

Marketing authorisations granted 15 November 2023 to 30 November 2023

PL Number	Grant Date	MA Holder	Licensed Name(s)	Active Ingredient	Quantity	Units	Legal Status	Territory
PL 25298/0316	15/11/2023	BROWN & BURK UK LIMITED	NEFOPAM HYDROCHLORIDE 60 MG FILM-COATED TABLETS	NEFOPAM HYDROCHLORIDE	60.000	MILIGRAMS	POM	UK
PL 26080/0008	15/11/2023	SERB	MYLSOLINE 125MG TABLETS	PRIMIDONE	125.00	MILIGRAMS	POM	UK
PL 26080/0008	15/11/2023	SERB	PRIMIDONE SERB 125MG TABLETS	PRIMIDONE	125.00	MILIGRAMS	POM	UK
PLGB 22352/0019	15/11/2023	VERTEX PHARMACEUTICALS (EUROPE) LIMITED	CAGSEVY 4-13 X 10 ⁶ CELLS/ML DISPERSION FOR INFUSION	EXGAGMLOGEINE AUTOTEMCEL	4000000	CELLS PER MILLILITRE	POM	GB
PLGB 22352/0020	15/11/2023	VERTEX PHARMACEUTICALS (EUROPE) LIMITED	KAFTRIO 60 MG/40 MG/80 MG GRANULES IN SACHET	ELEXACFTOR	80	MILIGRAMS PER DOSE	POM	GB
PLGB 22352/0020	15/11/2023	VERTEX PHARMACEUTICALS (EUROPE) LIMITED	KAFTRIO 60 MG/40 MG/80 MG GRANULES IN SACHET	IVACFTOR	60	MILIGRAMS PER DOSE	POM	GB
PLGB 22352/0020	15/11/2023	VERTEX PHARMACEUTICALS (EUROPE) LIMITED	KAFTRIO 60 MG/40 MG/80 MG GRANULES IN SACHET	TEZACFTOR	40	MILIGRAMS PER DOSE	POM	GB
PLGB 22352/0021	15/11/2023	VERTEX PHARMACEUTICALS (EUROPE) LIMITED	KALYDECO 59.5 MG GRANULES IN SACHET	IVACFTOR	59.5	MILIGRAMS PER DOSE	POM	GB
PLGB 22352/0022	15/11/2023	VERTEX PHARMACEUTICALS (EUROPE) LIMITED	KAFTRIO 75MG/50MG/100MG GRANULES IN SACHET	ELEXACFTOR	100.0	MILIGRAMS PER DOSE	POM	GB
PLGB 22352/0022	15/11/2023	VERTEX PHARMACEUTICALS (EUROPE) LIMITED	KAFTRIO 75MG/50MG/100MG GRANULES IN SACHET	IVACFTOR	75.0	MILIGRAMS PER DOSE	POM	GB
PLGB 22352/0022	15/11/2023	VERTEX PHARMACEUTICALS (EUROPE) LIMITED	KAFTRIO 75MG/50MG/100MG GRANULES IN SACHET	TEZACFTOR	50.0	MILIGRAMS PER DOSE	POM	GB
PLGB 22352/0023	15/11/2023	VERTEX PHARMACEUTICALS (EUROPE) LIMITED	KALYDECO 13.4 MG GRANULES IN SACHET	IVACFTOR	13.4	MILIGRAMS PER DOSE	POM	GB
PLNI 35646/0098	15/11/2023	ASCEND GMBH	TAMSULOSIN ASCEND 400 MCG MODIFIED-RELEASE CAPSULE, HARD	TAMSULOSIN HYDROCHLORIDE	0.400	MILIGRAMS	POM	NI
PL 15413/0110	16/11/2023	HKMA FARMACEUTICA (PORTUGAL) SA	MELPHALAN 50 MG POWDER AND SOLVENT FOR SOLUTION FOR INJECTION/INFUSION	MELPHALAN HYDROCHLORIDE	56	MILIGRAMS	POM	UK
PL 17907/0746	16/11/2023	BRISTOL LABORATORIES LIMITED	MEBEVERINE HYDROCHLORIDE 135 MG COATED TABLETS	MEBEVERINE HYDROCHLORIDE	135	MILIGRAMS	POM	UK
