

Marketing authorisations granted 1 December to 14 December 2024

PL Number	Grant Date	MA Holder	Licensed Name(s)	Active Ingredient	Quantity	Units	Legal Status	Territory
PL 17780/1190	02/12/2024	ZENTIVA PHARMA UK LIMITED	MIRABEGRON ZENTIVA 50 MG PROLONGED-RELEASE TABLETS	MIRABEGRON	50.000	MILLIGRAMS	POM	UK
PL 39721/0005	02/12/2024	GEDEON RICHTER POLSKA SP ZOO	DIMETHYL FUMARATE GEDEON RICHTER 120 MG GASTRO-RESISTANT CAPSULES, HARD	DIMETHYL FUMARATE	120	MILLIGRAMS	POM	UK
PL 39721/0006	02/12/2024	GEDEON RICHTER POLSKA SP ZOO	DIMETHYL FUMARATE GEDEON RICHTER 240 MG GASTRO-RESISTANT CAPSULES, HARD	DIMETHYL FUMARATE	240	MILLIGRAMS	POM	UK
PLGB 20075/1529	02/12/2024	ACCORD HEALTHCARE LIMITED	NILOTINIB 50 MG HARD CAPSULES	NILOTINIB	50	MILLIGRAMS	POM	GB
PLGB 20075/1530	02/12/2024	ACCORD HEALTHCARE LIMITED	NILOTINIB 150 MG HARD CAPSULES	NILOTINIB	150	MILLIGRAMS	POM	GB
PLGB 20075/1531	02/12/2024	ACCORD HEALTHCARE LIMITED	NILOTINIB 200 MG HARD CAPSULES	NILOTINIB	200	MILLIGRAMS	POM	GB
PL 00289/2628	04/12/2024	TEVA UK LIMITED	MIRABEGRON 50 MG PROLONGED-RELEASE TABLETS	MIRABEGRON	50.000	MILLIGRAMS	POM	UK
PL 15413/0162	04/12/2024	HIKMA FARMACEUTICA (PORTUGAL) SA	FULVESTRANT 250 MG SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE	FULVESTRANT	250	MILLIGRAMS PER 5 MILLILITRES	POM	UK
PL 16363/0794	04/12/2024	MILPHARM LIMITED	PREDNISOLONE 5 MG SOLUBLE TABLETS	PREDNISOLONE SODIUM PHOSPHATE	6.72	MILLIGRAMS	POM	UK
PL 54594/0007	04/12/2024	MACURE PHARMA UK LIMITED	GLYCERYL TRINITRATE MACURE 1 MG/ML SOLUTION FOR INFUSION	GLYCERYL TRINITRATE	1.00	MILLIGRAMS PER MILLILITRE	POM	UK
PL 54977/0012	04/12/2024	ENZYMEX LIMITED	ESOMEPRAZOLE 20 MG GASTRO-RESISTANT TABLETS	ESOMEPRAZOLE MAGNESIUM TRIHYDRATE	22.21	MILLIGRAMS	POM	UK
PL 54977/0013	04/12/2024	ENZYMEX LIMITED	ESOMEPRAZOLE 40 MG GASTRO-RESISTANT TABLETS	ESOMEPRAZOLE MAGNESIUM TRIHYDRATE	44.42	MILLIGRAMS	POM	UK
PL 20117/0442	05/12/2024	MORNINGSIDE HEALTHCARE LIMITED	MEMANTINE HYDROCHLORIDE 10 MG ORODISPERSIBLE TABLETS	MEMANTINE HYDROCHLORIDE	10	MILLIGRAMS	POM	UK
PL 20117/0443	05/12/2024	MORNINGSIDE HEALTHCARE LIMITED	MEMANTINE HYDROCHLORIDE 20 MG ORODISPERSIBLE TABLETS	MEMANTINE HYDROCHLORIDE	20	MILLIGRAMS	POM	UK
PL 20117/0447	05/12/2024	MORNINGSIDE HEALTHCARE LIMITED	MEMANTINE HYDROCHLORIDE 5 MG ORODISPERSIBLE TABLETS	MEMANTINE HYDROCHLORIDE	5	MILLIGRAMS	POM	UK
PL 20117/0448	05/12/2024	MORNINGSIDE HEALTHCARE LIMITED	MEMANTINE HYDROCHLORIDE 15 MG ORODISPERSIBLE TABLETS	MEMANTINE HYDROCHLORIDE	15	MILLIGRAMS	POM	UK
