

Marketing authorisations granted 15 December to 31 December 2022

PL Number	Grant Date	MA Holder	Licensed Name(s)	Active Ingredient	Quantity	Units	Legal Status	Territory
PL 13621/0082	15/12/2022	FLYNN PHARMA LIMITED	FINGOLIMOD 0.25 MG HARD CAPSULES	FINGOLIMOD HYDROCHLORIDE	0.28	MILLIGRAMS	POM	UK
PL 13621/0083	15/12/2022	FLYNN PHARMA LIMITED	FINGOLIMOD 0.5MG HARD CAPSULES	FINGOLIMOD HYDROCHLORIDE	0.56	MILLIGRAMS	POM	UK
PL 16363/0763	15/12/2022	MILPHARM LIMITED	PLERIXAFOR 20 MG/ML SOLUTION FOR INJECTION	PLERIXAFOR	24.0	MILLIGRAMS	POM	UK
PL 25256/0369	15/12/2022	GLENMARK PHARMACEUTICALS EUROPE LIMITED	CYANOCOBALAMIN 50 MICROGRAMS FILM-COATED TABLETS	CYANOCOBALAMIN	0.055	MILLIGRAMS	P	UK
PL 43870/0047	15/12/2022	MEDLEY PHARMA LIMITED	LACTULOSE 3.335 G/5 ML ORAL SOLUTION	LACTULOSE LIQUID	0.667	GRAMS PER MILLILITRE	POM	UK
PL 48259/0056	15/12/2022	NORTHUMBRIA PHARMA LIMITED	SODIUM CITRATE 0.3M ORAL SOLUTION	SODIUM CITRATE DIHYDRATE	2847	MILLIGRAMS	POM	UK
PL 48974/0017	15/12/2022	LYRUS LIFE SCIENCES LIMITED	NITROFURANTOIN 25 MG/5 ML ORAL SUSPENSION	NITROFURANTOIN MONOHYDRATE	0.50	PERCENTAGE WEIGHT IN VOLUME	POM	UK
PL 48974/0018	15/12/2022	LYRUS LIFE SCIENCES LIMITED	NITROFURANTOIN 50 MG/5 ML ORAL SUSPENSION	NITROFURANTOIN MONOHYDRATE	1.00	PERCENTAGE WEIGHT IN VOLUME	POM	UK
PL 00142/1284	16/12/2022	ACCORD-UK LIMITED	BEXAROTENE 75 MG SOFT CAPSULES	BEXAROTENE	75	MILLIGRAMS	POM	UK
PL 17780/1115	16/12/2022	ZENTIVA PHARMA UK LIMITED	NICORANDIL 10 MG TABLETS	NICORANDIL	10	MILLIGRAMS	POM	UK
PL 17780/1116	16/12/2022	ZENTIVA PHARMA UK LIMITED	NICORANDIL 20 MG TABLETS	NICORANDIL	20	MILLIGRAMS	POM	UK
PL 19156/0157	16/12/2022	JUBILANT PHARMACEUTICALS NV	DEFERASIROX 90 MG FILM-COATED TABLETS	DEFERASIROX	90	MILLIGRAMS	POM	UK
PL 19156/0158	16/12/2022	JUBILANT PHARMACEUTICALS NV	DEFERASIROX 180 MG FILM-COATED TABLETS	DEFERASIROX	180	MILLIGRAMS	POM	UK
PL 19156/0159	16/12/2022	JUBILANT PHARMACEUTICALS NV	DEFERASIROX 360 MG FILM-COATED TABLETS	DEFERASIROX	360	MILLIGRAMS	POM	UK
PL 28278/0063	16/12/2022	IPCA LABORATORIES UK LIMITED	CO-AMOXICLAV 250/125 MG FILM-COATED TABLETS	AMOXICILLIN	286.946	MILLIGRAMS	POM	UK
PL 28278/0063	16/12/2022	IPCA LABORATORIES UK LIMITED	CO-AMOXICLAV 250/125 MG FILM-COATED TABLETS	CLAVULANIC ACID	297.876	MILLIGRAMS	POM	UK
PL 28444/0249	16/12/2022	ACTIVASE PHARMACEUTICALS LIMITED	FLUOXETINE 10 MG HARD CAPSULES	FLUOXETINE HYDROCHLORIDE	11.20	MILLIGRAMS	POM	UK
PL 28444/0250	16/12/2022	ACTIVASE PHARMACEUTICALS LIMITED	FLUOXETINE 30 MG HARD CAPSULES	FLUOXETINE HYDROCHLORIDE	33.60	MILLIGRAMS	POM	UK