PL 20646/0038	16/11/2023	REGULUS CONSULTING LIMITED	DABIGATRAN ETEXILATE 75 MG HARD CAPSULES	DABIGATRAN ETEXILATE MESLATE	86.475	MILIGRAMS	POM	UK
PL 20646/0039	16/11/2023	REGULUS CONSULTING LIMITED	DABIGATRAN ETEXILATE 110 MG HARD CAPSULES	DABIGATRAN ETEXILATE MESLATE	126.83	MILIGRAMS	POM	UK
PL 20646/0040	16/11/2023	REGULUS CONSULTING LIMITED	DABIGATRAN ETEXILATE 150 MG HARD CAPSULES	DABIGATRAN ETEXILATE MESLATE	172.95	MILIGRAMS	POM	UK
PL 56740/0017	16/11/2023	ABDI FARMA GMBH	TICAGRELOR ABDI 60 MG FILM-COATED TABLETS	TICAGRELOR	60.0	MILIGRAMS	POM	UK
PL 56740/0025	16/11/2023	ABDI FARMA GMBH	TICAGRELOR ABDI 90 MG FILM-COATED TABLETS	TICAGRELOR	90.0	MILIGRAMS	POM	UK
PLGB 20079/1475	16/11/2023	ACCORD HEALTHCARE LIMITED	TERIFLUNOMIDE 14 MG FILM-COATED TABLETS	TERIFLUNOMIDE	14.00	MILIGRAMS	POM	GB
PL 00142/1313	17/11/2023	ACCORD-UK LIMITED	DEXAMETHASONE 3.3 MG/ML SOLUTION FOR INJECTION/INFUSION	DEXAMETHASONE SODIUM PHOSPHATE	4.37	MILIGRAMS	POM	UK
PL 29556/0005	20/11/2023	ZAKLADY FARMACEUTYCZNE POLPHARMA SA	LOTACRYN, 50 MICROGRAMS/ML, EYE DROPS, SOLUTION	LATANOPROST	50	MICROGRAMS	POM	UK
PL 08553/0756	21/11/2023	DR REDDY'S LABORATORIES (UK) LIMITED	FEXOFENADINE HYDROCHLORIDE 180 MG FILM-COATED TABLETS	FEXOFENADINE HYDROCHLORIDE	180.00	MILIGRAMS	POM	UK
PLGB 00031/0916	21/11/2023	ROCHE PRODUCTS LIMITED	ENSPRYNG 120 MG SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE	SATRALIZUMAB	120	MILIGRAMS PER MILLILITRE	POM	GB
PLGB 00057/1722	21/11/2023	PFIZER LIMITED	ABRYSVO POWDER AND SOLVENT FOR SOLUTION FOR INJECTION	RESPIRATORY SYNCYTIAL VIRUS SUBGROUP A STABILISED PREFUSION F PROTEIN 847A	0.06	MILIGRAMS	POM	GB
PLGB 00057/1722	21/11/2023	PFIZER LIMITED	ABRYSVO POWDER AND SOLVENT FOR SOLUTION FOR INJECTION	RESPIRATORY SYNCYTIAL VIRUS SUBGROUP B STABILISED PREFUSION F PROTEIN 847B	0.06	MILIGRAMS	POM	GB
PLGB 13591/0006	21/11/2023	NOVA LABORATORIES LIMITED	QALDLO 10 MG/ML ORAL SUSPENSION	SPIRONOLACTONE	10.0	MILIGRAMS PER MILLILITRE	POM	GB
PL 49445/0118	22/11/2023	AMAROX LIMITED	RAMPRIIL 1.25 MG HARD CAPSULES	RAMPRIIL	1.250	MILIGRAMS	POM	UK
PL 49445/0119	22/11/2023	AMAROX LIMITED	RAMPRIIL 2.5 MG HARD CAPSULES	RAMPRIIL	2.50	MILIGRAMS	POM	UK
PL 49445/0120	22/11/2023	AMAROX LIMITED	RAMPRIIL 5 MG HARD CAPSULES	RAMPRIIL	5.00	MILIGRAMS	POM	UK
