

Marketing authorisations granted in April 2022

PL Number	Grant Date	MA Holder	Licensed Name(s)	Active Ingredient	Quantity	Units	Legal Status	Territory
PL 08831/0355	01/04/2022	GENUS PHARMACEUTICALS LIMITED	BIMATOPROST 0.3 MG/ML EYE DROPS, SOLUTION, IN SINGLE-DOSE CONTAINER	BIMATOPROST	0.3	MILLIGRAMS	POM	UK
PL 20075/1398	01/04/2022	ACCORD HEALTHCARE LIMITED	TRAMADOL HYDROCHLORIDE AND PARACETAMOL ACCORD 37.5MG/325MG EFFERVESCENT TABLETS	PARACETAMOL	325.000	MILLIGRAMS	POM	UK
PL 20075/1398	01/04/2022	ACCORD HEALTHCARE LIMITED	TRAMADOL HYDROCHLORIDE AND PARACETAMOL ACCORD 37.5MG/325MG EFFERVESCENT TABLETS	TRAMADOL HYDROCHLORIDE	37.500	MILLIGRAMS	POM	UK
PL 40546/0213	01/04/2022	ARISTO PHARMA GMBH	PREGABALIN ARISTO 25 MG HARD CAPSULES	PREGABALIN	25	MILLIGRAMS	POM	UK
PL 40546/0214	01/04/2022	ARISTO PHARMA GMBH	PREGABALIN ARISTO 50 MG HARD CAPSULES	PREGABALIN	50	MILLIGRAMS	POM	UK
PL 40546/0215	01/04/2022	ARISTO PHARMA GMBH	PREGABALIN ARISTO 75 MG HARD CAPSULES	PREGABALIN	75	MILLIGRAMS	POM	UK
PL 40546/0216	01/04/2022	ARISTO PHARMA GMBH	PREGABALIN ARISTO 100 MG HARD CAPSULES	PREGABALIN	100	MILLIGRAMS	POM	UK
PL 40546/0217	01/04/2022	ARISTO PHARMA GMBH	PREGABALIN ARISTO 150MG HARD CAPSULES	PREGABALIN	150	MILLIGRAMS	POM	UK
PL 40546/0218	01/04/2022	ARISTO PHARMA GMBH	PREGABALIN ARISTO 200 MG HARD CAPSULES	PREGABALIN	200	MILLIGRAMS	POM	UK
PL 40546/0219	01/04/2022	ARISTO PHARMA GMBH	PREGABALIN ARISTO 225 MG HARD CAPSULES	PREGABALIN	225	MILLIGRAMS	POM	UK
PL 40546/0220	01/04/2022	ARISTO PHARMA GMBH	PREGABALIN ARISTO 300 MG HARD CAPSULES	PREGABALIN	300	MILLIGRAMS	POM	UK
PLGB 43805/0135	01/04/2022	ASCEND LABORATORIES (UK) LIMITED	TOLVAPTAN ASCEND 30 MG TABLETS	TOLVAPTAN	30.00	MILLIGRAMS	POM	GB
PL 08553/0729	05/04/2022	DR REDDY'S LABORATORIES (UK) LIMITED	SUGAMMADEX 100MG/ML SOLUTION FOR INJECTION	SUGAMMADEX SODIUM	108.8	MILLIGRAMS	POM	UK
PL 16363/0724	05/04/2022	MILPHARM LIMITED	LEFLUNOMIDE 10MG FILM-COATED TABLETS	LEFLUNOMIDE	10	MILLIGRAMS	POM	UK
PL 16363/0725	05/04/2022	MILPHARM LIMITED	LEFLUNOMIDE 15MG FILM-COATED TABLETS	LEFLUNOMIDE	15.000	MILLIGRAMS	POM	UK
PL 16363/0726	05/04/2022	MILPHARM LIMITED	LEFLUNOMIDE 20MG FILM-COATED TABLETS	LEFLUNOMIDE	20.000	MILLIGRAMS	POM	UK
PL 34985/0014	05/04/2022	VENUS PHARMA GMBH	CARBOPLATIN VENUS PHARMA 10 MG/ML CONCENTRATE FOR SOLUTION FOR INFUSION	CARBOPLATIN	10	MILLIGRAMS PER MILLILITRE	POM	UK
