

Marketing authorisations granted 15 August 2023 to 31 August 2023

PL Number	Grant Date	MA Holder	Licensed Name(s)	Active Ingredient	Quantity	Units	Legal Status	Territory
PL 00142/1308	15/08/2023	ACCORD-UK LIMITED	CO-CODAMOL 30/500MG TABLETS	CODEINE PHOSPHATE HEMIHYDRATE	30	MILLIGRAMS	POM	UK
PL 00142/1308	15/08/2023	ACCORD-UK LIMITED	CO-CODAMOL 30/500MG TABLETS	PARACETAMOL	500	MILLIGRAMS	POM	UK
PL 12063/0144	15/08/2023	WRAFTON LABORATORIES LIMITED	BOOTS PARACETAMOL EXTRA 500 MG/65 MG TABLETS	CAFFEINE	65	MILLIGRAMS	GSL	UK
PL 12063/0144	15/08/2023	WRAFTON LABORATORIES LIMITED	BOOTS PARACETAMOL EXTRA 500 MG/65 MG TABLETS	PARACETAMOL	500	MILLIGRAMS	GSL	UK
PL 14338/0013	15/08/2023	PATHEON SOFTGELS BV	PARACETAMOL 500 MG CAPSULES, SOFT	PARACETAMOL	500	MILLIGRAMS	GSL	UK
PL 34078/0037	16/08/2023	BAXALTA INNOVATIONS GMBH	PROTHROMPLEX TOTAL 500 IU POWDER AND SOLVENT FOR SOLUTION FOR INJECTION	HUMAN COAGULATION FACTOR II	708	INTERNATIONAL UNITS	POM	UK
PL 34078/0037	16/08/2023	BAXALTA INNOVATIONS GMBH	PROTHROMPLEX TOTAL 500 IU POWDER AND SOLVENT FOR SOLUTION FOR INJECTION	HUMAN COAGULATION FACTOR IX	500	INTERNATIONAL UNITS	POM	UK
PL 34078/0037	16/08/2023	BAXALTA INNOVATIONS GMBH	PROTHROMPLEX TOTAL 500 IU POWDER AND SOLVENT FOR SOLUTION FOR INJECTION	HUMAN COAGULATION FACTOR VII	417	INTERNATIONAL UNITS	POM	UK
PL 34078/0037	16/08/2023	BAXALTA INNOVATIONS GMBH	PROTHROMPLEX TOTAL 500 IU POWDER AND SOLVENT FOR SOLUTION FOR INJECTION	HUMAN COAGULATION FACTOR X	500	INTERNATIONAL UNITS	POM	UK
PL 34078/0037	16/08/2023	BAXALTA INNOVATIONS GMBH	PROTHROMPLEX TOTAL 500 IU POWDER AND SOLVENT FOR SOLUTION FOR INJECTION	HUMAN PROTEIN C	333	INTERNATIONAL UNITS	POM	UK
PL 34078/0037	16/08/2023	BAXALTA INNOVATIONS GMBH	PROTHROMPLEX TOTAL 500 IU POWDER AND SOLVENT FOR SOLUTION FOR INJECTION	NO ACTIVES PRESENT	0	NONE	POM	UK
PL 49105/0018	17/08/2023	THERAMEX HQ UK LIMITED	RISEDRONATE SODIUM 35 MG GASTRO-RESISTANT TABLETS	RISEDRONATE SODIUM	35.0	MILLIGRAMS	POM	GB
PLGB 00031/0937	17/08/2023	ROCHE PRODUCTS LIMITED	TECENTRIQ 1,875 MG SOLUTION FOR INJECTION	ATEZOLIZUMAB	1875.0	MILLIGRAMS	POM	GB
PL 31103/0014	18/08/2023	BLUMONT PHARMA LIMITED	LATANOPROST/TIMOLOL 50 MICROGRAMS/ML + 5 MG/ML EYE DROPS, SOLUTION	LATANOPROST	0.05	MILLIGRAMS PER MILLILITRE	POM	UK
PL 31103/0014	18/08/2023	BLUMONT PHARMA LIMITED	LATANOPROST/TIMOLOL 50 MICROGRAMS/ML + 5 MG/ML EYE DROPS, SOLUTION	TIMOLOL MALEATE	6.83	MILLIGRAMS PER MILLILITRE	POM	UK
PLGB 41225/0001	18/08/2023	TAIHO PHARMA EUROPE, LIMITED	LYTOGBI 4 MG FILM-COATED TABLETS	FUTIBATINIB	4.0	MILLIGRAMS	POM	GB
PL 47015/0032	22/08/2023	AS KALCEKS	PIPERACILLIN/TAZOBACTAM 2 G/0.25 G POWDER FOR SOLUTION FOR INFUSION	PIPERACILLIN MONOHYDRATE	2069.600	MILLIGRAMS	POM	UK
