

Marketing authorisations granted 15 December 2023 to 31 December 2023

PL Number	Grant Date	MA Holder	Licensed Name(s)	Active Ingredient	Quantity	Units	Legal Status	Territory
PL 08977/0070	15/12/2023	ASPAR PHARMACEUTICALS LIMITED	PARACETAMOL 500 MG TABLETS	PARACETAMOL	500.000	MILIGRAMS	GSL	UK
PL 08977/0071	15/12/2023	ASPAR PHARMACEUTICALS LIMITED	PARACETAMOL 500 MG TABLETS	PARACETAMOL	500.000	MILIGRAMS	GSL	UK
PL 25258/0393	15/12/2023	GLENMARK PHARMACEUTICALS EUROPE LIMITED	DABIGATRAN ETEXILATE 75MG HARD CAPSULES	DABIGATRAN ETEXILATE MESYLATE	86.48	MILIGRAMS	POM	UK
PL 25258/0394	15/12/2023	GLENMARK PHARMACEUTICALS EUROPE LIMITED	DABIGATRAN ETEXILATE 110 MG HARD CAPSULES	DABIGATRAN ETEXILATE MESYLATE	126.83	MILIGRAMS	POM	UK
PL 25258/0395	15/12/2023	GLENMARK PHARMACEUTICALS EUROPE LIMITED	DABIGATRAN ETEXILATE 150 MG HARD CAPSULES	DABIGATRAN ETEXILATE MESYLATE	172.95	MILIGRAMS	POM	UK
PL 36390/0420	15/12/2023	CIPLA (EU) LIMITED	APIXABAN 2.5 MG FILM-COATED TABLETS	APIXABAN	2.500	MILIGRAMS	POM	UK
PL 36390/0421	15/12/2023	CIPLA (EU) LIMITED	APIXABAN 5 MG FILM-COATED TABLETS	APIXABAN	5.000	MILIGRAMS	POM	UK
PL 55863/0001	15/12/2023	NOVUMGEN LIMITED	APOZYL 5 MG ORODISPERSIBLE TABLETS	DONEPEZIL HYDROCHLORIDE MONOHYDRATE	5.0	MILIGRAMS	POM	UK
PL 55863/0002	15/12/2023	NOVUMGEN LIMITED	APOZYL 10 MG ORODISPERSIBLE TABLETS	DONEPEZIL HYDROCHLORIDE MONOHYDRATE	10.0	MILIGRAMS	POM	UK
PLGB 20075/1476	15/12/2023	ACCORD HEALTHCARE LIMITED	DMETHYL FUMARATE 120 MG GASTRO-RESISTANT HARD CAPSULES	DMETHYL FUMARATE	120.00	MILIGRAMS	POM	GB
PLGB 20075/1477	15/12/2023	ACCORD HEALTHCARE LIMITED	DMETHYL FUMARATE 240 MG GASTRO-RESISTANT HARD CAPSULES	DMETHYL FUMARATE	240.00	MILIGRAMS	POM	GB
PL 00111/0210	18/12/2023	DHP HEALTHCARE LIMITED	PRUCALOPRIDE 1 MG FILM-COATED TABLETS	PRUCALOPRIDE SUCCINATE	1.32	MILIGRAMS	POM	UK
PL 00111/0211	18/12/2023	DHP HEALTHCARE LIMITED	PRUCALOPRIDE 2 MG FILM-COATED TABLETS	PRUCALOPRIDE SUCCINATE	2.64	MILIGRAMS	POM	UK
PL 16363/0739	18/12/2023	MILPHARM LIMITED	BUPRENORPHINE 2 MG SUBLINGUAL TABLETS	BUPRENORPHINE HYDROCHLORIDE	2.16	MILIGRAMS	POM	UK
PL 16363/0740	18/12/2023	MILPHARM LIMITED	BUPRENORPHINE 8 MG SUBLINGUAL TABLETS	BUPRENORPHINE HYDROCHLORIDE	8.64	MILIGRAMS	POM	UK
PL 17780/1026	18/12/2023	ZENTIVA PHARMA UK LIMITED	RAMPRIL 1.25 MG TABLETS	RAMPRIL	1.25	MILIGRAMS	POM	UK
