

Marketing authorisations granted 15 March to 31 March 2023

PL Number	Grant Date	MA Holder	Licensed Name(s)	Active Ingredient	Quantity	Units	Legal Status	Territory
PL 17780/1169	15/03/2023	ZENTIVA PHARMA UK LIMITED	DICLOFENAC 2.32% GEL	DICLOFENAC DIETHYLAMINE	23.2	MILLIGRAMS PER GRAM	P	UK
PL 17780/1202	15/03/2023	ZENTIVA PHARMA UK LIMITED	MIDODRINE 2.5 MG TABLETS	MIDODRINE HYDROCHLORIDE	2.5	MILLIGRAMS	POM	UK
PL 17780/1203	15/03/2023	ZENTIVA PHARMA UK LIMITED	MIDODRINE 5 MG TABLETS	MIDODRINE HYDROCHLORIDE	5	MILLIGRAMS	POM	UK
PL 18920/0047	15/03/2023	BRACCO UK LIMITED	CARDIOGEN-82 3.3-5.6 GBQ RADIONUCLIDE GENERATOR	RUBIDIUM CHLORIDE	3.3	GIGA BECQUEREL UNITS	POM	UK
PL 18920/0047	15/03/2023	BRACCO UK LIMITED	CARDIOGEN-82 3.3-5.6 GBQ RADIONUCLIDE GENERATOR	STRONTIUM CHLORIDE	3.3	GIGA BECQUEREL UNITS	POM	UK
PL 36687/0418	15/03/2023	TORRENT PHARMA (UK) LIMITED	FINGOLMOD 0.5 MG HARD CAPSULES	FINGOLMOD HYDROCHLORIDE	0.560	MILLIGRAMS	POM	UK
PL 44081/0009	15/03/2023	EXELTIS HEALTHCARE SL	GEPRETIX 100 MG SOFT CAPSULES	PROGESTERONE	100	MILLIGRAMS	POM	UK
PL 44081/0010	15/03/2023	EXELTIS HEALTHCARE SL	GEPRETIX 200 MG SOFT CAPSULES	PROGESTERONE	200	MILLIGRAMS	POM	UK
PLGB 53720/0008	15/03/2023	MODERNA BIOTECH SPAIN SL	COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED)	DAVESOMERAN	0.05	MILLIGRAMS PER MILLILITRE	POM	GB
PLGB 53720/0008	15/03/2023	MODERNA BIOTECH SPAIN SL	COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED)	ELASOMERAN	0.05	MILLIGRAMS PER MILLILITRE	POM	GB
PLGB 53720/0008	15/03/2023	MODERNA BIOTECH SPAIN SL	SPIKEVAX BIVALENT ORIGINAL/OMICRON BA.4-5 25 MCG/25 MCG DISPERSION FOR INJECTION IN PFS	DAVESOMERAN	0.05	MILLIGRAMS PER MILLILITRE	POM	GB
PLGB 53720/0008	15/03/2023	MODERNA BIOTECH SPAIN SL	SPIKEVAX BIVALENT ORIGINAL/OMICRON BA.4-5 25 MCG/25 MCG DISPERSION FOR INJECTION IN PFS	ELASOMERAN	0.05	MILLIGRAMS PER MILLILITRE	POM	GB
PL 16647/0054	16/03/2023	GRINDEKS AS	SITAGLIPTIN GRINDEKS 50 MG FILM-COATED TABLETS	SITAGLIPTIN HYDROCHLORIDE MONOHYDRATE	28.35	MILLIGRAMS	POM	UK
PL 16647/0055	16/03/2023	GRINDEKS AS	SITAGLIPTIN GRINDEKS 50 MG FILM-COATED TABLETS	SITAGLIPTIN HYDROCHLORIDE MONOHYDRATE	56.7	MILLIGRAMS	POM	UK
PL 16647/0056	16/03/2023	GRINDEKS AS	SITAGLIPTIN GRINDEKS 100 MG FILM-COATED TABLETS	SITAGLIPTIN HYDROCHLORIDE MONOHYDRATE	113.4	MILLIGRAMS	POM	UK
PLGB 22352/0018	17/03/2023	VERTEX PHARMACEUTICALS (EUROPE) LIMITED	ORKAMBI 75 MG/94 MG GRANULES IN SACHET	IVACAFTOR	94	MILLIGRAMS PER DOSE	POM	GB
PLGB 22352/0018	17/03/2023	VERTEX PHARMACEUTICALS (EUROPE) LIMITED	ORKAMBI 75 MG/94 MG GRANULES IN SACHET	LUMACAFTOR	75	MILLIGRAMS PER DOSE	POM	GB
