

Marketing authorisations granted 1 October 2023 to 14 October 2023

PL Number	Grant Date	MA Holder	Licensed Name(s)	Active Ingredient	Quantity	Units	Legal Status	Territory
PL 14251/0179	02/10/2023	MANX HEALTHCARE LIMITED	FLUOXETINE 20 MG HARD CAPSULES	FLUOXETINE HYDROCHLORIDE	22.36	MILLIGRAMS	POM	UK
PLGB 00242/0750	02/10/2023	JANSSEN-CILAG LIMITED	ERLEADA 240 MG FILM-COATED TABLETS	APALUTAMIDE	240.00	MILLIGRAMS	POM	GB
PLGB 45613/0015	02/10/2023	SAMSUNG BIOEPIUS UK LIMITED	EPYSQLI 300 MG CONCENTRATE FOR SOLUTION FOR INFUSION	ECULIZUMAB	300.0	MILLIGRAMS	POM	GB
PL 00142/1286	03/10/2023	ACCORD-UK LIMITED	NALOXONE 400MICROGRAMS/ML SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE	NALOXONE HYDROCHLORIDE DIHYDRATE	0.44	MILLIGRAMS PER MILLILITRE	POM	UK
PL 00240/0583	03/10/2023	THORNTON & ROSS LIMITED	TIXYLIX CHILDREN'S DRY & TICKLY COUGH 15%/V/V SYRUP	GLYCEROL	15	PERCENTAGE VOLUME IN VOLUME	GSL	UK
PL 21597/0101	03/10/2023	G L PHARMA GMBH	TADOMON 25 MG PROLONGED-RELEASED TABLETS	TAPENTADOL TARTRATE	41.9525	MILLIGRAMS	POM	UK
PL 21597/0102	03/10/2023	G L PHARMA GMBH	TADOMON 50 MG PROLONGED-RELEASED TABLETS	TAPENTADOL TARTRATE	83.9050	MILLIGRAMS	POM	UK
PL 21597/0103	03/10/2023	G L PHARMA GMBH	TADOMON 100 MG PROLONGED-RELEASED TABLETS	TAPENTADOL TARTRATE	167.81	MILLIGRAMS	POM	UK
PL 21597/0104	03/10/2023	G L PHARMA GMBH	TADOMON 150 MG PROLONGED-RELEASED TABLETS	TAPENTADOL TARTRATE	251.7150	MILLIGRAMS	POM	UK
PL 21597/0105	03/10/2023	G L PHARMA GMBH	TADOMON 200 MG PROLONGED-RELEASED TABLETS	TAPENTADOL TARTRATE	335.62	MILLIGRAMS	POM	UK
PL 21597/0106	03/10/2023	G L PHARMA GMBH	TADOMON 250 MG PROLONGED-RELEASED TABLETS	TAPENTADOL TARTRATE	419.525	MILLIGRAMS	POM	UK
PL 43461/0030	03/10/2023	FLAMINGO PHARMA (UK) LIMITED	FLUCLOXACILLIN 250MG/5ML SUGAR FREE POWDER FOR ORAL SOLUTION	FLUCLOXACILLIN SODIUM	272.000	MILLIGRAMS PER 5 MILLILITRES	POM	UK
PL 43461/0031	04/10/2023	FLAMINGO PHARMA (UK) LIMITED	FLUCLOXACILLIN 125 MG/5ML POWDER FOR ORAL SOLUTION	FLUCLOXACILLIN SODIUM	136.000	MILLIGRAMS PER 5 MILLILITRES	POM	UK
PL 43461/0032	04/10/2023	FLAMINGO PHARMA (UK) LIMITED	FLUCLOXACILLIN 250 MG/5ML POWDER FOR ORAL SOLUTION	FLUCLOXACILLIN SODIUM	272.000	MILLIGRAMS PER 5 MILLILITRES	POM	UK
PLGB 17780/1272	04/10/2023	ZENTIVA PHARMA UK LIMITED	DIMETHYL FUMARATE 120 MG GASTRO-RESISTANT HARD CAPSULES	DIMETHYL FUMARATE	120.0	MILLIGRAMS	POM	GB
PLGB 17780/1273	04/10/2023	ZENTIVA PHARMA UK LIMITED	DIMETHYL FUMARATE 240 MG GASTRO-RESISTANT HARD CAPSULES	DIMETHYL FUMARATE	240.0	MILLIGRAMS	POM	GB
PLGB 53632/0028	04/10/2023	BIONTECH MANUFACTURING GMBH	COMIRNATY OMICRON XBB.1.5 30 MICROGRAMS/DOSE DISPERSION FOR INJECTION, SINGLE DOSE VIAL	RAXTOZINAMERAN	0.1	MILLIGRAMS PER MILLILITRE	POM	GB