PL 28444/0251	16/12/2022	ACTIVASE PHARMACEUTICALS LIMITED	FLUOXETINE 40 MG HARD CAPSULES	FLUOXETINE HYDROCHLORIDE	44.80	MILLIGRAMS	POM	UK
PL 28444/0252	16/12/2022	ACTIVASE PHARMACEUTICALS LIMITED	FLUOXETINE 60 MG HARD CAPSULES	FLUOXETINE HYDROCHLORIDE	67.2	MILLIGRAMS	POM	UK
PL 39307/0106	16/12/2022	SYRI LIMITED	LAMOTRIGINE SYRIMED 10MG/ML ORAL SUSPENSION	LAMOTRIGINE	50	MILLIGRAMS	POM	UK
PL 39307/0107	16/12/2022	SYRI LIMITED	LAMOTRIGINE SYRIMED 20MG/ML ORAL SUSPENSION	LAMOTRIGINE	100	MILLIGRAMS	POM	UK
PL 53475/0012	16/12/2022	BIOVANTIC PHARMA LIMITED	ESOMEPRAZOLE 20 MG GASTRO-RESISTANT TABLETS	ESOMEPRAZOLE MAGNESIUM TRIHYDRATE	22.21	MILLIGRAMS	POM	UK
PL 53475/0013	16/12/2022	BIOVANTIC PHARMA LIMITED	ESOMEPRAZOLE 40 MG GASTRO-RESISTANT TABLETS	ESOMEPRAZOLE MAGNESIUM TRIHYDRATE	44.42	MILLIGRAMS	POM	UK
PL 15764/0158	19/12/2022	STRANDHAVEN LIMITED	ONDANSETRON 4MG/5ML ORAL SOLUTION	ONDANSETRON HYDROCHLORIDE DIHYDRATE	0.8	MILLIGRAMS PER MILLILITRE	POM	UK
PL 21880/0302	19/12/2022	MEDREICH PLC	TORASEMIDE 2.5 MG TABLETS	TORASEMIDE	2.50	MILLIGRAMS	POM	UK
PL 21880/0303	19/12/2022	MEDREICH PLC	TORASEMIDE 5 MG TABLETS	TORASEMIDE	5.00	MILLIGRAMS	POM	UK
PL 21880/0304	19/12/2022	MEDREICH PLC	TORASEMIDE 10 MG TABLETS	TORASEMIDE	10	MILLIGRAMS	POM	UK
PL 21880/0305	19/12/2022	MEDREICH PLC	TORASEMIDE 20 MG TABLETS	TORASEMIDE	20.00	MILLIGRAMS	POM	UK
PL 26080/0010	19/12/2022	SERB	LEVOTHYROXINE SERB 200 MICROGRAMS/ML SOLUTION FOR INJECTION/INFUSION	LEVOTHYROXINE SODIUM	200	MICROGRAMS PER MILLILITRE	POM	UK
PL 50674/0010	19/12/2022	BIOCON PHARMA UK LIMITED	FINGOLIMOD 0.5 MG CAPSULES, HARD	FINGOLIMOD HYDROCHLORIDE	0.560	MILLIGRAMS	POM	UK
PL 00289/2528	20/12/2022	TEVA UK LIMITED	PLERIXAFOR 20 MG/ML SOLUTION FOR INJECTION	PLERIXAFOR	20.0	MILLIGRAMS PER MILLILITRE	POM	UK
PLGB 46602/0028	20/12/2022	SANOFI PASTEUR EUROPE	COVID-19 VACCINE	SARS-COV-2 PREFUSION SPIKE DELTA TM PROTEIN, RECOMBINANT	0	MILLIGRAMS	POM	GB
PLGB 46602/0028	20/12/2022	SANOFI PASTEUR EUROPE	COVID-19 VACCINE	SARS-COV-2 PREFUSION SPIKE DELTA TM PROTEIN, RECOMBINANT	5	MICROGRAMS	POM	GB
PLGB 46602/0028	20/12/2022	SANOFI PASTEUR EUROPE	VIDPREVTYN BETA SOLUTION AND EMULSION FOR EMULSION FOR INJECTION	SARS-COV-2 PREFUSION SPIKE DELTA TM PROTEIN, RECOMBINANT	0	MILLIGRAMS	POM	GB
PLGB 46602/0028	20/12/2022	SANOFI PASTEUR EUROPE	VIDPREVTYN BETA SOLUTION AND EMULSION FOR EMULSION FOR INJECTION	SARS-COV-2 PREFUSION SPIKE DELTA TM PROTEIN, RECOMBINANT	5	MICROGRAMS	POM	GB
PLGB 52779/0001	20/12/2022	AGIOS NETHERLANDS B.V.	PYRUKYND 5 MG FILM-COATED TABLETS	MITAPIVAT SULFATE	5.850	MILLIGRAMS	POM	GB
