

Marketing authorisations granted in November 2018

PL Number	Grant Date	MA Holder	Licensed Name(s)	Active Ingredient	Quantity	Units	Legal Status
PL 00289/2204	01/11/2018	TEVA UK LIMITED	VARDENAFIL 5MG FILM-COATED TABLETS	VARDENAFIL HYDROCHLORIDE TRIHYDRATE	5.926	MILLIGRAMMES	POM
PL 00289/2205	01/11/2018	TEVA UK LIMITED	VARDENAFIL 10MG FILM-COATED TABLETS	VARDENAFIL HYDROCHLORIDE TRIHYDRATE	11.853	MILLIGRAMMES	POM
PL 00289/2206	01/11/2018	TEVA UK LIMITED	VARDENAFIL 20MG FILM-COATED TABLETS	VARDENAFIL HYDROCHLORIDE TRIHYDRATE	23.705	MILLIGRAMMES	POM
PL 01656/0264	01/11/2018	KRKA DD NOVO MESTO	TRAMADOL HYDROCHLORIDE KRKA 100 MG PROLONGED-RELEASE TABLETS	TRAMADOL HYDROCHLORIDE	100	MILLIGRAMMES	POM
PL 01656/0265	01/11/2018	KRKA DD NOVO MESTO	TRAMADOL HYDROCHLORIDE KRKA 150 MG PROLONGED-RELEASE TABLETS	TRAMADOL HYDROCHLORIDE	150	MILLIGRAMMES	POM
PL 01656/0266	01/11/2018	KRKA DD NOVO MESTO	TRAMADOL HYDROCHLORIDE KRKA 200 MG PROLONGED-RELEASE TABLETS	TRAMADOL HYDROCHLORIDE	200	MILLIGRAMMES	POM
PL 04854/0159	02/11/2018	GEDEON RICHTER PLC	LEVONORGESTREL RICHTER 20MICROG./24H INTRAUTERINE DELIVERY SYSTEM	LEVONORGESTREL	52.00	MILLIGRAMMES	POM
PL 34088/0050	07/11/2018	ALKALOID-INT DOO	ROPUIDO 5 MG FILM-COATED TABLETS	ROSUVASTATIN CALCIUM	5.210	MILLIGRAMMES	POM
PL 34088/0051	07/11/2018	ALKALOID-INT DOO	ROPUIDO 10 MG FILM-COATED TABLETS	ROSUVASTATIN CALCIUM	10.42	MILLIGRAMMES	POM
PL 34088/0052	07/11/2018	ALKALOID-INT DOO	ROPUIDO 20 MG FILM-COATED TABLETS	ROSUVASTATIN CALCIUM	20.84	MILLIGRAMMES	POM
PL 34088/0053	07/11/2018	ALKALOID-INT DOO	ROPUIDO 40 MG FILM-COATED TABLETS	ROSUVASTATIN CALCIUM	41.68	MILLIGRAMMES	POM
PL 46302/0060	07/11/2018	MYLAN PRODUCTS LIMITED	TWICOR 10 MG/10 MG FILM-COATED TABLETS	EZETIMIBE	10.00	MILLIGRAMMES	POM
PL 46302/0060	07/11/2018	MYLAN PRODUCTS LIMITED	TWICOR 10 MG/10 MG FILM-COATED TABLETS	ROSUVASTATIN CALCIUM	10.42	MILLIGRAMMES	POM
PL 46302/0061	07/11/2018	MYLAN PRODUCTS LIMITED	TWICOR 20 MG/10 MG FILM-COATED TABLETS	EZETIMIBE	10.00	MILLIGRAMMES	POM
PL 46302/0061	07/11/2018	MYLAN PRODUCTS LIMITED	TWICOR 20 MG/10 MG FILM-COATED TABLETS	ROSUVASTATIN CALCIUM	20.84	MILLIGRAMMES	POM
PL 24598/0052	08/11/2018	NORIDEM ENTERPRISES LIMITED	METRONIDAZOLE 500MG/100ML SOLUTION FOR INFUSION	METRONIDAZOLE	5	MILLIGRAMMES PER MILLILITRE	POM
PL 00289/2227	09/11/2018	TEVA UK LIMITED	DICYCLOVERINE HYDROCHLORIDE 10 MG/5 ML ORAL SOLUTION	DICYCLOVERINE HYDROCHLORIDE	2	MILLIGRAMMES PER MILLILITRE	POM