PL 49445/0121	22/11/2023	AMAROX LIMITED	RAMPRIIL 10 MG HARD CAPSULES	RAMPRIIL	10.00	MILIGRAMS	POM	UK
PL 49565/0070	22/11/2023	RUDIPHARM LIMITED	RUDIMET 500MG PROLONGED-RELEASE TABLETS	METFORMIN HYDROCHLORIDE	500	MILIGRAMS	POM	UK
PL 49445/0175	23/11/2023	AMAROX LIMITED	LACOSAMIDE AMAROX 10 MG/ML SOLUTION FOR INFUSION	LACOSAMIDE	10	MILIGRAMS PER MILLILITRE	POM	UK
PL 50640/0005	23/11/2023	CAREFORSONS LIMITED	MINOXIDIL 5% CUTANEOUS SOLUTION	MINOXIDIL	50.00	MILIGRAMS PER MILLILITRE	GSL	UK
PL 51483/0072	23/11/2023	KENT PHARMA UK LIMITED	PYRIDOXINE HYDROCHLORIDE 50MG TABLETS	PYRIDOXINE HYDROCHLORIDE	50	MILIGRAMS	POM	UK
PL 55863/0073	24/11/2023	NOVUMGEN LIMITED	MIDODRINE HYDROCHLORIDE 2.5 MG TABLETS	MIDODRINE HYDROCHLORIDE	2.5	MILIGRAMS	POM	UK
PL 55863/0074	24/11/2023	NOVUMGEN LIMITED	MIDODRINE HYDROCHLORIDE 5 MG TABLETS	MIDODRINE HYDROCHLORIDE	5	MILIGRAMS	POM	UK
PL 08553/0781	27/11/2023	DR REDDY'S LABORATORIES (UK) LIMITED	TERIFLUNOMIDE 14 MG FILM-COATED TABLETS	TERIFLUNOMIDE	14	MILIGRAMS	POM	UK
PL 29472/0001	27/11/2023	S.A.L.F. SPA LABORATORIO FARMACOLOGICO	CORHUM SOLUTION FOR CARDIOPLEGIA	ALPHA-KETOGLUTARIC ACID	0.1461	GRAMS PER LITRE	POM	UK
PL 29472/0001	27/11/2023	S.A.L.F. SPA LABORATORIO FARMACOLOGICO	CORHUM SOLUTION FOR CARDIOPLEGIA	CALCIUM CHLORIDE DIHYDRATE	0.0222	GRAMS PER LITRE	POM	UK
PL 29472/0001	27/11/2023	S.A.L.F. SPA LABORATORIO FARMACOLOGICO	CORHUM SOLUTION FOR CARDIOPLEGIA	HISTIDINE	27.9289	GRAMS PER LITRE	POM	UK
PL 29472/0001	27/11/2023	S.A.L.F. SPA LABORATORIO FARMACOLOGICO	CORHUM SOLUTION FOR CARDIOPLEGIA	HISTIDINE HYDROCHLORIDE MONOHYDRATE	3.7733	GRAMS PER LITRE	POM	UK

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PL 294720001	27/11/2023	S.A.L.F. SPA LABORATORIO FARMACOLOGICO	CORHUM SOLUTION FOR CARDIOPLEGIA	MAGNESIUM CHLORIDE HEXAHYDRATE	0.8132	GRAMS PER LITRE	POM	UK
PL 294720001	27/11/2023	S.A.L.F. SPA LABORATORIO FARMACOLOGICO	CORHUM SOLUTION FOR CARDIOPLEGIA	MANNITOL	5.4651	GRAMS PER LITRE	POM	UK
PL 294720001	27/11/2023	S.A.L.F. SPA LABORATORIO FARMACOLOGICO	CORHUM SOLUTION FOR CARDIOPLEGIA	POTASSIUM CHLORIDE	0.6710	GRAMS PER LITRE	POM	UK
PL 294720001	27/11/2023	S.A.L.F. SPA LABORATORIO FARMACOLOGICO	CORHUM SOLUTION FOR CARDIOPLEGIA	SODIUM CHLORIDE	0.8766	GRAMS PER LITRE	POM	UK