PLGB 53632/0030	04/10/2023	BIONTECH MANUFACTURING GMBH	COMIRNATY OMICRON XBB.1.5 10 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION	RAXTOZINAMERAN	0.10	MILLIGRAMS PER MILLILITRE	POM	GB
PLGB 53632/0034	04/10/2023	BIONTECH MANUFACTURING GMBH	COMIRNATY OMICRON XBB.1.5 10 MICROGRAMS/DOSE DISPERSION FOR INJECTION, SINGLE DOSE VIAL	RAXTOZINAMERAN	0.033	MILLIGRAMS PER MILLILITRE	POM	GB
PL 34885/0016	05/10/2023	VENUS PHARMA GMBH	BLEOMYCIN VENUS PHARMA 15,000 IU POWDER FOR SOLUTION FOR INJECTION / INFUSION	BLEOMYCIN SULFATE	16030	INTERNATIONAL UNITS	POM	UK
PL 43805/0137	06/10/2023	ASCEND LABORATORIES (UK) LIMITED	GABAPENTIN ASCEND 100MG HARD CAPSULES	GABAPENTIN	100.0	MILLIGRAMS	POM	UK
PL 43805/0138	06/10/2023	ASCEND LABORATORIES (UK) LIMITED	GABAPENTIN ASCEND 300MG HARD CAPSULES	GABAPENTIN	300.0	MILLIGRAMS	POM	UK
PL 43805/0139	06/10/2023	ASCEND LABORATORIES (UK) LIMITED	GABAPENTIN ASCEND 400MG HARD CAPSULES	GABAPENTIN	400.0	MILLIGRAMS	POM	UK
PL 56697/0018	06/10/2023	INDOCO REMEDIES UK LIMITED	PREGABALIN INDOCO 25 MG HARD CAPSULES	PREGABALIN	25	MILLIGRAMS	POM	UK
PL 56697/0019	06/10/2023	INDOCO REMEDIES UK LIMITED	PREGABALIN INDOCO 50 MG HARD CAPSULES	PREGABALIN	50	MILLIGRAMS	POM	UK
PL 56697/0020	06/10/2023	INDOCO REMEDIES UK LIMITED	PREGABALIN INDOCO 75 MG HARD CAPSULES	PREGABALIN	75	MILLIGRAMS	POM	UK
PL 56697/0021	06/10/2023	INDOCO REMEDIES UK LIMITED	PREGABALIN INDOCO 100 MG HARD CAPSULES	PREGABALIN	100	MILLIGRAMS	POM	UK
PL 56697/0022	06/10/2023	INDOCO REMEDIES UK LIMITED	PREGABALIN INDOCO 150 MG HARD CAPSULES	PREGABALIN	150	MILLIGRAMS	POM	UK
PL 56697/0023	06/10/2023	INDOCO REMEDIES UK LIMITED	PREGABALIN INDOCO 200 MG HARD CAPSULES	PREGABALIN	200	MILLIGRAMS	POM	UK
PL 56697/0024	06/10/2023	INDOCO REMEDIES UK LIMITED	PREGABALIN INDOCO 225 MG HARD CAPSULES	PREGABALIN	225	MILLIGRAMS	POM	UK
PL 56697/0025	06/10/2023	INDOCO REMEDIES UK LIMITED	PREGABALIN INDOCO 300 MG HARD CAPSULES	PREGABALIN	300	MILLIGRAMS	POM	UK
PLGB 04520/0244	06/10/2023	SANDOZ GMBH	HYRIMOZ 20 MG/0.2 ML SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE	ADALIMUMAB	100	MILLIGRAMS PER MILLILITRE	POM	GB
PLGB 04520/0245	06/10/2023	SANDOZ GMBH	HYRIMOZ 40 MG/0.4 ML SOLUTION FOR INJECTION IN PRE-FILLED PEN	ADALIMUMAB	100	MILLIGRAMS PER MILLILITRE	POM	GB
PLGB 04520/0246	06/10/2023	SANDOZ GMBH	HYRIMOZ 80 MG/0.8 ML SOLUTION FOR INJECTION IN PRE-FILLED PEN	ADALIMUMAB	100	MILLIGRAMS PER MILLILITRE	POM	GB
PLGB 04520/0247	06/10/2023	SANDOZ GMBH	HYRIMOZ 40 MG/0.4 ML SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE	ADALIMUMAB	100	MILLIGRAMS PER MILLILITRE	POM	GB