PL 47015/0035	05/12/2024	AS KALCEKS	SUGAMMADEX 100 MG/ML SOLUTION FOR INJECTION	SUGAMMADEX SODIUM	108.8	MILLIGRAMS PER MILLILITRE	POM	UK
PL 58839/0051	05/12/2024	ZYDUS PHARMACEUTICALS UK LTD	TICAGRELOR 60 MG FILM-COATED TABLETS	TICAGRELOR	60.00	MILLIGRAMS	POM	UK
PL 58839/0052	05/12/2024	ZYDUS PHARMACEUTICALS UK LTD	TICAGRELOR 90 MG FILM-COATED TABLETS	TICAGRELOR	90.00	MILLIGRAMS	POM	UK
PLGB 46302/0251	05/12/2024	MYLAN PRODUCTS LIMITED	INFLUENZA VACCINE TIV MYL SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	A/DARWIN/9/2021 (H3N2)-LIKE STRAIN (A/DARWIN/9/2021, SAN-010)	15	MICROGRAMS	POM	GB
PLGB 46302/0251	05/12/2024	MYLAN PRODUCTS LIMITED	INFLUENZA VACCINE TIV MYL SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	A/VICTORIA/4897/2022 (H1N1)PDM09-LIKE STRAIN (A/VICTORIA/4897/2022 IVR-238)	15	MICROGRAMS	POM	GB
PLGB 46302/0251	05/12/2024	MYLAN PRODUCTS LIMITED	INFLUENZA VACCINE TIV MYL SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	B/AUSTRIA/1359417/2021-LIKE STRAIN (B/AUSTRIA/1359417/2021 BVR-26)	15	MICROGRAMS	POM	GB
PL 16363/0787	06/12/2024	MILPHARM LIMITED	CLOBAZAM MILPHARM 10 MG TABLETS	CLOBAZAM	10.00	MILLIGRAMS	POM	UK
PL 42082/0029	06/12/2024	NEXCAPE PHARMACEUTICALS LIMITED	LEVETIRACETAM ENEXI 100 MG/ML CONCENTRATE FOR SOLUTION FOR INFUSION	LEVETIRACETAM	100.00	MILLIGRAMS PER MILLILITRE	POM	UK
PL 52570/0007	06/12/2024	TAW PHARMA LIMITED	OSPOLOT 20 MG/ML ORAL SUSPENSION	SULTHIAMINE	20.00	MILLIGRAMS PER MILLILITRE	POM	UK
PLGB 04668/0451	06/12/2024	NOVO NORDISK AS	RYBELSUS 1.5 MG TABLETS	SEMAGLUTIDE	1.5	MILLIGRAMS	POM	GB
PLGB 04668/0452	06/12/2024	NOVO NORDISK AS	RYBELSUS 4 MG TABLETS	SEMAGLUTIDE	4	MILLIGRAMS	POM	GB
PLGB 04668/0453	06/12/2024	NOVO NORDISK AS	RYBELSUS 9 MG TABLETS	SEMAGLUTIDE	9	MILLIGRAMS	POM	GB
PLGB 20075/1501	06/12/2024	ACCORD HEALTHCARE LIMITED	NAVERUCLIF 5 MG/ML POWDER FOR DISPERSION FOR INFUSION	PACLITAXEL	5.00	MILLIGRAMS PER MILLILITRE	POM	GB
PLGB 53720/0017	06/12/2024	MODERNA BIOTECH SPAIN SL	SPIKEVAX JN.1 50 MICROGRAMS DISPERSION FOR INJECTION	SARS-COV-2 JN.1 MRNA	0.065	MILLIGRAMS	POM	GB
PL 13621/0086	09/12/2024	FLYNN PHARMA LIMITED	KETAMINE 50 MG/ML SOLUTION FOR INJECTION/INFUSION	KETAMINE HYDROCHLORIDE	0.5765	GRAMS	POM	UK
PL 54977/0002	09/12/2024	ENZYMEX LIMITED	TELMISARTAN 40 MG TABLETS	TELMISARTAN	40.00	MILLIGRAMS	POM	UK
PL 54977/0003	09/12/2024	ENZYMEX LIMITED	TELMISARTAN 80 MG TABLETS	TELMISARTAN	80.00	MILLIGRAMS	POM	UK
PL 55912/0001	09/12/2024	INVENTIA HEALTHCARE (UK) LIMITED	SUGAMMADEX 100 MG/ ML SOLUTION FOR INJECTION	SUGAMMADEX SODIUM	108.8	MILLIGRAMS	POM	UK
