

Marketing authorisations granted 1 September 2023 to 14 September 2023

PL Number	Grant Date	MA Holder	Licensed Name(s)	Active Ingredient	Quantity	Units	Legal Status	Territory
PL 00221/0400	01/09/2023	GE HEALTHCARE LIMITED	GADOBUTROL 1.0 MMOL/ML SOLUTION FOR INJECTION	GADOBUTROL	604.720	MILLIGRAMS PER MILLILITRE	POM	UK
PL 00221/0401	01/09/2023	GE HEALTHCARE LIMITED	GADOBUTROL 1.0 MMOL/ML SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE	GADOBUTROL	604.720	MILLIGRAMS PER MILLILITRE	POM	UK
PL 16363/0653	01/09/2023	MILPHARM LIMITED	RITONAVIR 100 MG FILM-COATED TABLETS	RITONAVIR	100	MILLIGRAMS	POM	UK
PL 47015/0030	01/09/2023	AS KALCEKS	CEFTRIAZONE 1 G POWDER FOR SOLUTION FOR INJECTION/INFUSION	CEFTRIAZONE SODIUM	1.193	GRAMS	POM	UK
PL 47015/0031	01/09/2023	AS KALCEKS	CEFTRIAZONE 2 G POWDER FOR SOLUTION FOR INJECTION/INFUSION	CEFTRIAZONE SODIUM	2.386	GRAMS	POM	UK
PL 48974/0025	01/09/2023	LYRUS LIFE SCIENCES LIMITED	LYMECYCLINE 408 MG HARD CAPSULES	LYMECYCLINE	408	MILLIGRAMS	POM	UK
PLGB 14895/0331	01/09/2023	ELI LILLY NEDERLAND B.V.	MOUNJARO 2.5 MG SOLUTION FOR INJECTION IN VIAL	TIRZEPATIDE	2.5	MILLIGRAMS	POM	GB
PLGB 14895/0332	01/09/2023	ELI LILLY NEDERLAND B.V.	MOUNJARO 5 MG SOLUTION FOR INJECTION IN VIAL	TIRZEPATIDE	5	MILLIGRAMS	POM	GB
PLGB 14895/0333	01/09/2023	ELI LILLY NEDERLAND B.V.	MOUNJARO 7.5 MG SOLUTION FOR INJECTION IN VIAL	TIRZEPATIDE	7.5	MILLIGRAMS	POM	GB
PLGB 14895/0334	01/09/2023	ELI LILLY NEDERLAND B.V.	MOUNJARO 10 MG SOLUTION FOR INJECTION IN VIAL	TIRZEPATIDE	10	MILLIGRAMS	POM	GB
PLGB 14895/0335	01/09/2023	ELI LILLY NEDERLAND B.V.	MOUNJARO 12.5 MG SOLUTION FOR INJECTION IN VIAL	TIRZEPATIDE	12.5	MILLIGRAMS	POM	GB
PLGB 14895/0336	01/09/2023	ELI LILLY NEDERLAND B.V.	MOUNJARO 15 MG SOLUTION FOR INJECTION IN VIAL	TIRZEPATIDE	15	MILLIGRAMS	POM	GB
PLGB 53835/0032	01/09/2023	CELIX PHARMA LTD	FESOTERODINE FUMARATE 4 MG PROLONGED-RELEASE TABLETS	FESOTERODINE FUMARATE	4.0	MILLIGRAMS	POM	GB
PLGB 53835/0033	01/09/2023	CELIX PHARMA LTD	FESOTERODINE FUMARATE 8 MG PROLONGED-RELEASE TABLETS	FESOTERODINE FUMARATE	8.0	MILLIGRAMS	POM	UK
PLGB 57572/0001	01/09/2023	PLUSULTRA PHARMA GMBH	HYFTOR 2MG/G GEL	SIRILIMUS	2.0	MILLIGRAMS PER GRAM	POM	GB
PL 30322/0059	04/09/2023	ALISSA HEALTHCARE RESEARCH LIMITED	BREEMISTA 27.5 MICROGRAMS/ACTUATION, NASAL SPRAY SUSPENSION	FLUTICASONONE FUROATE	27.5	MICROGRAMS PER ACTUATION	POM	UK
PL 33280/0025	04/09/2023	SYNCHRONY PHARMA LIMITED	METHYLPHENIDATE HYDROCHLORIDE 2MG/ML ORAL SOLUTION	METHYLPHENIDATE HYDROCHLORIDE	2	MILLIGRAMS PER MILLILITRE	POM	UK
PLGB 53632/0026	04/09/2023	BIONTECH MANUFACTURING GMBH	COMIRNATY OMICRON XBB.1.5 (30 MICROGRAMS)/DOSE DISPERSION FOR INJECTION	RAXTOZINAMERAN	0.1	MILLIGRAMS PER MILLILITRE	POM	GB
