

Marketing authorisations granted in September 2022

PL Number	Grant Date	MA Holder	Licensed Name(s)	Active Ingredient	Quantity	Units	Legal Status	Territory
PLGB 53632/0010	02/09/2022	BIONTECH MANUFACTURING GMBH	COMIRNATY ORIGINAL/OMICRON BA.1 (15/15 MICROGRAMS)/DOSE DISPERSION FOR INJECTION	RILTOZINAMERAN	0.05	MILLIGRAMS PER MILLILITRE	POM	GB
PLGB 53632/0010	02/09/2022	BIONTECH MANUFACTURING GMBH	COMIRNATY ORIGINAL/OMICRON BA.1 (15/15 MICROGRAMS)/DOSE DISPERSION FOR INJECTION	TOZINAMERAN	0.05	MILLIGRAMS PER MILLILITRE	POM	GB
PL 52104/0020	05/09/2022	HUALAN PHARMACEUTICALS LIMITED	HYDROCORTISONE 10 MG TABLETS	HYDROCORTISONE	10	MILLIGRAMS	POM	UK
PL 52104/0021	05/09/2022	HUALAN PHARMACEUTICALS LIMITED	HYDROCORTISONE 20 MG TABLETS	HYDROCORTISONE	20	MILLIGRAMS	POM	UK
PL 39305/0012	06/09/2022	UMEDICA LIMITED	TADALAFIL 5 MG FILM-COATED TABLETS	TADALAFIL	5	MILLIGRAMS	POM	UK
PL 39305/0013	06/09/2022	UMEDICA LIMITED	TADALAFIL 10 MG FILM-COATED TABLETS	TADALAFIL	10	MILLIGRAMS	POM	UK
PL 39305/0019	06/09/2022	UMEDICA LIMITED	TADALAFIL 20 MG FILM-COATED TABLETS	TADALAFIL	20	MILLIGRAMS	POM	UK
PLGB 04569/2059	06/09/2022	GENERICS (UK) LIMITED	PIRFENDONE 267 MG FILM-COATED TABLETS	PIRFENDONE	267	MILLIGRAMS	POM	GB
PLGB 04569/2060	06/09/2022	GENERICS (UK) LIMITED	PIRFENDONE 534 MG FILM-COATED TABLETS	PIRFENDONE	534	MILLIGRAMS	POM	GB
PLGB 04569/2061	06/09/2022	GENERICS (UK) LIMITED	PIRFENDONE 801 MG FILM-COATED TABLETS	PIRFENDONE	801	MILLIGRAMS	POM	GB
PL 14251/0134	07/09/2022	MANX HEALTHCARE LIMITED	CARBOCISTEINE 250MG/5ML ORAL SOLUTION	CARBOCISTEINE	50.00	MILLIGRAMS PER MILLILITRE	POM	UK
PL 51316/0001	09/09/2022	ACURE PHARMACEUTICALS LIMITED	VITAMIN D3 ACURE 800 IU SOFT CAPSULES	COLECALCIFEROL	0.020	MILLIGRAMS	POM	UK
PL 51316/0002	09/09/2022	ACURE PHARMACEUTICALS LIMITED	VITAMIN D3 ACURE 1000 IU SOFT CAPSULES	COLECALCIFEROL	0.025	MILLIGRAMS	POM	UK
PL 51316/0003	09/09/2022	ACURE PHARMACEUTICALS LIMITED	VITAMIN D3 ACURE 3200 IU SOFT CAPSULES	COLECALCIFEROL	0.08	MILLIGRAMS	POM	UK
PLGB 53941/0016	09/09/2022	SIFI PHARMACEUTICALS LIMITED	NETILMICIN 3 MG/ML EYE DROPS, SOLUTION IN SINGLE-DOSE CONTAINER	NETILMICIN SULFATE	0.455	GRAMS	POM	GB
PL 46447/0033	12/09/2022	JCSH PHARMA LIMITED	REMIFENTANIL 1 MG POWDER FOR CONCENTRATE FOR SOLUTION FOR INJECTION/INFUSION	REMIFENTANIL	1	MILLIGRAMS PER MILLILITRE	POM	UK
PL 46447/0034	12/09/2022	JCSH PHARMA LIMITED	REMIFENTANIL 2 MG POWDER FOR CONCENTRATE FOR SOLUTION FOR INJECTION/INFUSION	REMIFENTANIL	2	MILLIGRAMS PER MILLILITRE	POM	UK
