

## Marketing authorisations granted in June 2019

PL Number	Grant Date	MA Holder	Licensed Name(s)	Active Ingredient	Quantity	Units	Legal Status
PL 41344/0051	04/06/2019	COLONIS PHARMA LIMITED	NORTRIPTYLINE COLONIS 10MG/ 5ML ORAL SOLUTION	NORTRIPTYLINE HYDROCHLORIDE	2.28	MILLIGRAMS	POM
PL 41344/0052	04/06/2019	COLONIS PHARMA LIMITED	NORTRIPTYLINE COLONIS 25MG/ 5ML ORAL SOLUTION	NORTRIPTYLINE HYDROCHLORIDE	5.70	MILLIGRAMS	POM
PL 00240/0417	05/06/2019	THORNTON & ROSS LIMITED	CARE DIARRHOEA RELIEF 2 MG ORODISPERSIBLE TABLET	LOPERAMIDE HYDROCHLORIDE	2	MILLIGRAMS	GSL
PL 39307/0090	06/06/2019	SYRI LIMITED	BACLOFEN 10MG/5ML ORAL SOLUTION	BACLOFEN	10.00	MILLIGRAMS PER MILLILITRE	POM
PL 08553/0624	07/06/2019	DR REDDY'S LABORATORIES (UK) LIMITED	OXYCODONE HYDROCHLORIDE 10 MG/ML SOLUTION FOR INJECTION/INFUSION	OXYCODONE HYDROCHLORIDE	10	MILLIGRAMS PER MILLILITRE	POM
PL 08553/0625	07/06/2019	DR REDDY'S LABORATORIES (UK) LIMITED	OXYCODONE HYDROCHLORIDE 50 MG/ML SOLUTION FOR INJECTION/INFUSION	OXYCODONE HYDROCHLORIDE	50	MILLIGRAMS PER MILLILITRE	POM
PL 47848/0002	07/06/2019	AXUNIO PHARMA GMBH	METFORMIN AXUNIO 500MG FILM-COATED TABLETS	METFORMIN HYDROCHLORIDE	500.00	MILLIGRAMS	POM
PL 47848/0004	07/06/2019	AXUNIO PHARMA GMBH	METFORMIN AXUNIO 1000MG FILM-COATED TABLETS	METFORMIN HYDROCHLORIDE	1000.00	MILLIGRAMS	POM
PL 47848/0013	07/06/2019	AXUNIO PHARMA GMBH	DARUNAVIR AXUNIO 400 MG FILM-COATED TABLETS	DARUNAVIR	400	MILLIGRAMS	POM
PL 47848/0014	07/06/2019	AXUNIO PHARMA GMBH	DARUNAVIR AXUNIO 600 MG FILM-COATED TABLETS	DARUNAVIR	600	MILLIGRAMS	POM
PL 47848/0015	07/06/2019	AXUNIO PHARMA GMBH	DARUNAVIR AXUNIO 800 MG FILM-COATED TABLETS	DARUNAVIR	800	MILLIGRAMS	POM
PL 41344/0050	10/06/2019	COLONIS PHARMA LIMITED	MELATONIN 1MG/ML ORAL SOLUTION	MELATONIN	1.00	MILLIGRAMS	POM
PL 49565/0013	10/06/2019	NORTH STAR HEALTHCARE LIMITED	PHENOXYMETHYLPENICILLIN POTASSIUM TABLETS 250MG	PHENOXYMETHYLPENICILLIN POTASSIUM	280.000	MILLIGRAMS	POM
PL 06831/0307	11/06/2019	GENUS PHARMACEUTICALS LIMITED	FULVESTRANT 250 MG SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE	FULVESTRANT	250	MILLIGRAMS PER 5 MILLILITRES	POM
PL 42176/0009	11/06/2019	LUCIS PHARMA LIMITED	CARBOCISTEINE 250 MG/5ML SUGAR FREE SYRUP	CARBOCISTEINE	250	MILLIGRAMS PER 5 MILLILITRES	POM
PL 46447/0015	11/06/2019	JCSH PHARMA LIMITED	TRAMADOL HYDROCHLORIDE AND PARACETAMOL 37.5 MG/325 MG FILM-COATED TABLETS	PARACETAMOL	325	MILLIGRAMS	POM
PL 46447/0015	11/06/2019	JCSH PHARMA LIMITED	TRAMADOL HYDROCHLORIDE AND PARACETAMOL 37.5 MG/325 MG FILM-COATED TABLETS	TRAMADOL HYDROCHLORIDE	37.5	MILLIGRAMS	POM
PL 24780/0022	12/06/2019	VILLERTON INVEST SA	ERTAPENEM VILLERTON 1 G POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION	ERTAPENEM SODIUM	1.046	GRAMS	POM
PL 16363/0559	17/06/2019	MILPHARM LIMITED	ARIPIRAZOLE 1 MG/ML ORAL SOLUTION	ARIPIRAZOLE	1.00	MILLIGRAMS PER MILLILITRE	POM