PL 08828/0274	09/11/2018	FRESENIUS KABI LIMITED	SMOFKABIVEN LOW OSMO PERIPHERAL, EMULSION FOR INFUSION	ALANINE	14.0	GRAMMES	POM
PL 08828/0274	09/11/2018	FRESENIUS KABI LIMITED	SMOFKABIVEN LOW OSMO PERIPHERAL, EMULSION FOR INFUSION	ARGININE	12.0	GRAMMES	POM
PL 08828/0274	09/11/2018	FRESENIUS KABI LIMITED	SMOFKABIVEN LOW OSMO PERIPHERAL, EMULSION FOR INFUSION	CALCIUM CHLORIDE DIHYDRATE	0.74	GRAMMES	POM
PL 08828/0274	09/11/2018	FRESENIUS KABI LIMITED	SMOFKABIVEN LOW OSMO PERIPHERAL, EMULSION FOR INFUSION	GLUCOSE MONOHYDRATE	130	GRAMMES	POM
PL 08828/0274	09/11/2018	FRESENIUS KABI LIMITED	SMOFKABIVEN LOW OSMO PERIPHERAL, EMULSION FOR INFUSION	GLYCINE	11.0	GRAMMES	POM
PL 08828/0274	09/11/2018	FRESENIUS KABI LIMITED	SMOFKABIVEN LOW OSMO PERIPHERAL, EMULSION FOR INFUSION	HISTIDINE	3.0	GRAMMES	POM
PL 08828/0274	09/11/2018	FRESENIUS KABI LIMITED	SMOFKABIVEN LOW OSMO PERIPHERAL, EMULSION FOR INFUSION	ISOLEUCINE	5.0	GRAMMES	POM
PL 08828/0274	09/11/2018	FRESENIUS KABI LIMITED	SMOFKABIVEN LOW OSMO PERIPHERAL, EMULSION FOR INFUSION	LEUCINE	7.4	GRAMMES	POM
PL 08828/0274	09/11/2018	FRESENIUS KABI LIMITED	SMOFKABIVEN LOW OSMO PERIPHERAL, EMULSION FOR INFUSION	LYSINE ACETATE	9.3	GRAMMES	POM
PL 08828/0274	09/11/2018	FRESENIUS KABI LIMITED	SMOFKABIVEN LOW OSMO PERIPHERAL, EMULSION FOR INFUSION	MAGNESIUM SULFATE HEPTAHYDRATE	2.47	GRAMMES	POM
PL 08828/0274	09/11/2018	FRESENIUS KABI LIMITED	SMOFKABIVEN LOW OSMO PERIPHERAL, EMULSION FOR INFUSION	MEDIUM CHAIN TRIGLYCERIDES	60	GRAMMES	POM
PL 08828/0274	09/11/2018	FRESENIUS KABI LIMITED	SMOFKABIVEN LOW OSMO PERIPHERAL, EMULSION FOR INFUSION	METHIONINE	4.3	GRAMMES	POM
PL 08828/0274	09/11/2018	FRESENIUS KABI LIMITED	SMOFKABIVEN LOW OSMO PERIPHERAL, EMULSION FOR INFUSION	OLIVE OIL REFINED	50	GRAMMES	POM
PL 08828/0274	09/11/2018	FRESENIUS KABI LIMITED	SMOFKABIVEN LOW OSMO PERIPHERAL, EMULSION FOR INFUSION	OMEGA-3 FISH OIL	30	GRAMMES	POM

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PL 08828/0274	09/11/2018	FRESENIUS KABI LIMITED	SMOFKABIVEN LOW OSMO PERIPHERAL, EMULSION FOR INFUSION	PHENYLALANINE	5.1	GRAMMES	POM
PL 08828/0274	09/11/2018	FRESENIUS KABI LIMITED	SMOFKABIVEN LOW OSMO PERIPHERAL, EMULSION FOR INFUSION	POTASSIUM CHLORIDE	4.48	GRAMMES	POM
PL 08828/0274	09/11/2018	FRESENIUS KABI LIMITED	SMOFKABIVEN LOW OSMO PERIPHERAL, EMULSION FOR INFUSION	PROLINE	11.2	GRAMMES	POM