PL 36722/0130	20/03/2023	SPECIAL CONCEPT DEVELOPMENT (UK) LIMITED	SENEASE TWELVE YEARS PLUS 7.5MG/5ML SYRUP	SENNOSIDES	7.5	MILLIGRAMS PER 5 MILLILITRES	P	UK
PLGB 21344/0035	20/03/2023	AOP ORPHAN PHARMACEUTICALS GMBH	SUGAMMADEX AOP 100 MG/ML SOLUTION FOR INJECTION	SUGAMMADEX SODIUM	217.6	MILLIGRAMS	POM	GB
PLGB 29556/0013	20/03/2023	ZAKLADY FARMACEUTYCZNE POLPHARMA SA	DIMETHYL FUMARATE POLPHARMA 120 MG GASTRO-RESISTANT CAPSULES, HARD	DIMETHYL FUMARATE	120	MILLIGRAMS	POM	UK
PLGB 29556/0014	20/03/2023	ZAKLADY FARMACEUTYCZNE POLPHARMA SA	DIMETHYL FUMARATE POLPHARMA 240 MG GASTRO-RESISTANT CAPSULES, HARD	DIMETHYL FUMARATE	240	MILLIGRAMS	POM	UK
PLGB 36390/0379	20/03/2023	CIPLA (EU) LIMITED	BIBECFO 100/6 MICROGRAMS PER ACTUATION PRESSURISED INHALATION SOLUTION	BECLOMETASONE DIPROPIONATE	100.00	MICROGRAMS	POM	UK
PLGB 36390/0379	20/03/2023	CIPLA (EU) LIMITED	BIBECFO 100/6 MICROGRAMS PER ACTUATION PRESSURISED INHALATION SOLUTION	FORMOTEROL FUMARATE DIHYDRATE	6.000	MICROGRAMS	POM	UK
PLGB 36390/0393	20/03/2023	CIPLA (EU) LIMITED	BIBECFO 200/6 MICROGRAMS PER ACTUATION PRESSURISED INHALATION SOLUTION	BECLOMETASONE DIPROPIONATE	200.000	MICROGRAMS PER ACTUATION	POM	GB
PLGB 36390/0393	20/03/2023	CIPLA (EU) LIMITED	BIBECFO 200/6 MICROGRAMS PER ACTUATION PRESSURISED INHALATION SOLUTION	FORMOTEROL FUMARATE DIHYDRATE	6.000	MICROGRAMS PER ACTUATION	POM	GB
PLGB 53835/0034	20/03/2023	CELIX PHARMA LTD	DIMETHYL FUMARATE 120 MG GASTRO-RESISTANT HARD CAPSULES	DIMETHYL FUMARATE	120	MILLIGRAMS	POM	GB
PLGB 53835/0035	20/03/2023	CELIX PHARMA LTD	DIMETHYL FUMARATE 240 MG GASTRO-RESISTANT HARD CAPSULES	DIMETHYL FUMARATE	240	MILLIGRAMS	POM	GB
PL 00142/1291	22/03/2023	ACCORD-UK LIMITED	NEFOPAM HYDROCHLORIDE 30 MG FILM-COATED TABLETS	NEFOPAM HYDROCHLORIDE	30.000	MILLIGRAMS	POM	UK
PL 00142/1292	22/03/2023	ACCORD-UK LIMITED	NEFOPAM HYDROCHLORIDE 60 MG FILM-COATED TABLETS	NEFOPAM HYDROCHLORIDE	60.000	MILLIGRAMS	POM	UK
PLGB 15036/0160	22/03/2023	CSL BEHRING GMBH	HEMGENIX 1 X 10 ¹³ GENOME COPIES/ML CONCENTRATE FOR SOLUTION FOR INFUSION	ETRANACOGENE DEZAPARVOVEC	10000000	GENOME COPIES PER ML	POM	GB
PLGB 15036/0160	22/03/2023	CSL BEHRING GMBH	HEMGENIX 1 X 10 ¹³ GENOME COPIES/ML CONCENTRATE FOR SOLUTION FOR INFUSION	ETRANACOGENE DEZAPARVOVEC	10000000	VIAL(S)	POM	GB
PL 33155/0098	24/03/2023	RIVOPHARM (UK) LIMITED	LORAZEPAM 1MG TABLETS	LORAZEPAM	1	MILLIGRAMS	POM	UK
PL 33155/0099	24/03/2023	RIVOPHARM (UK) LIMITED	LORAZEPAM 2.5MG TABLETS	LORAZEPAM	2.5	MILLIGRAMS	POM	UK
PL 49565/0119	24/03/2023	RUDIPHARM LIMITED	AMLODIPINE 5 MG TABLETS	AMLODIPINE BESILATE	6.935	MILLIGRAMS	POM	UK