PL 47015/0032	22/08/2023	AS KALCEKS	PIPERACILLIN/TAZOBACTAM 2 G/0.25 G POWDER FOR SOLUTION FOR INFUSION	TAZOBACTAM	250.000	MILLIGRAMS	POM	UK
PL 47015/0033	22/08/2023	AS KALCEKS	PIPERACILLIN/TAZOBACTAM 4 G/0.5 G POWDER FOR SOLUTION FOR INFUSION	PIPERACILLIN MONOHYDRATE	4139.200	MILLIGRAMS	POM	UK
PL 47015/0033	22/08/2023	AS KALCEKS	PIPERACILLIN/TAZOBACTAM 4 G/0.5 G POWDER FOR SOLUTION FOR INFUSION	TAZOBACTAM	500.000	MILLIGRAMS	POM	UK
PLGB 56448/0001	22/08/2023	LINUS PHARMA LTD	FLUORESCIEIN 100 MG/ML SOLUTION FOR INJECTION	FLUORESCIEIN SODIUM	600.0	MILLIGRAMS	POM	GB
PL 20416/0747	23/08/2023	CRESCENT PHARMA LIMITED	RIVAROXABAN 2.5 MG FILM-COATED TABLETS	RIVAROXABAN	2.50	MILLIGRAMS	POM	UK
PL 20416/0748	23/08/2023	CRESCENT PHARMA LIMITED	RIVAROXABAN 10 MG FILM-COATED TABLETS	RIVAROXABAN	10.00	MILLIGRAMS	POM	UK
PL 20416/0749	23/08/2023	CRESCENT PHARMA LIMITED	RIVAROXABAN 15 MG FILM-COATED TABLETS	RIVAROXABAN	15	MILLIGRAMS	POM	UK
PL 20416/0750	23/08/2023	CRESCENT PHARMA LIMITED	RIVAROXABAN 20 MG FILM-COATED TABLETS	RIVAROXABAN	20.00	MILLIGRAMS	POM	UK
PL 20416/0755	23/08/2023	CRESCENT PHARMA LIMITED	RIVAROXABAN 15 & 20 MG FILM-COATED TABLETS	RIVAROXABAN	15	MILLIGRAMS	POM	UK
PL 20416/0755	23/08/2023	CRESCENT PHARMA LIMITED	RIVAROXABAN 15 & 20 MG FILM-COATED TABLETS	RIVAROXABAN	20.00	MILLIGRAMS	POM	UK
PLGB 44570/0032	23/08/2023	QILU PHARMA SPAIN SL	SUGAMMADEX QILU 100 MG/ML SOLUTION FOR INJECTION	SUGAMMADEX SODIUM	108.8	MILLIGRAMS PER MILLILITRE	POM	GB
PL 04569/1840	24/08/2023	GENERICS (UK) LIMITED	TAPENTADOL MYLAN 25 MG PROLONGED-RELEASE TABLETS	TAPENTADOL PHOSPHATE	38.285	MILLIGRAMS	POM	UK
PL 04569/1841	24/08/2023	GENERICS (UK) LIMITED	TAPENTADOL MYLAN 50 MG PROLONGED-RELEASE TABLETS	TAPENTADOL PHOSPHATE	76.570	MILLIGRAMS	POM	UK
PL 04569/1842	24/08/2023	GENERICS (UK) LIMITED	TAPENTADOL MYLAN 100 MG PROLONGED-RELEASE TABLETS	TAPENTADOL PHOSPHATE	153.139	MILLIGRAMS	POM	UK
PL 04569/1843	24/08/2023	GENERICS (UK) LIMITED	TAPENTADOL MYLAN 150 MG PROLONGED-RELEASE TABLETS	TAPENTADOL PHOSPHATE	229.709	MILLIGRAMS	POM	UK
PL 04569/1844	24/08/2023	GENERICS (UK) LIMITED	TAPENTADOL MYLAN 200 MG PROLONGED-RELEASE TABLETS	TAPENTADOL PHOSPHATE	306.279	MILLIGRAMS	POM	UK
PL 04569/1845	24/08/2023	GENERICS (UK) LIMITED	TAPENTADOL MYLAN 250 MG PROLONGED-RELEASE TABLETS	TAPENTADOL PHOSPHATE	382.848	MILLIGRAMS	POM	UK
PL 20075/1463	25/08/2023	ACCORD HEALTHCARE LIMITED	QUETIAPINE 50 MG FILM-COATED TABLETS	QUETIAPINE FUMARATE	57.56	MILLIGRAMS	POM	UK
PL 20075/1464	25/08/2023	ACCORD HEALTHCARE LIMITED	QUETIAPINE 400 MG FILM-COATED TABLETS	QUETIAPINE FUMARATE	460.48	MILLIGRAMS	POM	UK
PLGB 00101/1225	25/08/2023	NOVARTIS PHARMACEUTICALS UK LIMITED	ENTRESTO 6 MG/6 MG GRANULES IN CAPSULES FOR OPENING	SACUBITRIL VALSARTAN SODIUM HYDRATE	12.500	MILLIGRAMS	POM	GB