PL 46447/0035	12/09/2022	JCSH PHARMA LIMITED	REMIFENTANIL 5 MG POWDER FOR CONCENTRATE FOR SOLUTION FOR INJECTION/INFUSION	REMIFENTANIL	5	MILLIGRAMS PER MILLILITRE	POM	UK
PL 35507/0206	13/09/2022	LUPIN HEALTHCARE (UK) LIMITED	BECLU 100 MICROGRAMS PER ACTUATION PRESSURISED INHALATION SOLUTION	BECLOMETASONE DIPROPIONATE	100	MICROGRAMS PER ACTUATION	POM	UK
PL 35507/0207	13/09/2022	LUPIN HEALTHCARE (UK) LIMITED	BECLU 200 MICROGRAMS PER ACTUATION PRESSURISED INHALATION SOLUTION	BECLOMETASONE DIPROPIONATE	200	MICROGRAMS PER ACTUATION	POM	UK
PLGB 53720/0003	13/09/2022	MODERNA BIOTECH SPAIN SL	COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED)	ELASOMERAN	0.10	MILLIGRAMS PER MILLILITRE	POM	GB
PLGB 53720/0003	13/09/2022	MODERNA BIOTECH SPAIN SL	SPIKEVAX 50 MICROGRAMS DISPERSION FOR INJECTION IN PRE-FILLED SYRINGE	ELASOMERAN	0.10	MILLIGRAMS PER MILLILITRE	POM	GB
PLGB 00242/0744	15/09/2022	JANSSEN-CILAG LIMITED	SIRTURO 20 MG TABLETS	BEDAQUILINE FUMARATE	120.89	MILLIGRAMS	POM	GB
PLGB 53835/0019	15/09/2022	CELIx PHARMA LTD	BEXAROTENE 75 MG SOFT CAPSULES	BEXAROTENE	75	MILLIGRAMS	POM	UK
PL 36390/0411	16/09/2022	CIPLA (EU) LIMITED	PARACETAMOL 1000 MG EFFERESCENT TABLETS	PARACETAMOL	1000.00	MILLIGRAMS	P	UK
PL 48278/0034	16/09/2022	ZISTA PHARMA LIMITED	TEMOZOLOMIDE ZISTA 5 MG HARD CAPSULES	TEMOZOLOMIDE	5	MILLIGRAMS	POM	UK
PLGB 20075/1478	16/09/2022	ACCORD HEALTHCARE LIMITED	PLERIXAFOR 20 MG/ML SOLUTION FOR INJECTION	PLERIXAFOR	20	MILLIGRAMS	POM	UK
PLGB 50597/0006	16/09/2022	ALNYLAM NETHERLANDS B.V.	AMVUTTRA 25 MG SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE	VUTRISIRAN SODIUM	26.5	MILLIGRAMS PER MILLILITRE	POM	GB
PLGB 51808/0011	16/09/2022	CELLTRION HEALTHCARE UNITED KINGDOM LIMITED	VEGZELMA 25 MG/ML CONCENTRATE FOR SOLUTION FOR INFUSION	BEVACIZUMAB	100	MILLIGRAMS	POM	GB
PLGB 51808/0012	16/09/2022	CELLTRION HEALTHCARE UNITED KINGDOM LIMITED	VEGZELMA 25 MG/ML CONCENTRATE FOR SOLUTION FOR INFUSION	BEVACIZUMAB	400	MILLIGRAMS	POM	GB
PL 20117/0367	20/09/2022	MORNINGSIDE HEALTHCARE LIMITED	TRIFLUOPERAZINE 1 MG TABLETS	TRIFLUOPERAZINE HYDROCHLORIDE	1.180	MILLIGRAMS	POM	UK
PL 20117/0367	20/09/2022	MORNINGSIDE HEALTHCARE LIMITED	TRIFLUOPERAZINE 1MG TABLETS	TRIFLUOPERAZINE HYDROCHLORIDE	1.180	MILLIGRAMS	POM	UK
PL 20117/0368	20/09/2022	MORNINGSIDE HEALTHCARE LIMITED	TRIFLUOPERAZINE 2MG TABLETS	TRIFLUOPERAZINE HYDROCHLORIDE	2.36	MILLIGRAMS	POM	UK
PL 20117/0369	20/09/2022	MORNINGSIDE HEALTHCARE LIMITED	TRIFLUOPERAZINE 5MG TABLETS	TRIFLUOPERAZINE HYDROCHLORIDE	5.9	MILLIGRAMS	POM	UK
