

Marketing authorisations granted 1 June to 14 June 2023

PL Number	Grant Date	MA Holder	Licensed Name(s)	Active Ingredient	Quantity	Units	Legal Status	Territory
PL 21566/0010	01/06/2023	BIAL - PORTELA & CA S.A.	KYNMOBI 10 MG SUBLINGUAL FILM	APOMORPHINE HYDROCHLORIDE HEMIHYDRATE	10.3	MILLIGRAMS	POM	UK
PL 21566/0011	01/06/2023	BIAL - PORTELA & CA S.A.	KYNMOBI 15 MG SUBLINGUAL FILM	APOMORPHINE HYDROCHLORIDE HEMIHYDRATE	15.4	MILLIGRAMS	POM	UK
PL 21566/0012	01/06/2023	BIAL - PORTELA & CA S.A.	KYNMOBI 20 MG SUBLINGUAL FILM	APOMORPHINE HYDROCHLORIDE HEMIHYDRATE	20.6	MILLIGRAMS	POM	UK
PL 21566/0013	01/06/2023	BIAL - PORTELA & CA S.A.	KYNMOBI 25 MG SUBLINGUAL FILM	APOMORPHINE HYDROCHLORIDE HEMIHYDRATE	25.7	MILLIGRAMS	POM	UK
PL 21566/0014	01/06/2023	BIAL - PORTELA & CA S.A.	KYNMOBI 30 MG SUBLINGUAL FILM	APOMORPHINE HYDROCHLORIDE HEMIHYDRATE	30.9	MILLIGRAMS	POM	UK
PL 21566/0015	01/06/2023	BIAL - PORTELA & CA S.A.	TREATMENT INITIATION PACK - KYNMOBI 10/15/20/25/30 MG SUBLINGUAL FILM	APOMORPHINE HYDROCHLORIDE HEMIHYDRATE	10.3	MILLIGRAMS	POM	UK
PL 21566/0015	01/06/2023	BIAL - PORTELA & CA S.A.	TREATMENT INITIATION PACK - KYNMOBI 10/15/20/25/30 MG SUBLINGUAL FILM	APOMORPHINE HYDROCHLORIDE HEMIHYDRATE	15.4	MILLIGRAMS	POM	UK
PL 21566/0015	01/06/2023	BIAL - PORTELA & CA S.A.	TREATMENT INITIATION PACK - KYNMOBI 10/15/20/25/30 MG SUBLINGUAL FILM	APOMORPHINE HYDROCHLORIDE HEMIHYDRATE	20.6	MILLIGRAMS	POM	UK
PL 21566/0015	01/06/2023	BIAL - PORTELA & CA S.A.	TREATMENT INITIATION PACK - KYNMOBI 10/15/20/25/30 MG SUBLINGUAL FILM	APOMORPHINE HYDROCHLORIDE HEMIHYDRATE	25.7	MILLIGRAMS	POM	UK
PL 21566/0015	01/06/2023	BIAL - PORTELA & CA S.A.	TREATMENT INITIATION PACK - KYNMOBI 10/15/20/25/30 MG SUBLINGUAL FILM	APOMORPHINE HYDROCHLORIDE HEMIHYDRATE	30.9	MILLIGRAMS	POM	UK
PL 47848/0042	01/06/2023	AXUNIO PHARMA GMBH	LUNIVIA 1 MG FILM-COATED TABLETS	ESZOPICLONE	1	MILLIGRAMS	POM	UK
PL 47848/0043	01/06/2023	AXUNIO PHARMA GMBH	LUNIVIA 2 MG FILM-COATED TABLETS	ESZOPICLONE	2	MILLIGRAMS	POM	UK
PL 47848/0044	01/06/2023	AXUNIO PHARMA GMBH	LUNIVIA 3 MG FILM-COATED TABLETS	ESZOPICLONE	3	MILLIGRAMS	POM	UK
PL 18945/0007	02/06/2023	FAES FARMA SA	DOMNISOL 266 MICROGRAMS SOFT CAPSULES	CALCIFEDIOL MONOHYDRATE	0.266	MILLIGRAMS	POM	UK
PL 46579/0008	05/06/2023	APC INSTYTUT SP. Z O.O.	BELNFREM 1.5 MG FILM-COATED TABLETS	CYTISINCLINE	1.50	MILLIGRAMS	POM	UK
PL 15764/0133	06/06/2023	STRANDHAVEN LIMITED	TRAZODONE HYDROCHLORIDE 150MG FILM-COATED TABLETS	TRAZODONE HYDROCHLORIDE	150	MILLIGRAMS	POM	UK