PLGB 14895/0315	05/04/2022	ELI LILLY NEDERLAND B.V.	LYUMJEV 100 U/ML SOLUTION FOR INJECTION IN PRE-FILLED PEN (TEMPO PEN)	INSULIN LISPRO	100	UNITS PER MILLILITRE	POM	GB
PL 08553/0699	06/04/2022	DR REDDY'S LABORATORIES (UK) LIMITED	VALSARTAN 40 MG FILM-COATED TABLETS	VALSARTAN	40	MILLIGRAMS	POM	UK
PL 08553/0700	06/04/2022	DR REDDY'S LABORATORIES (UK) LIMITED	VALSARTAN 80 MG FILM-COATED TABLETS	VALSARTAN	80	MILLIGRAMS	POM	UK
PL 08553/0702	06/04/2022	DR REDDY'S LABORATORIES (UK) LIMITED	VALSARTAN 160 MG FILM-COATED TABLETS	VALSARTAN	160	MILLIGRAMS	POM	UK
PL 08553/0703	06/04/2022	DR REDDY'S LABORATORIES (UK) LIMITED	VALSARTAN 320 MG FILM-COATED TABLETS	VALSARTAN	320	MILLIGRAMS	POM	UK
PL 39360/0034	06/04/2022	ABDI FARMA UNIPESOAAL LIMITADA	TADAFIL 5 MG FILM-COATED TABLETS	TADALAFIL	5	MILLIGRAMS	POM	UK
PL 39360/0035	06/04/2022	ABDI FARMA UNIPESOAAL LIMITADA	TADAFIL 10 MG FILM-COATED TABLETS	TADALAFIL	10	MILLIGRAMS	POM	UK
PL 39360/0036	06/04/2022	ABDI FARMA UNIPESOAAL LIMITADA	TADAFIL 20 MG FILM-COATED TABLETS	TADALAFIL	20	MILLIGRAMS	POM	UK
PL 41013/0026	06/04/2022	SEACROSS PHARMACEUTICALS LIMITED	SODIUM VALPROATE 100MG/ML SOLUTION FOR INJECTION OR INFUSION	SODIUM VALPROATE	100	MILLIGRAMS PER MILLILITRE	POM	UK
PL 41013/0028	06/04/2022	SEACROSS PHARMACEUTICALS LIMITED	LEVETIRACETAM SEACROSS 100 MG/ML CONCENTRATE FOR SOLUTION FOR INFUSION	LEVETIRACETAM	500	MILLIGRAMS	POM	UK
PLGB 04416/1649	06/04/2022	SANDOZ LIMITED	MIRABEGRON SANDOZ 25 MG PROLONGED-RELEASE TABLETS	MIRABEGRON	25.000	MILLIGRAMS	POM	GB
PLGB 04416/1650	06/04/2022	SANDOZ LIMITED	MIRABEGRON SANDOZ 50 MG PROLONGED-RELEASE TABLETS	MIRABEGRON	50.000	MILLIGRAMS	POM	GB
PL 20646/0094	07/04/2022	REGULIS CONSULTING LIMITED	DEFERASIROX 900 MG FILM-COATED TABLETS	DEFERASIROX	900	MILLIGRAMS	POM	UK
PL 25258/0366	07/04/2022	GLENMARK PHARMACEUTICALS EUROPE LIMITED	CINACALCET 30 MG FILM-COATED TABLETS	CINACALCET HYDROCHLORIDE	33.063	MILLIGRAMS	POM	UK
PL 25258/0367	07/04/2022	GLENMARK PHARMACEUTICALS EUROPE LIMITED	CINACALCET 60 MG FILM-COATED TABLETS	CINACALCET HYDROCHLORIDE	66.127	MILLIGRAMS	POM	UK
PL 25258/0368	07/04/2022	GLENMARK PHARMACEUTICALS EUROPE LIMITED	CINACALCET 90 MG FILM-COATED TABLETS	CINACALCET HYDROCHLORIDE	33.063	MILLIGRAMS	POM	UK