PLGB 53632/0032	04/09/2023	BIONTECH MANUFACTURING GMBH	COMIRNATY OMICRON XBB.1.5 (10 MICROGRAMS)/DOSE DISPERSION FOR INJECTION	RAXTOZINAMERAN	0.033	MILLIGRAMS PER MILLILITRE	POM	GB
PLGB 53632/0036	04/09/2023	BIONTECH MANUFACTURING GMBH	COMIRNATY OMICRON XBB.1.5 (3 MICROGRAMS)/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION	RAXTOZINAMERAN	0.1	MILLIGRAMS PER MILLILITRE	POM	GB
PL 16363/0764	05/09/2023	MILPHARM LIMITED	SUNITINIB 12.5 MG HARD CAPSULES	SUNITINIB MALATE	16.71	MILLIGRAMS	POM	UK
PL 16363/0765	05/09/2023	MILPHARM LIMITED	SUNITINIB 25 MG HARD CAPSULES	SUNITINIB MALATE	33.41	NONE	POM	UK
PL 16363/0766	05/09/2023	MILPHARM LIMITED	SUNITINIB 50 MG HARD CAPSULES	SUNITINIB MALATE	66.83	NONE	POM	UK
PL 11587/0139	06/09/2023	MEDAC GESELLSCHAFT FUR KLINISCHE SPEZIALPRAPARATE MBH	BCG MEDAC 2 X 10 ⁸ - 1.5 X 10 ⁹ CFU POWDER AND SOLVENT FOR INTRAVESICAL SUSPENSION	BACILLUS CALMETTE GUERIN (LIVE ATTENUATED) RIVM PASTEUR 1173 P2 - LIKE STRAIN	2000	MEGA COLONY FORMING UNITS	POM	UK
PL 11587/0140	06/09/2023	MEDAC GESELLSCHAFT FUR KLINISCHE SPEZIALPRAPARATE MBH	BCG MEDAC 2 X 10 ⁸ - 1.5 X 10 ⁹ CFU POWDER FOR INTRAVESICAL SUSPENSION	BACILLUS CALMETTE GUERIN (LIVE ATTENUATED) RIVM PASTEUR 1173 P2 - LIKE STRAIN	2000	MEGA COLONY FORMING UNITS	POM	UK
PL 31103/0038	06/09/2023	BLUMONT PHARMA LIMITED	BIMATOPROST 0.3MG/ML EYE DROPS, SOLUTION	BIMATOPROST	0.300	MILLIGRAMS PER MILLILITRE	POM	UK
PL 33360/0040	06/09/2023	ABDI FARMA UNPESSOAL LIMITADA	BENZYLAMINE HYDROCHLORIDE 0.15 % W/V OROMUCOSAL SPRAY	BENZYLAMINE HYDROCHLORIDE	1.5000	MILLIGRAMS PER MILLILITRE	P	UK
PL 45043/0013	06/09/2023	NEON HEALTHCARE LIMITED	LEVOCARNITINE PAEDIATRIC 30% ORAL SOLUTION	LEVOCARNITINE	300.0	MILLIGRAMS	POM	UK
PL 49255/0004	06/09/2023	CYGNUS PHARMA LIMITED	TRAZODONE HYDROCHLORIDE 50MG/5ML ORAL SOLUTION	TRAZODONE HYDROCHLORIDE	50	MILLIGRAMS PER 5 MILLILITRES	POM	UK
PL 06464/3118	07/09/2023	WAYMADE PLC	MELPHALAN 50 MG POWDER AND SOLVENT FOR SOLUTION FOR INJECTION/INFUSION	MELPHALAN HYDROCHLORIDE	0.0	NONE	POM	UK
PL 06464/3118	07/09/2023	WAYMADE PLC	MELPHALAN 50 MG POWDER AND SOLVENT FOR SOLUTION FOR INJECTION/INFUSION	MELPHALAN HYDROCHLORIDE	55.97	MILLIGRAMS	POM	UK
PL 14338/0015	07/09/2023	PATHEON SOFTGELS BV	PARACETAMOL 500 MG SOFT, CAPSULES	PARACETAMOL	500	MILLIGRAMS	GSL	UK
PL 44490/0001	07/09/2023	ALTURIX LIMITED	CEVESTO 1 MG/ML ORAL SOLUTION	MELATONIN	1	MILLIGRAMS PER MILLILITRE	POM	UK
PL 45043/0110	07/09/2023	NEON HEALTHCARE LIMITED	LEVOCARNITINE PAEDIATRIC 30 % ORAL SOLUTION	LEVOCARNITINE	300.0	MILLIGRAMS	POM	UK
PL 49255/0003	07/09/2023	CYGNUS PHARMA LIMITED	LOPERAMIDE 2 MG CAPSULES, HARD	LOPERAMIDE HYDROCHLORIDE	2	MILLIGRAMS	P	UK
PL 44570/0028	08/09/2023	QILU PHARMA SPAIN SL	MEROPENEM 500 MG POWDER FOR SOLUTION FOR INJECTION/INFUSION	MEROPENEM TRIHYDRATE	570	MILLIGRAMS	POM	UK