PLGB 52779/0002	20/12/2022	AGIOS NETHERLANDS B.V.	PYRUKYND 20 MG FILM-COATED TABLETS	MITAPIVAT SULFATE	23.40	MILLIGRAMS	POM	GB
PLGB 52779/0003	20/12/2022	AGIOS NETHERLANDS B.V.	PYRUKYND 50 MG FILM-COATED TABLETS	MITAPIVAT SULFATE	58.50	MILLIGRAMS	POM	GB
PLGB 52779/0004	20/12/2022	AGIOS NETHERLANDS B.V.	PYRUKYND 20 MG FILM-COATED TABLETS	MITAPIVAT SULFATE	23.40	MILLIGRAMS	POM	GB
PLGB 52779/0004	20/12/2022	AGIOS NETHERLANDS B.V.	PYRUKYND 20 MG FILM-COATED TABLETS	MITAPIVAT SULFATE	5.850	MILLIGRAMS	POM	GB

Marketing authorisations granted 15 December to 31 December 2022

PL Number	Grant Date	MA Holder	Licensed Name(s)	Active Ingredient	Quantity	Units	Legal Status	Territory
PLGB 52779/0004	20/12/2022	AGIOS NETHERLANDS B.V.	PYRUKYND 5 MG FILM-COATED TABLETS	MITAPIVAT SULFATE	23.40	MILLIGRAMS	POM	GB
PLGB 52779/0004	20/12/2022	AGIOS NETHERLANDS B.V.	PYRUKYND 5 MG FILM-COATED TABLETS	MITAPIVAT SULFATE	5.850	MILLIGRAMS	POM	GB
PLGB 52779/0005	20/12/2022	AGIOS NETHERLANDS B.V.	PYRUKYND 20 MG FILM-COATED TABLETS	MITAPIVAT SULFATE	23.40	MILLIGRAMS	POM	GB
PLGB 52779/0005	20/12/2022	AGIOS NETHERLANDS B.V.	PYRUKYND 20 MG FILM-COATED TABLETS	MITAPIVAT SULFATE	58.50	MILLIGRAMS	POM	GB
PLGB 52779/0005	20/12/2022	AGIOS NETHERLANDS B.V.	PYRUKYND 50 MG FILM-COATED TABLETS	MITAPIVAT SULFATE	23.40	MILLIGRAMS	POM	GB
PLGB 52779/0005	20/12/2022	AGIOS NETHERLANDS B.V.	PYRUKYND 50 MG FILM-COATED TABLETS	MITAPIVAT SULFATE	58.50	MILLIGRAMS	POM	GB
PL 49718/0067	21/12/2022	NEURAXPHARM UK LIMITED	TRANLYCYPROMINE 10 MG FILM COATED TABLETS	TRANLYCYPROMINE SULFATE	13.68	MILLIGRAMS	POM	UK
PL 39280/0021	22/12/2022	SYNCHRONY PHARMA LIMITED	ONDANSETRON 2 MG/ML SOLUTION FOR INJECTION/INFUSION	ONDANSETRON HYDROCHLORIDE DIHYDRATE	2.5	MILLIGRAMS	POM	UK
PL 48836/0012	22/12/2022	OSGEN PHARMACEUTICALS LIMITED	CHOU-D3 10,000 IU CAPSULES, SOFT	COLECALCIFEROL	0.25	MILLIGRAMS	POM	UK
PL 48836/0013	22/12/2022	OSGEN PHARMACEUTICALS LIMITED	CHOU-D3 50,000 IU CAPSULES, SOFT	COLECALCIFEROL	1.25	MILLIGRAMS	POM	UK
PLGB 04416/1666	28/12/2022	SANDOZ LIMITED	RELETRANS 25 MICROGRAM/HOUR TRANSDERMAL PATCH	BUPRENORPHINE	25.0	MILLIGRAMS	POM	GB
PLGB 04416/1667	28/12/2022	SANDOZ LIMITED	RELETRANS 30 MICROGRAM/HOUR TRANSDERMAL PATCH	BUPRENORPHINE	30	MILLIGRAMS	POM	GB
PLGB 04416/1668	28/12/2022	SANDOZ LIMITED	RELETRANS 40 MICROGRAM/HOUR TRANSDERMAL PATCH	BUPRENORPHINE	40	MILLIGRAMS	POM	GB
PLGB 42924/0029	29/12/2022	FONTUS HEALTH LIMITED	HANXOL 50 MG TABLETS	MERCAPTOPYRINE MONOHYDRATE	50	MILLIGRAMS	POM	GB