PLGB 04520/0248	06/10/2023	SANDOZ GMBH	HYRIMOZ 80 MG/0.8 ML SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE	ADALIMUMAB	100	MILLIGRAMS PER MILLILITRE	POM	GB
PLGB 47991/0013	06/10/2023	SEQRUS UK LIMITED	ADJUVANTED ZOONOTIC INFLUENZA VACCINE SEQRUS SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	A/TURKEY/TURKEY/11/2005 (H5N1)-LIKE STRAIN (NIBRG-23)	7.5	MICROGRAMS	POM	GB
PL 52539/0001	09/10/2023	SEDANA MEDICAL AB	SEDACONDA 100 % INHALATION VAPOUR, LIQUID	ISOFLURANE	100	PERCENTAGE VOLUME IN VOLUME	POM	UK
PLGB 00242/0755	09/10/2023	JANSSEN-CILAG LIMITED	TALVEY 2 MG/ML SOLUTION FOR INJECTION	TALQUETAMAB	2	MILLIGRAMS PER MILLILITRE	POM	GB
PLGB 00242/0756	09/10/2023	JANSSEN-CILAG LIMITED	TALVEY 40 MG/ML SOLUTION FOR INJECTION	TALQUETAMAB	40	MILLIGRAMS PER MILLILITRE	POM	GB
PLGB 04416/1706	09/10/2023	SANDOZ LIMITED	TYRUKO 300 MG CONCENTRATE FOR SOLUTION FOR INFUSION	NATALIZUMAB	300	MILLIGRAMS	POM	GB

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PLGB 50697/0033	11/10/2023	OTSUKA PHARMACEUTICAL NETHERLANDS BV	INAQOVI 35 MG/100 MG FILM-COATED TABLETS	CEDAZURIDINE	100	MILLIGRAMS	POM	GB
PLGB 50697/0033	11/10/2023	OTSUKA PHARMACEUTICAL NETHERLANDS BV	INAQOVI 35 MG/100 MG FILM-COATED TABLETS	DECITABINE	35	MILLIGRAMS	POM	GB
PLGB 57848/0001	11/10/2023	FENNEC PHARMACEUTICALS (EU) LIMITED	PEDMARQSI 80 MG/ML SOLUTION FOR INFUSION	SODIUM THIOSULFATE	80.00	MILLIGRAMS PER MILLILITRE	POM	GB
PL 04416/1629	12/10/2023	SANDOZ LIMITED	DABIGATRAN ETEXILATE SANDOZ 75MG HARD CAPSULES	DABIGATRAN ETEXILATE MESILATE	86.475	MILLIGRAMS	POM	UK
PL 04416/1630	12/10/2023	SANDOZ LIMITED	DABIGATRAN ETEXILATE SANDOZ 110MG HARD CAPSULES	DABIGATRAN ETEXILATE MESILATE	126.830	MILLIGRAMS	POM	UK
PL 04416/1631	12/10/2023	SANDOZ LIMITED	DABIGATRAN ETEXILATE SANDOZ 150MG HARD CAPSULES	DABIGATRAN ETEXILATE MESILATE	172.950	MILLIGRAMS	POM	UK
PL 15011/0039	12/10/2023	INFECTORPHARM ARZNEIMITTEL UND CONSILIUM GMBH	IPRATROPIUM BROMIDE 21 MICROGRAMS PER METERED DOSE NASAL SPRAY, SOLUTION	IPRATROPIUM BROMIDE MONOHYDRATE	0.313	MILLIGRAMS PER MILLILITRE	POM	UK
PL 44041/0233	12/10/2023	NOUMED LIFE SCIENCES LIMITED	FEXOFENADINE HYDROCHLORIDE 120 MG FILM-COATED TABLETS	FEXOFENADINE HYDROCHLORIDE	120	MILLIGRAMS	POM	UK
PLGB 00031/0930	13/10/2023	ROCHE PRODUCTS LIMITED	XOFLUZA 2 MG/ML GRANULES FOR ORAL SUSPENSION	BALOXAVIR MARBOXIL	2.0	MILLIGRAMS PER MILLILITRE	POM	GB
PLGB 00289/2553	13/10/2023	TEVA UK LIMITED	DIMETHYL FUMARATE TEVA 120 MG GASTRO-RESISTANT HARD CAPSULES	DIMETHYL FUMARATE	120	MILLIGRAMS	POM	GB
PLGB 00289/2554	13/10/2023	TEVA UK LIMITED	DIMETHYL FUMARATE TEVA 240 MG GASTRO-RESISTANT HARD CAPSULES	DIMETHYL FUMARATE	240	MILLIGRAMS	POM	GB