PL 17780/1140	21/09/2022	ZENTIVA PHARMA UK LIMITED	PIRFENDONE 267 MG FILM-COATED TABLETS	PIRFENDONE	267	MILLIGRAMS	POM	UK
PL 17780/1142	21/09/2022	ZENTIVA PHARMA UK LIMITED	PIRFENDONE 801 MG FILM-COATED TABLETS	PIRFENDONE	801	MILLIGRAMS	POM	UK
PL 20117/0392	21/09/2022	MORNINGSIDE HEALTHCARE LIMITED	GLYCOPYRRONIUM BROMIDE 200 MICROGRAMS/ML SOLUTION FOR INJECTION	GLYCOPYRRONIUM BROMIDE	200	MICROGRAMS PER MILLILITRE	POM	UK
PL 48974/0024	21/09/2022	LYRUS LIFE SCIENCES LIMITED	CO-CODAMOL 8 MG/500 MG TABLETS	CODEINE PHOSPHATE HEMIHYDRATE	8	MILLIGRAMS	P	UK
PL 48974/0024	21/09/2022	LYRUS LIFE SCIENCES LIMITED	CO-CODAMOL 8 MG/500 MG TABLETS	PARACETAMOL	500	MILLIGRAMS	P	UK
PL 37071/0032	23/09/2022	PIRAMAL CRITICAL CARE LIMITED	TIGECYCLINE 50 MG POWDER FOR SOLUTION FOR INFUSION	TIGECYCLINE	50	MILLIGRAMS	POM	UK
PL 39307/0124	23/09/2022	SYRI LIMITED	SERTRALINE 100MG/5ML CONCENTRATE FOR ORAL SOLUTION	SERTRALINE HYDROCHLORIDE	22.38	MILLIGRAMS PER MILLILITRE	POM	UK

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PL 48278/0024	23/09/2022	ZISTA PHARMA LIMITED	TEMOZOLOMIDE ZISTA 20 MG HARD CAPSULES	TEMOZOLOMIDE	20	MILLIGRAMS	POM	UK
PL 48278/0025	23/09/2022	ZISTA PHARMA LIMITED	TEMOZOLOMIDE ZISTA 100 MG HARD CAPSULES	TEMOZOLOMIDE	100	MILLIGRAMS	POM	UK
PL 48278/0026	23/09/2022	ZISTA PHARMA LIMITED	TEMOZOLOMIDE ZISTA 140 MG HARD CAPSULES	TEMOZOLOMIDE	140	MILLIGRAMS	POM	UK
PL 48278/0027	23/09/2022	ZISTA PHARMA LIMITED	TEMOZOLOMIDE ZISTA 180 MG HARD CAPSULES	TEMOZOLOMIDE	180	MILLIGRAMS	POM	UK
PL 48278/0028	23/09/2022	ZISTA PHARMA LIMITED	TEMOZOLOMIDE ZISTA 250 MG HARD CAPSULES	TEMOZOLOMIDE	250	MILLIGRAMS	POM	UK
PL 49565/0038	23/09/2022	RUDIPHARM LIMITED	ATORVASTATIN 10MG FILM-COATED TABLETS	ATORVASTATIN CALCIUM TRIHYDRATE	10.360	MILLIGRAMS	POM	UK
PL 49565/0039	23/09/2022	RUDIPHARM LIMITED	ATORVASTATIN 20MG FILM-COATED TABLETS	ATORVASTATIN CALCIUM TRIHYDRATE	20.720	MILLIGRAMS	POM	UK
PL 49565/0040	23/09/2022	RUDIPHARM LIMITED	ATORVASTATIN 30MG FILM-COATED TABLETS	ATORVASTATIN CALCIUM TRIHYDRATE	31.080	MILLIGRAMS	POM	UK
PL 49565/0041	23/09/2022	RUDIPHARM LIMITED	ATORVASTATIN 40MG FILM-COATED TABLETS	ATORVASTATIN CALCIUM TRIHYDRATE	41.440	MILLIGRAMS	POM	UK
PL 49565/0042	23/09/2022	RUDIPHARM LIMITED	ATORVASTATIN 60MG FILM-COATED TABLETS	ATORVASTATIN CALCIUM TRIHYDRATE	62.160	MILLIGRAMS	POM	UK
PL 49565/0043	23/09/2022	RUDIPHARM LIMITED	ATORVASTATIN 80MG FILM-COATED TABLETS	ATORVASTATIN CALCIUM TRIHYDRATE	82.880	MILLIGRAMS	POM	UK