PL 17780/1027	18/12/2023	ZENTIVA PHARMA UK LIMITED	RAMPRIL 2.5 MG TABLETS	RAMPRIL	2.5	MILIGRAMS	POM	UK
PL 17780/1028	18/12/2023	ZENTIVA PHARMA UK LIMITED	RAMPRIL 5 MG TABLETS	RAMPRIL	5	MILIGRAMS	POM	UK
PL 17780/1029	18/12/2023	ZENTIVA PHARMA UK LIMITED	RAMPRIL 10 MG TABLETS	RAMPRIL	10	MILIGRAMS	POM	UK
PL 25258/0353	18/12/2023	GLENMARK PHARMACEUTICALS EUROPE LIMITED	SITAGLIFTIN 50 MG/2 ML ORAL SOLUTION	SITAGLIFTIN HYDROCHLORIDE MONOHYDRATE	13.619	MILIGRAMS PER MILLILITRE	POM	UK
PL 46654/0012	18/12/2023	EVER VALINJECT GMBH	TRABECTEDIN EVER PHARMA 0.25 MG POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION	TRABECTEDIN	0.25	MILIGRAMS	POM	UK
PL 46654/0013	18/12/2023	EVER VALINJECT GMBH	TRABECTEDIN EVER PHARMA 1 MG POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION	TRABECTEDIN	1	MILIGRAMS	POM	UK
PL 55863/0034	18/12/2023	NOVUMGEN LIMITED	TEICOPLANIN 200 MG POWDER FOR SOLUTION FOR INJECTION/INFUSION OR ORAL SOLUTION	TEICOPLANIN	200	MILIGRAMS	POM	UK
PL 55863/0035	18/12/2023	NOVUMGEN LIMITED	TEICOPLANIN 400 MG POWDER FOR SOLUTION FOR INJECTION/INFUSION OR ORAL SOLUTION	TEICOPLANIN	400	MILIGRAMS	POM	UK
PLGB 04569/1979	18/12/2023	GENERICIS (UK) LIMITED	ARIPRAZOLE MYLAN 5 MG TABLETS	ARIPRAZOLE	5.00	MILIGRAMS	POM	GB
PLGB 04569/1980	18/12/2023	GENERICIS (UK) LIMITED	ARIPRAZOLE MYLAN 10 MG TABLETS	ARIPRAZOLE	10.00	MILIGRAMS	POM	GB
PLGB 04569/1981	18/12/2023	GENERICIS (UK) LIMITED	ARIPRAZOLE MYLAN 15MG TABLETS	ARIPRAZOLE	15.00	MILIGRAMS	POM	GB
PLGB 04569/1982	18/12/2023	GENERICIS (UK) LIMITED	ARIPRAZOLE MYLAN 30 MG TABLETS	ARIPRAZOLE	30.00	MILIGRAMS	POM	GB
PL 016556/0451	19/12/2023	KRKA DD NOVO MESTO	TERIFLUNOMIDE KRKA 14 MG FILM-COATED TABLETS	TERIFLUNOMIDE	14	MILIGRAMS	POM	UK
PL 28444/0274	19/12/2023	ACTIVASE PHARMACEUTICALS LIMITED	DOMPERIDONE 10MG TABLETS	DOMPERIDONE MALEATE	12.72	MILIGRAMS	POM	UK
PLGB 16973/0048	19/12/2023	ALMIRALL SA	EBGLYSS 250 MG SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE	LEBRKIZUMAB	250	MILIGRAMS	POM	GB
PLGB 16973/0049	19/12/2023	ALMIRALL SA	EBGLYSS 250 MG SOLUTION FOR INJECTION IN PRE-FILLED PEN	LEBRKIZUMAB	250	MILIGRAMS	POM	GB
PL 00010/0747	20/12/2023	BAYER PLC	CLARINAZE HAYFEVER RELIEF 0.05% NASAL SPRAY	MONETASONE FURDATE MONOHYDRATE	0.05	PERCENTAGE VOLUME IN VOLUME	GSL	UK