PL 49445/0068	07/04/2022	AMAROX LIMITED	LEVETIRACETAM AMAROX 100 MG/ML ORAL SOLUTION	LEVETIRACETAM	100	MILLIGRAMS	POM	UK
PLGB 43805/0134	07/04/2022	ASCEND LABORATORIES (UK) LIMITED	TOLVAPTAN ASCEND 15 MG TABLETS	TOLVAPTAN	15.00	MILLIGRAMS	POM	GB
PLNI 35646/0103	07/04/2022	ASCEND GMBH	TOLVAPTAN ASCEND 15 MG TABLETS	TOLVAPTAN	15.00	MILLIGRAMS	POM	NI
PLNI 35646/0104	07/04/2022	ASCEND GMBH	TOLVAPTAN ASCEND 30 MG TABLETS	TOLVAPTAN	30.00	MILLIGRAMS	POM	NI
PL 13621/0081	08/04/2022	FLYNN PHARMA LIMITED	PYRIDOSTIGMINE BROMIDE 60MG TABLETS	PYRIDOSTIGMINE BROMIDE	60	MILLIGRAMS	POM	UK

## Marketing authorisations granted in April 2022

PL Number	Grant Date	MA Holder	Licensed Name(s)	Active Ingredient	Quantity	Units	Legal Status	Territory
PL 24837/0132	08/04/2022	CONSILIENT HEALTH LIMITED	METHOCARBAMOL 1500 MG FILM-COATED TABLETS	METHOCARBAMOL	1500	MILLIGRAMS	POM	UK
PL 39360/0027	08/04/2022	ABDI FARMA UNIPESOAL LIMITADA	RIVAROXABAN ABDI 2.5 MG FILM-COATED TABLETS	RIVAROXABAN	2.5	MILLIGRAMS	POM	UK
PL 39360/0028	08/04/2022	ABDI FARMA UNIPESOAL LIMITADA	RIVAROXABAN ABDI 10 MG FILM-COATED TABLETS	RIVAROXABAN	10	MILLIGRAMS	POM	UK
PL 39360/0029	08/04/2022	ABDI FARMA UNIPESOAL LIMITADA	RIVAROXABAN ABDI 15 MG FILM-COATED TABLETS	RIVAROXABAN	15	MILLIGRAMS	POM	UK
PL 39360/0030	08/04/2022	ABDI FARMA UNIPESOAL LIMITADA	RIVAROXABAN ABDI 20 MG FILM-COATED TABLETS	RIVAROXABAN	20	MILLIGRAMS	POM	UK
PL 41013/0024	08/04/2022	SEACROSS PHARMACEUTICALS LIMITED	OCTREOTIDE 100 MICROGRAMML SOLUTION FOR INJECTION/INFUSION	OCTREOTIDE ACETATE	110	MICROGRAMS	POM	UK
PL 49452/0017	08/04/2022	MIBE PHARMA UK LIMITED	MBETIN 1 MG/G + 0.5 MG/G CREAM	BETAMETHASONE DIPROPIONATE	0.64	MILLIGRAMS	POM	UK
PL 49452/0017	08/04/2022	MIBE PHARMA UK LIMITED	MBETIN 1 MG/G + 0.5 MG/G CREAM	GENTAMICIN SULFATE	1.67	MILLIGRAMS	POM	UK
PL 20242/0039	11/04/2022	FAIRMED HEALTHCARE GMBH	IRBESARTAN FAIRMED HEALTHCARE 75 MG FILM-COATED TABLETS	IRBESARTAN	75.0	MILLIGRAMS	POM	UK
PL 20242/0040	11/04/2022	FAIRMED HEALTHCARE GMBH	IRBESARTAN FAIRMED HEALTHCARE 150 MG FILM-COATED TABLETS	IRBESARTAN	150.0	MILLIGRAMS	POM	UK
PL 20242/0041	11/04/2022	FAIRMED HEALTHCARE GMBH	IRBESARTAN FAIRMED HEALTHCARE 300 MG FILM-COATED TABLETS	IRBESARTAN	300.0	MILLIGRAMS	POM	UK