PL 20240/0012	18/06/2019	INTERDOS PHARMA BV	SILDENAFIL INTERDOS 50 MG FILM-COATED TABLETS	SILDENAFIL CITRATE	70.24	MILLIGRAMS	POM
PL 20240/0013	18/06/2019	INTERDOS PHARMA BV	SILDENAFIL INTERDOS 100 MG FILM-COATED TABLETS	SILDENAFIL CITRATE	140.48	MILLIGRAMS	POM
PL 34088/0054	18/06/2019	ALKALOID-INT DOO	METHADONE ALKALOID 1 MG/ML ORAL SOLUTION	METHADONE HYDROCHLORIDE	1.000	MILLIGRAMS PER MILLILITRE	POM
PL 46973/0001	18/06/2019	NAARI BV	LEVONORGESTREL 1.5 MG TABLET	LEVONORGESTREL	1.5	MILLIGRAMS	P
PL 04416/1577	19/06/2019	SANDOZ LIMITED	ALMURIVA 13.3/24H TRANSDERMAL PATCH	RIVASTIGMINE	1.8	MILLIGRAMS PER SQUARE CENT	POM
PL 13931/0130	19/06/2019	CHANELLE MEDICAL	LBUPROFEN 200 MG SOFT CAPSULES	IBUPROFEN LYSINE	342	MILLIGRAMS	GSL
PL 13931/0131	19/06/2019	CHANELLE MEDICAL	LBUPROFEN 400 MG SOFT CAPSULES	IBUPROFEN LYSINE	684	MILLIGRAMS	P
PL 28278/0046	20/06/2019	IPCA LABORATORIES UK LIMITED	LOPERAMIDE HYDROCHLORIDE 2MG CAPSULES, HARD	LOPERAMIDE HYDROCHLORIDE	2.0	MILLIGRAMS	POM
PL 14434/0042	21/06/2019	LABORATOIRE AGUETTANT	METARAMINOL 0.5 MG/ML, SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE	METARAMINOL TARTRATE	0.5	MILLIGRAMS PER MILLILITRE	POM
PL 47991/0001	21/06/2019	SEQIRUS UK LIMITED	ADJUVANTED TRIVALENT INFLUENZA VACCINE SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	A/MICHIGAN/45/2015 (H1N1) PDM09-LIKE STRAIN (A/SINGAPORE/GP1908/2015, IVR-180A)	15.0	MICROGRAMS	POM
PL 47991/0001	21/06/2019	SEQIRUS UK LIMITED	ADJUVANTED TRIVALENT INFLUENZA VACCINE SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	A/SINGAPORE/INF1MH-16-0019/2016 (H3 2) - LIKE STRAIN (A/SINGAPORE/INF1MH-16-0019/2016, IVR-186)	15.0	MICROGRAMS	POM
PL 47991/0001	21/06/2019	SEQIRUS UK LIMITED	ADJUVANTED TRIVALENT INFLUENZA VACCINE SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	B/COLORADO/06/2017 - LIKE STRAIN (B/MARYLAND/15/2016, WILD TYPE)	15.0	MICROGRAMS	POM
PL 47991/0001	21/06/2019	SEQIRUS UK LIMITED	ADJUVANTED TRIVALENT INFLUENZA VACCINE SUSPENSION FOR INJECTION IN PRE-FILLED SYRINGE	INFLUENZA VIRUS STRAINS INACTIVATED	0.0	MICROGRAMS	POM

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PL 20416/0667	26/06/2019	CRESCENT PHARMA LIMITED	AMBELINA 0.15 MG / 0.03 MG FILM-COATED TABLETS	ETHINYLESTRADIOL	0.03	MILLIGRAMS	POM
PL 20416/0667	26/06/2019	CRESCENT PHARMA LIMITED	AMBELINA 0.15 MG / 0.03 MG FILM-COATED TABLETS	LEVONORGESTREL	0.15	MILLIGRAMS	POM
PL 43021/0004	27/06/2019	CREATIVE PHARMA SOLUTIONS SRO	FEXARELL 120 MG FILM-COATED TABLETS	FEXOFENADINE HYDROCHLORIDE	120	MILLIGRAMS	POM
PL 16363/0560	28/06/2019	MILPHARM LIMITED	FEBUXOSTAT MILPHARM 80MG FILM-COATED TABLETS	FEBUXOSTAT HEMIHYDRATE	80.00	MILLIGRAMS	POM
PL 16363/0561	28/06/2019	MILPHARM LIMITED	FEBUXOSTAT MILPHARM 120MG FILM-COATED TABLETS	FEBUXOSTAT HEMIHYDRATE	120.00	MILLIGRAMS	POM