PL 44570/0029	08/09/2023	QILU PHARMA SPAIN SL	MEROPENEM 1 G POWDER FOR SOLUTION FOR INJECTION/INFUSION	MEROPENEM TRIHYDRATE	1.14	GRAMS	POM	UK
PLGB 11587/0132	08/09/2023	MEDAC GESELLSCHAFT FUR KLINISCHE SPEZIALPRAPARATE MBH	THIOTEPA MEDAC 15 MG POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION	THIOTEPA	15.000	MILLIGRAMS	POM	GB
PLGB 11587/0133	08/09/2023	MEDAC GESELLSCHAFT FUR KLINISCHE SPEZIALPRAPARATE MBH	THIOTEPA MEDAC 100 MG POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION	THIOTEPA	100.0	MILLIGRAMS	POM	GB
PL 15413/0112	11/09/2023	HIKMA FARMACEUTICA (PORTUGAL) SA	OMEPRAZOLE 40 MG POWDER FOR SOLUTION FOR INFUSION	OMEPRAZOLE	40	MILLIGRAMS	POM	UK
PL 23218/0191	11/09/2023	LABORATORIOS LICONSA SA	FINGOLIMOD 0.5 MG HARD CAPSULES	FINGOLIMOD HYDROCHLORIDE	0.56	MILLIGRAMS	POM	UK

Marketing authorisations granted 1 September 2023 to 14 September 2023

PL Number	Grant Date	MA Holder	Licensed Name(s)	Active Ingredient	Quantity	Units	Legal Status	Territory
PL 27925/0121	11/09/2023	ORION CORPORATION	SUGAMMADEX ORION 100 MG/ML SOLUTION FOR INJECTION	SUGAMMADEX SODIUM	108.8	MILLIGRAMS PER MILLILITRE	POM	UK
PL 51288/0015	11/09/2023	ADALVO LIMITED	DIENOGEST 2 MG TABLETS	DIENOGEST	2.000	MILLIGRAMS	POM	UK
PL 21597/0094	12/09/2023	G L PHARMA GMBH	OXYLAN 15MG PROLONGED-RELEASE TABLETS	OXYCODONE HYDROCHLORIDE	15.0	MILLIGRAMS	POM	UK
PL 21597/0095	12/09/2023	G L PHARMA GMBH	OXYLAN 30MG PROLONGED-RELEASE TABLETS	OXYCODONE HYDROCHLORIDE	30.0	MILLIGRAMS	POM	UK
PL 21597/0096	12/09/2023	G L PHARMA GMBH	OXYLAN 60MG PROLONGED-RELEASE TABLETS	OXYCODONE HYDROCHLORIDE	60.0	MILLIGRAMS	POM	UK
PL 48804/0010	13/09/2023	RIDGE PHARMA LIMITED	ANZI PRO 375MG PROLONGED-RELEASE TABLETS	RANOLAZINE	375	MILLIGRAMS	POM	UK
PL 48804/0011	13/09/2023	RIDGE PHARMA LIMITED	ANZI PRO 500MG PROLONGED-RELEASE TABLETS	RANOLAZINE	500	MILLIGRAMS	POM	UK
PL 48804/0012	13/09/2023	RIDGE PHARMA LIMITED	ANZI PRO 750MG PROLONGED-RELEASE TABLETS	RANOLAZINE	750	MILLIGRAMS	POM	UK
PL 49255/0018	13/09/2023	CYGNUS PHARMA LIMITED	IBUPROFEN 200 MG FILM-COATED TABLETS	IBUPROFEN	200	MILLIGRAMS	POM	UK
PL 49255/0019	13/09/2023	CYGNUS PHARMA LIMITED	IBUPROFEN 400 MG FILM-COATED TABLETS	IBUPROFEN	400	MILLIGRAMS	POM	UK
PL 49255/0021	13/09/2023	CYGNUS PHARMA LIMITED	IBUPROFEN 600 MG FILM-COATED TABLETS	IBUPROFEN	600	MILLIGRAMS	POM	UK
PLGB 04569/2074	14/09/2023	GENERICIS (UK) LIMITED	DIMETHYL FUMARATE MYLAN 120 MG GASTRO-RESISTANT HARD CAPSULES	DIMETHYL FUMARATE	120.000	MILLIGRAMS	POM	GB
PLGB 04569/2075	14/09/2023	GENERICIS (UK) LIMITED	DIMETHYL FUMARATE MYLAN 240 MG GASTRO-RESISTANT HARD CAPSULES	DIMETHYL FUMARATE	240.000	MILLIGRAMS	POM	GB
PLGB 53720/0011	14/09/2023	MODERNA BIOTECH SPAIN SL	SPIKEVAX XBB.1.5 0.1 MG/ML DISPERSION FOR INJECTION	ANDUSOMERAN	0.100	MILLIGRAMS PER MILLILITRE	POM	GB