PLGB 53487/0007	20/12/2023	MMEDICA PHARMA AB	LOARGYS 5 MG/ML SOLUTION FOR INJECTION/INFUSION	PEGZARGANASE	5.0	MILIGRAMS PER MILLILITRE	POM	GB
PL 44873/0228	21/12/2023	GLAXOSMITHKLINE CONSUMER HEALTHCARE	VOLTAROL ONE A DAY MUSCLE PAIN RELIEF 140 MG MEDICATED PLASTER	DICLOFENAC SODIUM	140.00	MILIGRAMS	GSL	UK
PLGB 53095/0091	21/12/2023	MERCK SHARP & DOHME (UK) LIMITED	LYFNUA 45 MG FILM-COATED TABLET	GEFAPIXANT CITRATE	69.48	MILIGRAMS	POM	GB
PL 3533/0197	22/12/2023	ASPIRE PHARMA LIMITED	FLUDROCORTISONE ACETATE 0.05 MG TABLETS	FLUDROCORTISONE ACETATE	50	MICROGRAMS	POM	UK
PL 55807/0003	22/12/2023	SGS PHARMA MAGYARORSZAG KFT.	TEICOPLANIN 200MG POWDER FOR SOLUTION FOR INJECTION/INFUSION OR ORAL SOLUTION	TEICOPLANIN	200	MILIGRAMS	POM	UK
PL 55807/0004	22/12/2023	SGS PHARMA MAGYARORSZAG KFT.	TEICOPLANIN 400MG POWDER FOR SOLUTION FOR INJECTION/INFUSION OR ORAL SOLUTION	TEICOPLANIN	400	MILIGRAMS	POM	UK
PL 34424/0091	27/12/2023	KEY PHARMACEUTICALS LIMITED	MELATONIN KEY XL 2 MG PROLONGED-RELEASE TABLETS	MELATONIN	2	MILIGRAMS	POM	UK
PLGB 15105/0192	27/12/2023	BRISTOL-MYERS SQUIBB PHARMA EEIG	OPDUALAG 240 MG/80 MG CONCENTRATE FOR SOLUTION FOR INFUSION	NIVOLUMAB	12	MILIGRAMS PER MILLILITRE	POM	GB
PLGB 15105/0192	27/12/2023	BRISTOL-MYERS SQUIBB PHARMA EEIG	OPDUALAG 240 MG/80 MG CONCENTRATE FOR SOLUTION FOR INFUSION	RELATIMAB	4	MILIGRAMS PER MILLILITRE	POM	GB
PL 06831/0358	28/12/2023	GENUS PHARMACEUTICALS LIMITED	RIVAROXABAN 2.5 MG FILM-COATED TABLETS	RIVAROXABAN	2.50	MILIGRAMS	POM	UK

Marketing authorisations granted 15 December 2023 to 31 December 2023

PL Number	Grant Date	MA Holder	Licensed Name(s)	Active Ingredient	Quantity	Units	Legal Status	Territory
PL_068310360	28/12/2023	GENUS PHARMACEUTICALS LIMITED	RIVAROXABAN 10 MG FILM-COATED TABLETS	RIVAROXABAN	10.00	MILLIGRAMS	POM	UK
PL_068310361	28/12/2023	GENUS PHARMACEUTICALS LIMITED	RIVAROXABAN 15 MG FILM-COATED TABLETS	RIVAROXABAN	15.00	MILLIGRAMS	POM	UK
PL_068310362	28/12/2023	GENUS PHARMACEUTICALS LIMITED	RIVAROXABAN 20 MG FILM-COATED TABLETS	RIVAROXABAN	20.00	MILLIGRAMS	POM	UK
PL_068310385	29/12/2023	GENUS PHARMACEUTICALS LIMITED	DABIGATRAN ETEXILATE 110 MG HARD CAPSULES	DABIGATRAN ETEXILATE MESLATE	126.830	MILLIGRAMS	POM	UK
PL_068310386	29/12/2023	GENUS PHARMACEUTICALS LIMITED	DABIGATRAN ETEXILATE 150 MG HARD CAPSULES	DABIGATRAN ETEXILATE MESLATE	172.95	MILLIGRAMS	POM	UK