PL 49445/0117	11/04/2022	AMAROX LIMITED	TRAMADOL HYDROCHLORIDE 50 MG CAPSULES	TRAMADOL HYDROCHLORIDE	50	MILLIGRAMS	POM	UK
PL 00551/0239	12/04/2022	TYPHARM LIMITED	FLUDROXYCORTIDE 4 MICROGRAMS PER SQUARE CENTIMETRE TAPE	FLUDROXYCORTIDE	4	MICROGRAMS PER SQUARE CENTIMETRE	POM	UK
PL 00551/0240	12/04/2022	TYPHARM LIMITED	FLUDROXYCORTIDE 4 MICROGRAMS PER SQUARE CENTIMETRE TAPE	FLUDROXYCORTIDE	4	MICROGRAMS PER SQUARE CENTIMETRE	POM	UK
PL 00551/0241	12/04/2022	TYPHARM LIMITED	FLUDROXYCORTIDE 4 MICROGRAMS PER SQUARE CENTIMETRE TAPE	FLUDROXYCORTIDE	4	MICROGRAMS PER SQUARE CENTIMETRE	POM	UK
PL 17780/1042	12/04/2022	ZENTIVA PHARMA UK LIMITED	DAPTOMYCIN 350 MG POWDER FOR SOLUTION FOR INJECTION/INFUSION	DAPTOMYCIN	350	MILLIGRAMS	POM	UK
PL 17780/1043	12/04/2022	ZENTIVA PHARMA UK LIMITED	DAPTOMYCIN 500 MG POWDER FOR SOLUTION FOR INJECTION OR INFUSION	DAPTOMYCIN	500	MILLIGRAMS	POM	UK
PL 43185/0002	13/04/2022	VALNEVA AUSTRIA GMBH	COVID-19 VACCINE (INACTIVATED, ADJUVANTED, ADSORBED)	SARS-COV-2 VIRUS (INACTIVATED, ADSORBED)	33	NONE	POM	UK
PL 43185/0002	13/04/2022	VALNEVA AUSTRIA GMBH	COVID-19 VACCINE VALNEVA SUSPENSION FOR INJECTION	SARS-COV-2 VIRUS (INACTIVATED, ADSORBED)	33	NONE	POM	UK
PLNI 35646/0102	13/04/2022	ASCEND GMBH	COLESEVELAM HYDROCHLORIDE 625 MG FILM-COATED TABLETS	COLESEVELAM HYDROCHLORIDE	625	MILLIGRAMS	POM	NI
PLNI 48870/0001	13/04/2022	SANDOZ FARMACEVTSKA DRUZBA DD	PIRFENIDONE SANDOZ 801 MG FILM-COATED TABLETS	PIRFENIDONE	267.00	MILLIGRAMS	POM	NI
PLNI 48870/0002	13/04/2022	SANDOZ FARMACEVTSKA DRUZBA DD	PIRFENIDONE SANDOZ 801 MG FILM-COATED TABLETS	PIRFENIDONE	801.00	MILLIGRAMS	POM	NI
PL 03468/0102	19/04/2022	BAUSCH & LOMB (UK) LIMITED	VIZBIM DUO 0.3 MG/ML + 5 MG/ML, EYE DROPS SOLUTION	BIMATOPOST	0.3	MILLIGRAMS PER MILLILITRE	POM	UK
PL 03468/0102	19/04/2022	BAUSCH & LOMB (UK) LIMITED	VIZBIM DUO 0.3 MG/ML + 5 MG/ML, EYE DROPS SOLUTION	TIMOLOL MALEATE	6.830	MILLIGRAMS PER MILLILITRE	POM	UK
PL 39360/0031	19/04/2022	ABDI FARMA UNIPESOAL LIMITADA	DEFERASIROX ABDI 90 MG FILM-COATED TABLET	DEFERASIROX	90	MILLIGRAMS	POM	UK
PL 39360/0032	19/04/2022	ABDI FARMA UNIPESOAL LIMITADA	DEFERASIROX ABDI 180 MG FILM-COATED TABLET	DEFERASIROX	180	MILLIGRAMS	POM	UK
PL 39360/0033	19/04/2022	ABDI FARMA UNIPESOAL LIMITADA	DEFERASIROX ABDI 360 MG FILM-COATED TABLET	DEFERASIROX	360	MILLIGRAMS	POM	UK