PL 49565/0120	24/03/2023	RUDIPHARM LIMITED	AMLODIPINE 10 MG TABLETS	AMLODIPINE BESILATE	13.870	MILLIGRAMS	POM	UK
PL 50805/0024	24/03/2023	MSN LABORATORIES EUROPE LIMITED	PRASUGREL 5MG FILM-COATED TABLETS	PRASUGREL HYDROCHLORIDE	5.490	MILLIGRAMS	POM	UK
PL 50805/0025	24/03/2023	MSN LABORATORIES EUROPE LIMITED	PRASUGREL 10MG FILM-COATED TABLETS	PRASUGREL HYDROCHLORIDE	10.980	MILLIGRAMS	POM	UK
PLGB 00101/1217	27/03/2023	NOVARTIS PHARMACEUTICALS UK LIMITED	TABRECTA 150 MG FILM-COATED TABLETS	CAMPATINIB DIHYDROCHLORIDE MONOHYDRATE	183.000	MILLIGRAMS	POM	UK
PLGB 00101/1218	27/03/2023	NOVARTIS PHARMACEUTICALS UK LIMITED	TABRECTA 200 MG FILM-COATED TABLETS	CAMPATINIB DIHYDROCHLORIDE MONOHYDRATE	244.000	MILLIGRAMS	POM	UK
PLGB 39972/0020	27/03/2023	KORA CORPORATION LIMITED	METAPEREX 400 IU SOFT CAPSULES	ALPHA-TOCOPHEROL RRR-	280	MILLIGRAMS	POM	GB
PLGB 56979/0001	27/03/2023	RADIUS HEALTH (IRELAND) LIMITED	ELADYNOS 80 MICROGRAMS/DOSE SOLUTION FOR INJECTION IN PRE-FILLED PEN	ABALOPARATIDE	80	MICROGRAMS PER MILLILITRE	POM	GB

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PL 08553/0741	29/03/2023	DR REDDY'S LABORATORIES (UK) LIMITED	LUPAXIS 25 MG PROLONGED-RELEASE TABLETS	TAPENTADOL PHOSPHATE	38.285	MILLIGRAMS	POM	UK
PL 08553/0742	29/03/2023	DR REDDY'S LABORATORIES (UK) LIMITED	LUPAXIS 50 MG PROLONGED-RELEASE TABLETS	TAPENTADOL PHOSPHATE	76.57	MILLIGRAMS	POM	UK
PL 08553/0743	29/03/2023	DR REDDY'S LABORATORIES (UK) LIMITED	LUPAXIS 100 MG PROLONGED-RELEASE TABLETS	TAPENTADOL PHOSPHATE	153.139	MILLIGRAMS	POM	UK
PL 08553/0744	29/03/2023	DR REDDY'S LABORATORIES (UK) LIMITED	LUPAXIS 150 MG PROLONGED-RELEASE TABLETS	TAPENTADOL PHOSPHATE	229.709	MILLIGRAMS	POM	UK
PL 08553/0745	29/03/2023	DR REDDY'S LABORATORIES (UK) LIMITED	LUPAXIS 200 MG PROLONGED-RELEASE TABLETS	TAPENTADOL PHOSPHATE	306.279	MILLIGRAMS	POM	UK
PL 08553/0746	29/03/2023	DR REDDY'S LABORATORIES (UK) LIMITED	LUPAXIS 250 MG PROLONGED-RELEASE TABLETS	TAPENTADOL PHOSPHATE	382.848	MILLIGRAMS	POM	UK
PL 17780/1131	29/03/2023	ZENTIVA PHARMA UK LIMITED	ALMOTRIPTAN 12.5MG FILM-COATED TABLETS	ALMOTRIPTAN MALATE	17.50	MILLIGRAMS	POM	UK
PL 24837/0156	29/03/2023	CONSILIENT HEALTH LIMITED	DAPOXETINE 30 MG FILM-COATED TABLETS	DAPOXETINE HYDROCHLORIDE	33.585	MILLIGRAMS	POM	UK
PL 24837/0157	29/03/2023	CONSILIENT HEALTH LIMITED	DAPOXETINE 60 MG FILM-COATED TABLETS	DAPOXETINE HYDROCHLORIDE	67.17	MILLIGRAMS	POM	UK
PL 13606/0263	30/03/2023	STRIDES PHARMA UK LIMITED	IBUPROFEN 200 MG SOFT CAPSULES	IBUPROFEN	200	MILLIGRAMS	GSL	UK
PL 13606/0264	30/03/2023	STRIDES PHARMA UK LIMITED	IBUPROFEN 400 MG SOFT CAPSULES	IBUPROFEN	400	MILLIGRAMS	P	UK