PL 21727/0100	06/06/2023	GRUNENTHAL LIMITED	PONSIC 1000 MG/4 ML SOLUTION FOR INJECTION	TESTOSTERONE UNDECANOATE	1000	MILLIGRAMS	POM	UK
PLGB 17901/0368	06/06/2023	ASTRAZENECA UK LIMITED	IMJUDO 20 MG/ML CONCENTRATE FOR SOLUTION FOR INFUSION	TREMELIMUMAB	20	MILLIGRAMS PER MILLILITRE	POM	GB
PL 16363/0682	08/06/2023	MILPHARM LIMITED	TRIMIPRAMINE 50MG CAPSULES, HARD	TRIMIPRAMINE MALEATE	69.7100	MILLIGRAMS	POM	UK
PLGB 17901/0372	09/06/2023	ASTRAZENECA UK LIMITED	TEZSPIRE 210 MG SOLUTION FOR INJECTION IN PRE-FILLED PEN	TEZPELUMAB	210	MILLIGRAMS	POM	GB
PL 40546/0232	12/06/2023	ARISTO PHARMA GMBH	PRUCALOPRIDE 1 MG FILM-COATED TABLETS	PRUCALOPRIDE SUCCINATE	1.321	MILLIGRAMS	POM	UK
PL 40546/0233	12/06/2023	ARISTO PHARMA GMBH	PRUCALOPRIDE 2 MG FILM-COATED TABLETS	PRUCALOPRIDE SUCCINATE	2.642	MILLIGRAMS	POM	UK
PLGB 00101/1210	12/06/2023	NOVARTIS PHARMACEUTICALS UK LIMITED	MAYZENT 1 MG FILM-COATED TABLETS	SIPONIMOD FUMARIC ACID	1.112	MILLIGRAMS	POM	GB
PL 24837/0129	13/06/2023	CONSILIENT HEALTH LIMITED	ELETRIPTAN 20 MG FILM-COATED TABLETS	ELETRIPTAN HYDROBROMIDE	24.230	MILLIGRAMS	POM	UK
PL 24837/0130	13/06/2023	CONSILIENT HEALTH LIMITED	ELETRIPTAN 40 MG FILM-COATED TABLETS	ELETRIPTAN HYDROBROMIDE	48.460	MILLIGRAMS	POM	UK
PL 35533/0184	14/06/2023	ASPIRE PHARMA LIMITED	CO-TRIMOXAZOLE 16MG/80MG PER ML SOLUTION FOR INFUSION	SULFAMETHOXAZOLE	80	MILLIGRAMS PER MILLILITRE	POM	UK
PL 35533/0184	14/06/2023	ASPIRE PHARMA LIMITED	CO-TRIMOXAZOLE 16MG/80MG PER ML SOLUTION FOR INFUSION	TRIMETHOPRIM	16	MILLIGRAMS PER MILLILITRE	POM	UK
PL 46447/0038	14/06/2023	JCSH PHARMA LIMITED	PREGABALIN JCSH 25 MG HARD CAPSULES	PREGABALIN	25.0	MILLIGRAMS	POM	UK
PL 46447/0039	14/06/2023	JCSH PHARMA LIMITED	PREGABALIN JCSH 50 MG HARD CAPSULES	PREGABALIN	50.0	MILLIGRAMS	POM	UK
PL 46447/0040	14/06/2023	JCSH PHARMA LIMITED	PREGABALIN JCSH 75 MG HARD CAPSULES	PREGABALIN	75.0	MILLIGRAMS	POM	UK
PL 46447/0041	14/06/2023	JCSH PHARMA LIMITED	PREGABALIN JCSH 100 MG HARD CAPSULES	PREGABALIN	100.0	MILLIGRAMS	POM	UK
PL 46447/0042	14/06/2023	JCSH PHARMA LIMITED	PREGABALIN JCSH 150 MG HARD CAPSULES	PREGABALIN	150.0	MILLIGRAMS	POM	UK
PL 46447/0043	14/06/2023	JCSH PHARMA LIMITED	PREGABALIN JCSH 300 MG HARD CAPSULES	PREGABALIN	300.0	MILLIGRAMS	POM	UK
PLGB 17901/0369	14/06/2023	ASTRAZENECA UK LIMITED	CALQUENCE 100 MG FILM-COATED TABLETS	ACALABRUTINIB MALEATE	129.0	MILLIGRAMS	POM	GB