

Marketing authorisations granted 1 December to 14 December 2022

PL Number	Grant Date	MA Holder	Licensed Name(s)	Active Ingredient	Quantity	Units	Legal Status	Territory
PL 46447/0045	01/12/2022	JCSH PHARMA LIMITED	ONDANSETRON 2 MG/ML SOLUTION FOR INJECTION	ONDANSETRON HYDROCHLORIDE DIHYDRATE	2.494	MILLIGRAMS PER MILLILITRE	POM	UK
PLGB 53095/0092	02/12/2022	MERCK SHARP & DOHME (UK) LIMITED	NOXAFIL 300 MG GASTRO-RESISTANT POWDER AND SOLVENT FOR ORAL SUSPENSION	NOT APPLICABLE	0	NONE	POM	GB
PLGB 53095/0092	02/12/2022	MERCK SHARP & DOHME (UK) LIMITED	NOXAFIL 300 MG GASTRO-RESISTANT POWDER AND SOLVENT FOR ORAL SUSPENSION	POSACONAZOLE	300.0	MILLIGRAMS	POM	GB
PLGB 53632/0008	05/12/2022	BIONTECH MANUFACTURING GMBH	COMIRNATY 3 MICROGRAMS/DOSE CONCENTRATE FOR DISPERSION FOR INJECTION	TOZINAMERAN	0.1	MILLIGRAMS PER MILLILITRE	POM	GB
PL 20416/0671	06/12/2022	CRESCENT PHARMA LIMITED	LEVOFLOXACIN 250 MG FILM - COATED TABLETS	LEVOFLOXACIN HEMIHYDRATE	250	MILLIGRAMS	POM	UK
PL 20416/0672	06/12/2022	CRESCENT PHARMA LIMITED	LEVOFLOXACIN 500 MG FILM - COATED TABLETS	LEVOFLOXACIN HEMIHYDRATE	500	MILLIGRAMS	POM	UK
PL 36722/0162	06/12/2022	SPECIAL CONCEPT DEVELOPMENT (UK) LIMITED	LOPERAMIDE 2 MG CAPSULES, HARD	LOPERAMIDE HYDROCHLORIDE	2	MILLIGRAMS	P	UK
PLGB 19484/0304	06/12/2022	GLAXOSMITHKLINE UK LIMITED	ZEJULA 100 MG FILM-COATED TABLETS	NIRAPARIB TOSYLATE MONOHYDRATE	159.3	MILLIGRAMS	POM	GB
PLNI 48870/0015	06/12/2022	SANDOZ FARMACEVTSKA DRUZBA DD	TERIFLUNOMIDE 14 MG FILM-COATED TABLETS	TERIFLUNOMIDE	14.000	MILLIGRAMS	POM	NI
PL 17780/1117	07/12/2022	ZENTIVA PHARMA UK LIMITED	OMEPRAZOLE 40 MG POWDER FOR SOLUTION FOR INFUSION	OMEPRAZOLE SODIUM	42.6	MILLIGRAMS	POM	UK
PL 43542/0055	07/12/2022	EURO-LINK PHARMA LIMITED	PARACETAMOL 500MG TABLETS	PARACETAMOL	500	MILLIGRAMS	POM	UK
PL 46740/0003	07/12/2022	PHARMASCIENCE INTERNATIONAL LIMITED	ABIRATERONE 500 MG FILM-COATED TABLETS	ABIRATERONE ACETATE	500	MILLIGRAMS	POM	UK
PL 50814/0024	07/12/2022	AZINPHARMA LTD	DARUNAVIR 400 MG FILM-COATED TABLETS	DARUNAVIR	400	MILLIGRAMS	POM	UK
PL 50814/0025	07/12/2022	AZINPHARMA LTD	DARUNAVIR 600 MG FILM-COATED TABLETS	DARUNAVIR	400	MILLIGRAMS	POM	UK
PL 50814/0026	07/12/2022	AZINPHARMA LTD	DARUNAVIR 800 MG FILM-COATED TABLETS	DARUNAVIR	400	MILLIGRAMS	POM	UK
PLGB 49718/0095	07/12/2022	NEURAXPHARM UK LIMITED	DIMETHYL FUMARATE NEURAXPHARM 120 MG GASTRO-RESISTANT CAPSULES HARD	DIMETHYL FUMARATE	120	MILLIGRAMS	POM	GB