PLGB 00101/1226	25/08/2023	NOVARTIS PHARMACEUTICALS UK LIMITED	ENTRESTO 15 MG/16 MG GRANULES IN CAPSULES FOR OPENING	SACUBITRIL VALSARTAN SODIUM HYDRATE	31.25	MILLIGRAMS	POM	GB
PL 11648/0292	30/08/2023	MERCK SERONO LIMITED	GLUCOPHAGE SR 850 MG PROLONGED RELEASE TABLETS	METFORMIN HYDROCHLORIDE	850	MILLIGRAMS	POM	UK
PL 30684/0361	30/08/2023	DAWA LIMITED	DOMPERIDONE 1MG/ML ORAL SUSPENSION	DOMPERIDONE	1.00	MILLIGRAMS PER MILLILITRE	POM	UK
PL 33155/0095	30/08/2023	RIVOPHARM (UK) LIMITED	FENOFIBRATE 267 MG CAPSULES	FENOFIBRATE	267.00	MILLIGRAMS	POM	UK

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PLGB 24626/0008	30/08/2023	PAION DEUTSCHLAND GMBH	BYFAVO 50 MG POWDER FOR CONCENTRATE FOR SOLUTION FOR INJECTION/INFUSION	REMIMAZOLAM BESYLATE	68	MILLIGRAMS	POM	GB
PLGB 41042/0088	30/08/2023	ABBVIE LTD	AQUIPTA 10 MG TABLETS	ATOGEPAANT MONOHYDRATE	10.0	MILLIGRAMS	POM	GB
PLGB 41042/0089	30/08/2023	ABBVIE LTD	AQUIPTA 80 MG TABLETS	ATOGEPAANT MONOHYDRATE	60.0	MILLIGRAMS	POM	GB
PL 25258/0382	31/08/2023	GLENMARK PHARMACEUTICALS EUROPE LIMITED	OMEPRAZOLE 10 MG ORAL SOLUTION	OMEPRAZOLE	0.67	MILLIGRAMS PER MILLILITRE	POM	UK
PL 25258/0383	31/08/2023	GLENMARK PHARMACEUTICALS EUROPE LIMITED	OMEPRAZOLE 20 MG ORAL SOLUTION	OMEPRAZOLE	1.33	MILLIGRAMS PER MILLILITRE	POM	UK
PL 44305/0029	31/08/2023	KOANAA HEALTHCARE LIMITED	BETAHISTINE DIHYDROCHLORIDE 24 MG ORODISPERSIBLE FILMS	BETAHISTINE DIHYDROCHLORIDE	24.00	MILLIGRAMS	POM	UK
PLGB 00427/0272	31/08/2023	ROSEMONT PHARMACEUTICALS LIMITED	MYCOPHENOLATE MOFETIL 1G/5ML ORAL SUSPENSION	MYCOPHENOLATE MOFETIL	200.00	MILLIGRAMS PER MILLILITRE	POM	GB
PLGB 53632/0020	31/08/2023	BIONTECH MANUFACTURING GMBH	COMIRNATY ORIGINAL/OMICRON BA.4/5 (1.5/1.5 MICROGRAMS)/DOSE CONCENTRATE FOR DISPERSION	FAMTOZINAMERAN	0.05	MILLIGRAMS PER MILLILITRE	POM	GB
PLGB 53632/0020	31/08/2023	BIONTECH MANUFACTURING GMBH	COMIRNATY ORIGINAL/OMICRON BA.4/5 (1.5/1.5 MICROGRAMS)/DOSE CONCENTRATE FOR DISPERSION	TOZINAMERAN	0.05	MILLIGRAMS PER MILLILITRE	POM	GB
PLGB 53632/0022	31/08/2023	BIONTECH MANUFACTURING GMBH	COMIRNATY ORIGINAL/OMICRON BA.4-5 (5/5 MICROGRAMS)/DOSE DISPERSION FOR INJECTION	FAMTOZINAMERAN	0.017	MILLIGRAMS PER MILLILITRE	POM	GB
PLGB 53632/0022	31/08/2023	BIONTECH MANUFACTURING GMBH	COMIRNATY ORIGINAL/OMICRON BA.4-5 (5/5 MICROGRAMS)/DOSE DISPERSION FOR INJECTION	TOZINAMERAN	0.017	MILLIGRAMS PER MILLILITRE	POM	GB
PLGB 53632/0024	31/08/2023	BIONTECH MANUFACTURING GMBH	COMIRNATY ORIGINAL/OMICRON BA.4-5 (5/5 MICROGRAMS)/DOSE DISPERSION FOR INJECTION, SINGLE	FAMTOZINAMERAN	0.017	MILLIGRAMS PER MILLILITRE	POM	GB
PLGB 53632/0024	31/08/2023	BIONTECH MANUFACTURING GMBH	COMIRNATY ORIGINAL/OMICRON BA.4-5 (5/5 MICROGRAMS)/DOSE DISPERSION FOR INJECTION, SINGLE	TOZINAMERAN	0.017	MILLIGRAMS PER MILLILITRE	POM	GB