PLGB 00166/0432	20/04/2022	ASTELLAS PHARMA LIMITED	PADCEV 20 MG POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION	ENFORTUMAB VEDOTIN	20	MILLIGRAMS	POM	GB
PLGB 00166/0433	20/04/2022	ASTELLAS PHARMA LIMITED	PADCEV 30 MG POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION	ENFORTUMAB VEDOTIN	30	MILLIGRAMS	POM	GB
PL 15413/0096	26/04/2022	HKMA FARMACEUTICA (PORTUGAL) SA	AZACITIDINE 25 MG/ML POWDER FOR SUSPENSION FOR INJECTION	AZACITIDINE	100	MILLIGRAMS	POM	UK
PL 52530/0001	26/04/2022	MEDIR B.V.	NASOLAM 2.5 MG NASAL SPRAY, SOLUTION IN SINGLE-DOSE CONTAINER	MIDAZOLAM HYDROCHLORIDE	2.78	MILLIGRAMS	POM	UK
PL 52530/0002	26/04/2022	MEDIR B.V.	NASOLAM 3.75 MG NASAL SPRAY, SOLUTION IN SINGLE-DOSE CONTAINER	MIDAZOLAM HYDROCHLORIDE	4.17	MILLIGRAMS	POM	UK
PL 52530/0003	26/04/2022	MEDIR B.V.	NASOLAM 5 MG NASAL SPRAY, SOLUTION IN SINGLE-DOSE CONTAINER	MIDAZOLAM HYDROCHLORIDE	5.56	MILLIGRAMS	POM	UK
PLGB 53835/0005	26/04/2022	CELIx PHARMA LTD	ICATIBANT 30 MG SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE	ICATIBANT ACETATE	31.38	MILLIGRAMS	POM	GB
PL 00427/0258	27/04/2022	ROSEMONT PHARMACEUTICALS LIMITED	SILDENAFIL 10 MG/ML ORAL SUSPENSION	SILDENAFIL CITRATE	14.048	MILLIGRAMS PER MILLILITRE	POM	UK
PL 25258/0362	28/04/2022	GLENMARK PHARMACEUTICALS EUROPE LIMITED	NITROFURANTOIN 50 MG TABLETS	NITROFURANTOIN ANHYDROUS	50	MILLIGRAMS	POM	UK
PL 25258/0363	28/04/2022	GLENMARK PHARMACEUTICALS EUROPE LIMITED	NITROFURANTOIN 100 MG TABLETS	NITROFURANTOIN ANHYDROUS	100	MILLIGRAMS	POM	UK
PL 52570/0008	28/04/2022	TAW PHARMA LIMITED	VELARIQ 1 MG/ML INTRAVESICAL SOLUTION	OXYBUTYNIN HYDROCHLORIDE	1.004	MILLIGRAMS	POM	UK

Marketing authorisations granted in April 2022

PL Number	Grant Date	MA Holder	Licensed Name(s)	Active Ingredient	Quantity	Units	Legal Status	Territory
PLGB 50784/0009	29/04/2022	VIFOR FRESENIUS MEDICAL CARE RENAL PHARMA FRANCE	KAPRUVIA 50 MICROGRAMS/ML SOLUTION FOR INJECTION	DIFELIKEFALIN ACETATE	55	MICROGRAMS PER MILLILITRE	POM	GB
PLGB 55184/0002	29/04/2022	AMIVAS IRELAND LIMITED	ARTESUNATE AMIVAS 110 MG POWDER AND SOLVENT FOR SOLUTION FOR INJECTION	ARTESUNATE	110	MILLIGRAMS	POM	GB
PLGB 55184/0002	29/04/2022	AMIVAS IRELAND LIMITED	ARTESUNATE AMIVAS 110 MG POWDER AND SOLVENT FOR SOLUTION FOR INJECTION	NO ACTIVES PRESENT	0	NONE	POM	GB