PL 294720001	27/11/2023	S.A.L.F. SPA LABORATORIO FARMACOLOGICO	CORHUM SOLUTION FOR CARDIOPLEGIA	TRYPTOPHAN	0.4085	GRAMS PER LITRE	POM	UK
PL 163630716	28/11/2023	MILPHARM LIMITED	MEMANTINE HYDROCHLORIDE 10 MG FILM-COATED TABLETS	MEMANTINE HYDROCHLORIDE	10.00	MILLIGRAMS	POM	UK
PL 163630717	28/11/2023	MILPHARM LIMITED	MEMANTINE HYDROCHLORIDE 20 MG FILM-COATED TABLETS	MEMANTINE HYDROCHLORIDE	20.00	MILLIGRAMS	POM	UK
PL 558630038	29/11/2023	NOVUMGEN LIMITED	IVABRADINE 5 MG FILM-COATED TABLETS	IVABRADINE OXALATE	5.96	MILLIGRAMS	POM	UK
PL 558630039	29/11/2023	NOVUMGEN LIMITED	IVABRADINE 7.5M G FILM-COATED TABLETS	IVABRADINE OXALATE	8.94	MILLIGRAMS	POM	UK
PLGB 20075/1482	29/11/2023	ACCORD HEALTHCARE LIMITED	TOLVAPTAN 7.5 MG TABLETS	TOLVAPTAN	7.500	MILLIGRAMS	POM	UK
PLGB 20075/1483	29/11/2023	ACCORD HEALTHCARE LIMITED	TOLVAPTAN 15 MG TABLETS	TOLVAPTAN	15.000	MILLIGRAMS	POM	UK
PLGB 20075/1484	29/11/2023	ACCORD HEALTHCARE LIMITED	TOLVAPTAN 30 MG TABLETS	TOLVAPTAN	30.000	MILLIGRAMS	POM	UK
PL 177801139	30/11/2023	ZENTIVA PHARMA UK LIMITED	TERIFLUNOMIDE 14 MG FILM-COATED TABLETS	TERIFLUNOMIDE	14.00	MILLIGRAMS	POM	UK
PL 422890026	30/11/2023	WAVE PHARMA LIMITED	VARENICLINE 0.5 MG FILM-COATED TABLETS	VARENICLINE TARTRATE	0.855	MILLIGRAMS	POM	UK
PL 422890027	30/11/2023	WAVE PHARMA LIMITED	VARENICLINE 1 MG FILM-COATED TABLETS	VARENICLINE TARTRATE	1.710	MILLIGRAMS	POM	UK
PL 422890028	30/11/2023	WAVE PHARMA LIMITED	VARENICLINE 0.5 MG FILM-COATED TABLETS, VARENICLINE 1 MG FILM-COATED TABLETS	VARENICLINE TARTRATE	0.855	MILLIGRAMS	POM	UK
PL 422890028	30/11/2023	WAVE PHARMA LIMITED	VARENICLINE 0.5 MG FILM-COATED TABLETS, VARENICLINE 1 MG FILM-COATED TABLETS	VARENICLINE TARTRATE	1.710	MILLIGRAMS	POM	UK
PL 450430106	30/11/2023	NEON HEALTHCARE LIMITED	BLEOMYCIN 15000 IU POWDER FOR SOLUTION FOR INJECTION/INFUSION	BLEOMYCIN SULFATE	15000	INTERNATIONAL UNITS	POM	UK
PLGB 119720060	30/11/2023	GILEAD SCIENCES LTD	BKTRVY 30 MG/120 MG/15 MG FILM-COATED TABLETS	BICTEGRAVIR SODIUM	31.47	MILLIGRAMS	POM	GB
PLGB 119720060	30/11/2023	GILEAD SCIENCES LTD	BKTRVY 30 MG/120 MG/15 MG FILM-COATED TABLETS	EMTRICITABINE	120	MILLIGRAMS	POM	GB
PLGB 119720060	30/11/2023	GILEAD SCIENCES LTD	BKTRVY 30 MG/120 MG/15 MG FILM-COATED TABLETS	TENOFOVIR ALAFENAMIDE FUMARATE	16.82	MILLIGRAMS	POM	GB