PLGB 49718/0096	07/12/2022	NEURAXPHARM UK LIMITED	DIMETHYL FUMARATE NEURAXPHARM 240 MG GASTRO-RESISTANT CAPSULES HARD	DIMETHYL FUMARATE	240	MILLIGRAMS	POM	GB
PL 30684/0259	08/12/2022	DAWA LIMITED	OLOPATADINE 1 MG/ML EYE DROPS, SOLUTION	OLOPATADINE HYDROCHLORIDE	1.11	MILLIGRAMS PER MILLILITRE	POM	UK
PL 49445/0176	08/12/2022	AMAROX LIMITED	PLERIXAFOR 20 MG/ML SOLUTION FOR INJECTION	PLERIXAFOR	20	MILLIGRAMS PER MILLILITRE	POM	UK
PL 28444/0169	09/12/2022	ACTIVASE PHARMACEUTICALS LIMITED	THIAMINE HYDROCHLORIDE 50 MG TABLETS	THIAMINE HYDROCHLORIDE	50.00	MILLIGRAMS	P	UK
PLGB 13606/0279	09/12/2022	STRIDES PHARMA UK LIMITED	TIBOLONE 2.5 MG TABLETS	TIBOLONE	2.5	MILLIGRAMS	POM	GB
PL 16363/0737	12/12/2022	MILPHARM LIMITED	DOXEPIN 25 MG CAPSULES, HARD	DOXEPIN HYDROCHLORIDE	28.250	MILLIGRAMS	POM	UK
PL 16363/0738	12/12/2022	MILPHARM LIMITED	DOXEPIN 50 MG CAPSULES, HARD	DOXEPIN HYDROCHLORIDE	56.500	MILLIGRAMS	POM	UK
PL 25174/0034	12/12/2022	LABORATORIO REIG JOFRE SA	CO-AMOXICLAV 1000 MG/200 MG POWDER FOR SOLUTION FOR INJECTION/INFUSION	AMOXICILLIN SODIUM	1060	MILLIGRAMS	POM	UK
PL 25174/0034	12/12/2022	LABORATORIO REIG JOFRE SA	CO-AMOXICLAV 1000 MG/200 MG POWDER FOR SOLUTION FOR INJECTION/INFUSION	POTASSIUM CLAVULANATE	238.2	MILLIGRAMS	POM	UK
PL 16363/0719	13/12/2022	MILPHARM LIMITED	ZONISAMIDE MILPHARM 25 MG HARD CAPSULES	ZONISAMIDE	25	MILLIGRAMS	POM	UK
PL 16363/0720	13/12/2022	MILPHARM LIMITED	ZONISAMIDE MILPHARM 50 MG HARD CAPSULES	ZONISAMIDE	50	MILLIGRAMS	POM	UK
PL 16363/0721	13/12/2022	MILPHARM LIMITED	ZONISAMIDE MILPHARM 100 MG HARD CAPSULES	ZONISAMIDE	100	MILLIGRAMS	POM	UK
PL 21880/0226	13/12/2022	MEDREICH PLC	MEIZINE 200 MG PROLONGED-RELEASE TABLETS	CARBAMAZEPINE	200.00	MILLIGRAMS	POM	UK
PL 21880/0227	13/12/2022	MEDREICH PLC	MEIZINE 400 MG PROLONGED-RELEASE TABLETS	CARBAMAZEPINE	400.00	MILLIGRAMS	POM	UK
PLGB 33271/0017	13/12/2022	BLACKROCK PHARMACEUTICALS LIMITED	HYDROXYCHLOROQUINE SULFATE 200 MG FILM-COATED TABLETS	HYDROXYCHLOROQUINE SULFATE	200	MILLIGRAMS	POM	GB
PLGB 41344/0072	13/12/2022	COLONIS PHARMA LIMITED	ACETYLCYSTEINE 200 MG POWDER FOR ORAL SOLUTION	ACETYLCYSTEINE	200.00	MILLIGRAMS	POM	GB
PLGB 47069/0008	13/12/2022	RAYNER PHARMACEUTICALS LIMITED	ILUBE 5% W/V	ACETYLCYSTEINE	5.000	PERCENTAGE WEIGHT IN VOLUME	POM	GB
PLNI 21039/0069	13/12/2022	IBSA FARMACEUTICI ITALIA S.R.L.	MERIOFERT PFS 900 IU, POWDER AND SOLVENT FOR SOLUTION FOR INJECTION	MENOTROPHIN	1012.500	INTERNATIONAL UNITS	POM	NI