PL 17780/1164	10/12/2024	ZENTIVA PHARMA UK LIMITED	FAMOTIDINE 20 MG FILM-COATED TABLETS	FAMOTIDINE	20	MILLIGRAMS	POM	UK
PL 17780/1165	10/12/2024	ZENTIVA PHARMA UK LIMITED	FAMOTIDINE 40 MG FILM-COATED TABLETS	FAMOTIDINE	40	MILLIGRAMS	POM	UK
PL 36722/0196	10/12/2024	SPECIAL CONCEPT DEVELOPMENT (UK) LIMITED	CETIRIZINE DIHYDROCHLORIDE 1MG/ML ORAL SOLUTION	CETIRIZINE DIHYDROCHLORIDE	1	MILLIGRAMS PER MILLILITRE	P	UK
PL 48278/0035	10/12/2024	ZISTA PHARMA LIMITED	BORTEZOMIB 3.5 MG POWDER FOR SOLUTION FOR INJECTION	BORTEZOMIB	3.50	MILLIGRAMS	POM	UK
PLGB 00289/2609	10/12/2024	TEVA UK LIMITED	POMALIDOMIDE 1 MG HARD CAPSULES	POMALIDOMIDE	1	MILLIGRAMS	POM	GB

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PLGB 00289/2610	10/12/2024	TEVA UK LIMITED	POMALIDOMIDE 2 MG HARD CAPSULES	POMALIDOMIDE	2	MILLIGRAMS	POM	GB
PLGB 00289/2611	10/12/2024	TEVA UK LIMITED	POMALIDOMIDE 3 MG HARD CAPSULES	POMALIDOMIDE	3	MILLIGRAMS	POM	GB
PLGB 00289/2612	10/12/2024	TEVA UK LIMITED	POMALIDOMIDE 4 MG HARD CAPSULES	POMALIDOMIDE	4	MILLIGRAMS	POM	GB
PLGB 16058/0036	10/12/2024	SANTEN OY	IKERVIS 1 MG/ML EYE DROPS, EMULSION.	CICLOSPORIN	1	MILLIGRAMS PER MILLILITRE	POM	GB
PL 39307/0135	11/12/2024	SYRI LIMITED	MEBEVERINE HYDROCHLORIDE 50MG/5ML ORAL SUSPENSION	MEBEVERINE HYDROCHLORIDE	50.00	MILLIGRAMS PER 5 MILLILITRES	POM	UK
PL 39307/0139	11/12/2024	SYRI LIMITED	MEBEVERINE HYDROCHLORIDE 150MG/5ML ORAL SUSPENSION	MEBEVERINE HYDROCHLORIDE	150.00	MILLIGRAMS PER 5 MILLILITRES	POM	UK
PL 47848/0040	11/12/2024	AXUNIO PHARMA GMBH	IVABRADINE 5 MG FILM-COATED TABLETS	IVABRADINE OXALATE	5.961	MILLIGRAMS	POM	UK
PL 47848/0041	11/12/2024	AXUNIO PHARMA GMBH	IVABRADINE 7.5 MG FILM-COATED TABLETS	IVABRADINE OXALATE	8.941	MILLIGRAMS	POM	UK
PLGB 35068/0009	11/12/2024	EUROCEPT INTERNATIONAL BV	PHEBURANE 350 MG/ML ORAL SOLUTION	SODIUM PHENYLBUTYRATE	350	GRAMS PER LITRE	POM	GB
PLGB 04416/1693	12/12/2024	SANDOZ LIMITED	AXITINIB 1 MG FILM-COATED TABLETS	AXITINIB	1	MILLIGRAMS	POM	GB
PLGB 04416/1694	12/12/2024	SANDOZ LIMITED	AXITINIB 3 MG FILM-COATED TABLETS	AXITINIB	3	MILLIGRAMS	POM	GB
PLGB 04416/1695	12/12/2024	SANDOZ LIMITED	AXITINIB 5 MG FILM-COATED TABLETS	AXITINIB	5	MILLIGRAMS	POM	GB
PLGB 20075/1515	13/12/2024	ACCORD HEALTHCARE LIMITED	AXITINIB 1MG FILM-COATED TABLETS	AXITINIB	1,000	MILLIGRAMS	POM	GB
PLGB 20075/1517	13/12/2024	ACCORD HEALTHCARE LIMITED	AXITINIB 5 MG FILM-COATED TABLETS	AXITINIB	5,000	MILLIGRAMS	POM	GB
PLGB 20075/1518	13/12/2024	ACCORD HEALTHCARE LIMITED	AXITINIB 3 MG FILM-COATED TABLETS	AXITINIB	3,000	MILLIGRAMS	POM	GB