

Marketing authorisations granted 1 August 2023 to 14 August 2023

PL Number	Grant Date	MA Holder	Licensed Name(s)	Active Ingredient	Quantity	Units	Legal Status	Territory
PL 36390/0405	01/08/2023	CIPLA (EU) LIMITED	RIVAROXABAN 2.5 MG FILM-COATED TABLETS	RIVAROXABAN	2.500	MILLIGRAMS	POM	UK
PL 36390/0406	01/08/2023	CIPLA (EU) LIMITED	RIVAROXABAN 10 MG FILM-COATED TABLETS	RIVAROXABAN	10.000	MILLIGRAMS	POM	UK
PL 36390/0407	01/08/2023	CIPLA (EU) LIMITED	RIVAROXABAN 15MG FILM-COATED TABLETS	RIVAROXABAN	15.000	MILLIGRAMS	POM	UK
PL 36390/0408	01/08/2023	CIPLA (EU) LIMITED	RIVAROXABAN 20 MG FILM-COATED TABLETS	RIVAROXABAN	20.000	MILLIGRAMS	POM	UK
PL 36390/0409	01/08/2023	CIPLA (EU) LIMITED	RIVAROXABAN 15 MG FILM-COATED TABLETS & RIVAROXABAN 20 MG FILM-COATED TABLETS	RIVAROXABAN	15.000	MILLIGRAMS	POM	UK
PL 36390/0409	01/08/2023	CIPLA (EU) LIMITED	RIVAROXABAN 15 MG FILM-COATED TABLETS & RIVAROXABAN 20 MG FILM-COATED TABLETS	RIVAROXABAN	20.000	MILLIGRAMS	POM	UK
PL 17907/0690	02/08/2023	BRISTOL LABORATORIES LIMITED	CLARITHROMYCIN 250 MG FILM-COATED TABLETS	CLARITHROMYCIN	250.000	MILLIGRAMS	POM	UK
PL 17907/0691	02/08/2023	BRISTOL LABORATORIES LIMITED	CLARITHROMYCIN 500 MG FILM-COATED TABLETS	CLARITHROMYCIN	500.000	MILLIGRAMS	POM	UK
PL 25258/0318	02/08/2023	GLENMARK PHARMACEUTICALS EUROPE LIMITED	TRAZODONE HYDROCHLORIDE 50MG/5ML ORAL SOLUTION	TRAZODONE HYDROCHLORIDE	50	MILLIGRAMS	POM	UK
PL 16189/0143	03/08/2023	TAKEDA UK LIMITED	ELVANSE ADULT 20 MG CAPSULES, HARD	LISDEXAMFETAMINE DIMESYLATE	20	MILLIGRAMS	POM	UK
PL 16189/0144	03/08/2023	TAKEDA UK LIMITED	ELVANSE ADULT 40 MG CAPSULES, HARD	LISDEXAMFETAMINE DIMESYLATE	40	MILLIGRAMS	POM	UK
PL 16189/0145	03/08/2023	TAKEDA UK LIMITED	ELVANSE ADULT 60 MG CAPSULES, HARD	LISDEXAMFETAMINE DIMESYLATE	60.0	MILLIGRAMS	POM	UK
PL 39699/0116	03/08/2023	ASPEN PHARMA TRADING LIMITED	SUGAMMADEX 100 MG/ML SOLUTION FOR INJECTION	SUGAMMADEX SODIUM	108.8	MILLIGRAMS PER MILLILITRE	POM	UK
PL 02855/0328	04/08/2023	OMEGA PHARMA LIMITED	NIQUITIN MINS MINT 2 MG LOZENGES	NICOTINE RESINATE	13.33	MILLIGRAMS	GSL	UK
PL 02855/0329	04/08/2023	OMEGA PHARMA LIMITED	NIQUITIN MINS 2 MG LOZENGES	NICOTINE RESINATE	13.33	MILLIGRAMS	GSL	UK
PL 02855/0330	04/08/2023	OMEGA PHARMA LIMITED	NIQUITIN MINS 4 MG LOZENGES	NICOTINE RESINATE	26.66	MILLIGRAMS	GSL	UK
PL 30684/0382	04/08/2023	DAWA LIMITED	MINOXIDIL 2.5 MG TABLETS	MINOXIDIL	2.5	MILLIGRAMS	POM	UK
PL 30684/0383	04/08/2023	DAWA LIMITED	MINOXIDIL 5 MG TABLETS	MINOXIDIL	5	MILLIGRAMS	POM	UK
PL 30684/0384	04/08/2023	DAWA LIMITED	MINOXIDIL 10 MG TABLETS	MINOXIDIL	10	MILLIGRAMS	POM	UK
PLGB 20075/1415	04/08/2023	ACCORD HEALTHCARE LIMITED	DABIGATRAN ETEXILATE ACCORD 75MG HARD CAPSULES	DABIGATRAN ETEXILATE MESILATE	86.475	MILLIGRAMS	POM	GB
PLGB 20075/1416	04/08/2023	ACCORD HEALTHCARE LIMITED	DABIGATRAN ETEXILATE ACCORD 110MG HARD CAPSULES	DABIGATRAN ETEXILATE MESILATE	126.830	MILLIGRAMS	POM	GB
PLGB 20075/1417	04/08/2023	ACCORD HEALTHCARE LIMITED	DABIGATRAN ETEXILATE ACCORD 150MG HARD CAPSULES	DABIGATRAN ETEXILATE MESILATE	172.950	MILLIGRAMS	POM	GB
PL 49255/0008	07/08/2023	CYGNUS PHARMA LIMITED	METFORMIN HYDROCHLORIDE CYGNUS PHARMA 500 MG PROLONGED-RELEASE TABLETS	METFORMIN HYDROCHLORIDE	500	MILLIGRAMS	POM	UK