PLGB 17901/0365	23/09/2022	ASTRAZENECA UK LIMITED	TEZSPIRE 210 MG SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE	TEZPELIMAB	210	MILLIGRAMS	POM	UK
PLGB 14895/0317	26/09/2022	ELI LILLY NEDERLAND B.V.	MOUNJARO 2.5 MG SOLUTION FOR INJECTION IN PRE-FILLED PEN	TIRZEPATIDE	5	MILLIGRAMS PER MILLILITRE	POM	GB
PLGB 14895/0318	26/09/2022	ELI LILLY NEDERLAND B.V.	MOUNJARO 5 MG SOLUTION FOR INJECTION IN PRE-FILLED PEN	TIRZEPATIDE	10	MILLIGRAMS PER MILLILITRE	POM	GB
PLGB 14895/0320	26/09/2022	ELI LILLY NEDERLAND B.V.	MOUNJARO 7.5 MG SOLUTION FOR INJECTION IN PRE-FILLED PEN	TIRZEPATIDE	15	MILLIGRAMS PER MILLILITRE	POM	GB
PLGB 14895/0321	26/09/2022	ELI LILLY NEDERLAND B.V.	MOUNJARO 10 MG SOLUTION FOR INJECTION IN PRE-FILLED PEN	TIRZEPATIDE	20	MILLIGRAMS PER MILLILITRE	POM	GB
PLGB 14895/0322	26/09/2022	ELI LILLY NEDERLAND B.V.	MOUNJARO 12.5 MG SOLUTION FOR INJECTION IN PRE-FILLED PEN	TIRZEPATIDE	25	MILLIGRAMS PER MILLILITRE	POM	GB
PLGB 14895/0323	26/09/2022	ELI LILLY NEDERLAND B.V.	MOUNJARO 15 MG SOLUTION FOR INJECTION IN PRE-FILLED PEN	TIRZEPATIDE	30	MILLIGRAMS PER MILLILITRE	POM	GB
PL 03551/0161	28/09/2022	B BRAUN MELSUNGEN AG	DEXMEDETOMIDINE 100 MICROGRAMS/ML CONCENTRATE FOR SOLUTION FOR INFUSION	DEXMEDETOMIDINE HYDROCHLORIDE	118	MICROLITRES PER MILLILITRE	POM	UK
PL 25298/0300	28/09/2022	BROWN & BURK UK LIMITED	FLUOXETINE 10 MG HARD CAPSULES	FLUOXETINE HYDROCHLORIDE	11.179	MILLIGRAMS	POM	UK
PL 25298/0301	28/09/2022	BROWN & BURK UK LIMITED	FLUOXETINE 20 MG HARD CAPSULES	FLUOXETINE HYDROCHLORIDE	22.358	MILLIGRAMS	POM	UK
PL 25298/0302	28/09/2022	BROWN & BURK UK LIMITED	FLUOXETINE 30 MG HARD CAPSULES	FLUOXETINE HYDROCHLORIDE	33.537	MILLIGRAMS	POM	UK
PL 25298/0303	28/09/2022	BROWN & BURK UK LIMITED	FLUOXETINE 40 MG HARD CAPSULES	FLUOXETINE HYDROCHLORIDE	44.716	MILLIGRAMS	POM	UK
PL 25298/0304	28/09/2022	BROWN & BURK UK LIMITED	FLUOXETINE 60 MG HARD CAPSULES	FLUOXETINE HYDROCHLORIDE	67.074	MILLIGRAMS	POM	UK
PL 20416/0665	29/09/2022	CRESCENT PHARMA LIMITED	LORMETAZEPAM 1 MG TABLETS	LORMETAZEPAM	1.0	MILLIGRAMS	POM	UK
PL 50674/0011	29/09/2022	BIOCON PHARMA UK LIMITED	POSACONAZOLE BIOCON 100 MG GASTRO-RESISTANT TABLETS	POSACONAZOLE	100	MILLIGRAMS	POM	UK
PL 13606/0265	30/09/2022	STRIDES PHARMA UK LIMITED	IBUPROFEN 200 MG FILM-COATED TABLETS	IBUPROFEN	200	MILLIGRAMS	GSL	UK
PL 13606/0266	30/09/2022	STRIDES PHARMA UK LIMITED	IBUPROFEN 400 MG FILM-COATED TABLETS	IBUPROFEN	400	MILLIGRAMS	P	UK
PL 13606/0267	30/09/2022	STRIDES PHARMA UK LIMITED	IBUPROFEN 600 MG FILM-COATED TABLETS	IBUPROFEN	600	MILLIGRAMS	POM	UK