM
PL 16028/0167	20/09/2019	GALPHARM HEALTHCARE LIMITED	BOOTS SLEEPEAZE LIQUID 10MG/5ML ORAL SOLUTION	DIPHENHYDRAMINE HYDROCHLORIDE	10.00	MILLIGRAMS	P
PL 35412/0015	20/09/2019	NEWLINE PHARMA, SOCIEDAD LIMITADA	DEXAMETHASONE SODIUM PHOSPHATE 1.5MG/ML EYE DROPS, SOLUTION	DEXAMETHASONE SODIUM PHOSPHATE	1.5	MILLIGRAMS PER MILLILITRE	POM
PL 35533/0141	20/09/2019	ASPIRE PHARMA LIMITED	PARECOXIB 40 MG POWDER FOR SOLUTION FOR INJECTION	PARECOXIB SODIUM	42.36	MILLIGRAMS	POM
PL 47513/0008	20/09/2019	KOANAA HEALTHCARE GMBH	MELPHALAN 50 MG POWDER AND SOLVENT FOR SOLUTION FOR INJECTION/INFUSION	MELPHALAN HYDROCHLORIDE	55.975	MILLIGRAMS	POM
PL 47513/0008	20/09/2019	KOANAA HEALTHCARE GMBH	MELPHALAN 50 MG POWDER AND SOLVENT FOR SOLUTION FOR INJECTION/INFUSION	SODIUM CITRATE ANHYDROUS	200	MILLIGRAMS	POM
PL 44853/0004	24/09/2019	KENSINGTON PHARMA LIMITED	LEVETIRACETAM KENSINGTON 100 MG/ML CONCENTRATE FOR SOLUTION FOR INFUSION	LEVETIRACETAM	500	MILLIGRAMS	POM
PL 46788/0019	25/09/2019	ALTAN PHARMA LIMITED	DEXMEDETOMIDINE ALTAN 4 MICROGRAMS/ML SOLUTION FOR INFUSION	DEXMEDETOMIDINE HYDROCHLORIDE	4.7274	MICROGRAMS PER MILLILITRE	POM

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PL 43461/0027	27/09/2019	FLAMINGO PHARMA (UK) LIMITED	PHENOXYMETHYLPENICILLIN 125MG/5ML POWDER FOR ORAL SOLUTION	PHENOXYMETHYLPENICILLIN POTASSIUM	139.0	MILLIGRAMS	POM
PL 43461/0028	27/09/2019	FLAMINGO PHARMA (UK) LIMITED	PHENOXYMETHYLPENICILLIN 250MG/5ML POWDER FOR ORAL SOLUTION	PHENOXYMETHYLPENICILLIN POTASSIUM	278	MILLIGRAMS	POM