

Marketing authorisations granted 15 July to 31 July 2023

PL Number	Grant Date	MA Holder	Licensed Name(s)	Active Ingredient	Quantity	Units	Legal Status	Territory
PL 25298/0286	17/07/2023	BROWN & BURK UK LIMITED	RIVAROXABAN 10 MG FILM-COATED TABLETS	RIVAROXABAN	10	MILLIGRAMS	POM	UK
PL 25298/0287	17/07/2023	BROWN & BURK UK LIMITED	RIVAROXABAN 15 MG FILM-COATED TABLETS	RIVAROXABAN	15	MILLIGRAMS	POM	UK
PL 25298/0288	17/07/2023	BROWN & BURK UK LIMITED	RIVAROXABAN 20 MG FILM-COATED TABLETS	RIVAROXABAN	20	MILLIGRAMS	POM	UK
PL 30684/0360	17/07/2023	DAWA LIMITED	GABAPENTIN DAWA 400 MG CAPSULES	GABAPENTIN	400	MILLIGRAMS	POM	UK
PL 28444/0266	21/07/2023	ACTIVASE PHARMACEUTICALS LIMITED	SULPRIDE 200MG TABLETS	SULPRIDE	200	MILLIGRAMS	POM	UK
PL 28444/0267	21/07/2023	ACTIVASE PHARMACEUTICALS LIMITED	SULPRIDE 400MG TABLETS	SULPRIDE	400	MILLIGRAMS	POM	UK
PLGB 00242/0747	21/07/2023	JANSSEN-CILAG LIMITED	AKEEGA 50 MG/500 MG FILM-COATED TABLETS	ABIRATERONE ACETATE	500.00	MILLIGRAMS	POM	UK
PLGB 00242/0747	21/07/2023	JANSSEN-CILAG LIMITED	AKEEGA 50 MG/500 MG FILM-COATED TABLETS	NRAPARIB TOSYLATE MONOHYDRATE	79.70	MILLIGRAMS	POM	UK
PLGB 00242/0748	21/07/2023	JANSSEN-CILAG LIMITED	AKEEGA 100 MG/500 MG FILM-COATED TABLETS	ABIRATERONE ACETATE	500.00	MILLIGRAMS	POM	UK
PLGB 00242/0748	21/07/2023	JANSSEN-CILAG LIMITED	AKEEGA 100 MG/500 MG FILM-COATED TABLETS	NRAPARIB TOSYLATE MONOHYDRATE	159.40	MILLIGRAMS	POM	UK
PLGB 04569/2068	21/07/2023	GENERICIS (UK) LIMITED	TERIFLUNOMIDE MYLAN 14 MG FILM-COATED TABLETS	TERIFLUNOMIDE	14.000	MILLIGRAMS	POM	UK
PL 08553/0694	24/07/2023	DR REDDY'S LABORATORIES (UK) LIMITED	VALIOS 5 MG ORODISPERSIBLE TABLETS	MEMANTINE HYDROCHLORIDE	5.00	MILLIGRAMS	POM	UK
PLNI 46602/0030	24/07/2023	SANOFI PASTEUR EUROPE	RABIES VACCINE, INACTIVATED	RABIES VIRUS STRAIN WISTAR PM/WI 38 1503-3M INACTIVATED	3.25	INTERNATIONAL UNITS	POM	NI
PLNI 46602/0030	24/07/2023	SANOFI PASTEUR EUROPE	RABIES VACCINE, INACTIVATED	RABIES VIRUS STRAIN WISTAR PM/WI 38 1503-3M INACTIVATED	3.250	INTERNATIONAL UNITS	POM	NI
PLNI 46602/0030	24/07/2023	SANOFI PASTEUR EUROPE	VERORAB, POWDER AND SOLVENT FOR SUSPENSION FOR INJECTION	RABIES VIRUS STRAIN WISTAR PM/WI 38 1503-3M INACTIVATED	3.25	INTERNATIONAL UNITS	POM	NI
PLNI 46602/0030	24/07/2023	SANOFI PASTEUR EUROPE	VERORAB, POWDER AND SOLVENT FOR SUSPENSION FOR INJECTION	RABIES VIRUS STRAIN WISTAR PM/WI 38 1503-3M INACTIVATED	3.250	INTERNATIONAL UNITS	POM	NI