PL 49255/0009	07/08/2023	CYGNUS PHARMA LIMITED	METFORMIN HYDROCHLORIDE CYGNUS PHARMA 750 MG PROLONGED-RELEASE TABLETS	METFORMIN HYDROCHLORIDE	750	MILLIGRAMS	POM	UK
PL 49255/0010	07/08/2023	CYGNUS PHARMA LIMITED	METFORMIN HYDROCHLORIDE CYGNUS PHARMA 1000 MG PROLONGED-RELEASE TABLETS	METFORMIN HYDROCHLORIDE	1000	MILLIGRAMS	POM	UK
PL 49565/0099	07/08/2023	RUDI PHARM LIMITED	GLICLAZIDE 40 MG TABLETS	GLICLAZIDE	40	MILLIGRAMS	POM	UK
PLGB 08829/0210	07/08/2023	CHESI LIMITED	ELFABRIO 2 MG/ML CONCENTRATE FOR SOLUTION FOR INFUSION	PEGUNIGALSIDASE ALFA	2.0	MILLIGRAMS	POM	GB
PL 04500/0018	08/08/2023	BIOTEST PHARMA GMBH	YIMMUGO 100MG/ML SOLUTION FOR INFUSION	HUMAN NORMAL IMMUNOGLOBULIN (IV)	100	MILLIGRAMS	POM	UK
PL 29444/0275	08/08/2023	ACTIVASE PHARMACEUTICALS LIMITED	SIMVASTATIN 80 MG FILM-COATED TABLETS	SIMVASTATIN	80.000	MILLIGRAMS	POM	UK
PL 34111/0005	08/08/2023	XEOLAS PHARMACEUTICALS LIMITED	OMEPRAZOLE 1 MG/ML POWDER FOR ORAL SUSPENSION	OMEPRAZOLE	1	MILLIGRAMS PER MILLILITRE	POM	UK
PL 39307/0130	08/08/2023	SYRI LIMITED	CALOTEP 50MICROGRAMS/5ML ORAL SOLUTION	CLONIDINE HYDROCHLORIDE	0.010	MILLIGRAMS	POM	UK
PL 43805/0058	08/08/2023	ASCEND LABORATORIES (UK) LIMITED	EZETIMIBE/SIMVASTATIN 10 MG/10 MG TABLETS	EZETIMIBE	10.000	MILLIGRAMS	POM	UK
PL 43805/0058	08/08/2023	ASCEND LABORATORIES (UK) LIMITED	EZETIMIBE/SIMVASTATIN 10 MG/10 MG TABLETS	SIMVASTATIN	10.000	MILLIGRAMS	POM	UK
PL 43805/0059	08/08/2023	ASCEND LABORATORIES (UK) LIMITED	EZETIMIBE/SIMVASTATIN 10 MG/20 MG TABLETS	EZETIMIBE	10.000	MILLIGRAMS	POM	UK
PL 43805/0059	08/08/2023	ASCEND LABORATORIES (UK) LIMITED	EZETIMIBE/SIMVASTATIN 10 MG/20 MG TABLETS	SIMVASTATIN	20.000	MILLIGRAMS	POM	UK
PL 43805/0060	08/08/2023	ASCEND LABORATORIES (UK) LIMITED	EZETIMIBE/SIMVASTATIN 10 MG/40 MG TABLETS	EZETIMIBE	10.000	MILLIGRAMS	POM	UK
PL 43805/0060	08/08/2023	ASCEND LABORATORIES (UK) LIMITED	EZETIMIBE/SIMVASTATIN 10 MG/40 MG TABLETS	SIMVASTATIN	40.000	MILLIGRAMS	POM	UK
PL 43805/0061	08/08/2023	ASCEND LABORATORIES (UK) LIMITED	EZETIMIBE/SIMVASTATIN 10 MG/80 MG TABLETS	EZETIMIBE	10.000	MILLIGRAMS	POM	UK
PL 43805/0061	08/08/2023	ASCEND LABORATORIES (UK) LIMITED	EZETIMIBE/SIMVASTATIN 10 MG/80 MG TABLETS	SIMVASTATIN	80.000	MILLIGRAMS	POM	UK
PLGB 25823/0004	08/08/2023	AMICUS THERAPEUTICS UK LIMITED	OPFOLDA 65MG HARD CAPSULES	MIGLUSTAT	65	MILLIGRAMS	POM	GB
PL 01502/0140	11/08/2023	HAMELN PHARMA LTD	AMIKACIN 250 MG/ML SOLUTION FOR INJECTION OR INFUSION	AMIKACIN SULFATE	333.80	MILLIGRAMS PER MILLILITRE	POM	UK

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PLGB 08829/0205	11/08/2023	CHIESI LIMITED	PROCYSBI 75MG GASTRO-RESISTANT GRANULES	MERCAPTAMINE BITARTRATE	221.1	MILLIGRAMS	POM	GB
PLGB 08829/0206	11/08/2023	CHIESI LIMITED	PROCYSBI 300MG GASTRO-RESISTANT GRANULES	MERCAPTAMINE BITARTRATE	884.4	MILLIGRAMS	POM	GB
PLNI 18719/0024	14/08/2023	FRESENIUS KABI DEUTSCHLAND GMBH	THIOTEPA FRESENIUS KABI 15 MG POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION	THIOTEPA	100	MILLIGRAMS	POM	NI
PLNI 18719/0025	14/08/2023	FRESENIUS KABI DEUTSCHLAND GMBH	THIOTEPA FRESENIUS KABI 100 MG POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION	THIOTEPA	100	MILLIGRAMS	POM	NI