PL 12063/0146	26/07/2023	WRAFTON LABORATORIES LIMITED	PARACETAMOL 500MG TABLETS	PARACETAMOL	500.00	MILLIGRAMS	GSL	UK
PL 40009/0001	27/07/2023	MODEPHARMA LIMITED	MELATONIN 1MG/ML ORAL SOLUTION	MELATONIN	1.0	MILLIGRAMS PER MILLILITRE	POM	UK
PLGB 14598/0238	27/07/2023	BOEHRINGER INGELHEIM INTERNATIONAL GMBH	SPEVIGO 450MG CONCENTRATE FOR SOLUTION FOR INFUSION	SPESSOLIMAB	450.0	MILLIGRAMS	POM	GB
PL 13621/0090	28/07/2023	FLYNN PHARMA LIMITED	MEFLYNATE XL 10 MG MODIFIED-RELEASE HARD CAPSULES	METHYLPHENIDATE HYDROCHLORIDE	5	MILLIGRAMS	POM	UK
PL 13621/0091	28/07/2023	FLYNN PHARMA LIMITED	MEFLYNATE XL 20 MG MODIFIED-RELEASE HARD CAPSULES	METHYLPHENIDATE HYDROCHLORIDE	10	MILLIGRAMS	POM	UK
PL 13621/0092	28/07/2023	FLYNN PHARMA LIMITED	MEFLYNATE XL 30 MG MODIFIED-RELEASE HARD CAPSULES	METHYLPHENIDATE HYDROCHLORIDE	15	MILLIGRAMS	POM	UK
PL 13621/0093	28/07/2023	FLYNN PHARMA LIMITED	MEFLYNATE XL 40 MG MODIFIED-RELEASE HARD CAPSULES	METHYLPHENIDATE HYDROCHLORIDE	20	MILLIGRAMS	POM	UK
PL 13621/0094	28/07/2023	FLYNN PHARMA LIMITED	MEFLYNATE XL 60 MG MODIFIED-RELEASE HARD CAPSULES	METHYLPHENIDATE HYDROCHLORIDE	30	MILLIGRAMS	POM	UK
PLGB 15105/0180	28/07/2023	BRISTOL-MYERS SQUIBB PHARMA EEIG	CAMZYOS 2.5MG HARD CAPSULES	MAVACAMTEN	2.5	MILLIGRAMS	POM	GB
PLGB 15105/0181	28/07/2023	BRISTOL-MYERS SQUIBB PHARMA EEIG	CAMZYOS 5MG HARD CAPSULES	MAVACAMTEN	5	MILLIGRAMS	POM	GB
PLGB 15105/0182	28/07/2023	BRISTOL-MYERS SQUIBB PHARMA EEIG	CAMZYOS 10MG HARD CAPSULES	MAVACAMTEN	10	MILLIGRAMS	POM	GB
PLGB 15105/0183	28/07/2023	BRISTOL-MYERS SQUIBB PHARMA EEIG	CAMZYOS 15MG HARD CAPSULES	MAVACAMTEN	15.0	MILLIGRAMS	POM	GB
PL 16363/0784	31/07/2023	MILPHARM LIMITED	LOPERAMIDE HYDROCHLORIDE 2 MG ORODISPERSIBLE TABLETS	LOPERAMIDE HYDROCHLORIDE	2.0	MILLIGRAMS	P	UK
PL 48785/0005	31/07/2023	ALTIEX LIFE SRO	MICAFUNGIN 50 MG POWDER FOR CONCENTRATION FOR SOLUTION FOR INFUSION	MICAFUNGIN SODIUM	50.86	MILLIGRAMS	POM	UK
PL 48785/0006	31/07/2023	ALTIEX LIFE SRO	MICAFUNGIN 100 MG POWDER FOR CONCENTRATION FOR SOLUTION FOR INFUSION	MICAFUNGIN SODIUM	101.72	MILLIGRAMS	POM	UK
PLGB 56346/0002	31/07/2023	HPRA HUMAN HEALTH S.L.	BIMERVAX EMULSION FOR INJECTION	RECOMBINANT SARS-COV-2 B.1.351 AND B.1.1.7 VARIANT SPIKE PROTEIN RECEPTOR BINDING DOMAIN FUSION HETERODIMER	80.00	MICROGRAMS PER MILLILITRE	POM	GB
PLGB 56346/0002	31/07/2023	HPRA HUMAN HEALTH S.L.	COVID-19 VACCINE (RECOMBINANT, ADJUVANTED)	RECOMBINANT SARS-COV-2 B.1.351 AND B.1.1.7 VARIANT SPIKE PROTEIN RECEPTOR BINDING DOMAIN FUSION HETERODIMER	80.00	MICROGRAMS PER MILLILITRE	POM	GB