PL 08828/0274	09/11/2018	FRESENIUS KABI LIMITED	SMOFKABIVEN LOW OSMO PERIPHERAL, EMULSION FOR INFUSION	SERINE	6.5	GRAMMES	POM
PL 08828/0274	09/11/2018	FRESENIUS KABI LIMITED	SMOFKABIVEN LOW OSMO PERIPHERAL, EMULSION FOR INFUSION	SODIUM ACETATE TRIHYDRATE	5.62	GRAMMES	POM
PL 08828/0274	09/11/2018	FRESENIUS KABI LIMITED	SMOFKABIVEN LOW OSMO PERIPHERAL, EMULSION FOR INFUSION	SODIUM GLYCEROPHOSPHATE HYDRATE	4.18	GRAMMES	POM
PL 08828/0274	09/11/2018	FRESENIUS KABI LIMITED	SMOFKABIVEN LOW OSMO PERIPHERAL, EMULSION FOR INFUSION	SOYA-BEAN OIL REFINED	60	GRAMMES	POM
PL 08828/0274	09/11/2018	FRESENIUS KABI LIMITED	SMOFKABIVEN LOW OSMO PERIPHERAL, EMULSION FOR INFUSION	TAURINE	1.0	GRAMMES	POM
PL 08828/0274	09/11/2018	FRESENIUS KABI LIMITED	SMOFKABIVEN LOW OSMO PERIPHERAL, EMULSION FOR INFUSION	THREONINE	4.4	GRAMMES	POM
PL 08828/0274	09/11/2018	FRESENIUS KABI LIMITED	SMOFKABIVEN LOW OSMO PERIPHERAL, EMULSION FOR INFUSION	TRYPTOPHAN	2.0	GRAMMES	POM
PL 08828/0274	09/11/2018	FRESENIUS KABI LIMITED	SMOFKABIVEN LOW OSMO PERIPHERAL, EMULSION FOR INFUSION	TYROSINE	0.40	GRAMMES	POM
PL 08828/0274	09/11/2018	FRESENIUS KABI LIMITED	SMOFKABIVEN LOW OSMO PERIPHERAL, EMULSION FOR INFUSION	VALINE	6.2	GRAMMES	POM
PL 08828/0274	09/11/2018	FRESENIUS KABI LIMITED	SMOFKABIVEN LOW OSMO PERIPHERAL, EMULSION FOR INFUSION	ZINC SULPHATE HEPTAHYDRATE	0.023	GRAMMES	POM
PL 23218/0167	09/11/2018	LABORATORIOS LICONSA SA	FEBUXOSTAT 80 MG FILM-COATED TABLETS	FEBUXOSTAT HEMIHYDRATE	80	MILLIGRAMMES	POM
PL 23218/0168	09/11/2018	LABORATORIOS LICONSA SA	FEBUXOSTAT 120 MG FILM-COATED TABLETS	FEBUXOSTAT HEMIHYDRATE	120	MILLIGRAMMES	POM
PL 25258/0282	09/11/2018	GLENMARK PHARMACEUTICALS EUROPE LIMITED	ZOLMITRIPTAN 2.5 MG FILM-COATED TABLETS	ZOLMITRIPTAN	2.50	MILLIGRAMMES	POM
PL 20075/1173	13/11/2018	ACCORD HEALTHCARE LIMITED	ATOMOXETINE ACCORD, 10MG HARD CAPSULES	ATOMOXETINE HYDROCHLORIDE	11.4278	MILLIGRAMMES	POM
PL 20075/1174	13/11/2018	ACCORD HEALTHCARE LIMITED	ATOMOXETINE ACCORD, 18MG HARD CAPSULES	ATOMOXETINE HYDROCHLORIDE	20.5700	MILLIGRAMMES	POM
PL 20075/1175	13/11/2018	ACCORD HEALTHCARE LIMITED	ATOMOXETINE ACCORD, 25MG HARD CAPSULES	ATOMOXETINE HYDROCHLORIDE	28.5695	MILLIGRAMMES	POM
PL 20075/1176	13/11/2018	ACCORD HEALTHCARE LIMITED	ATOMOXETINE ACCORD, 40MG HARD CAPSULES	ATOMOXETINE HYDROCHLORIDE	45.7111	MILLIGRAMMES	POM
PL 20075/1177	13/11/2018	ACCORD HEALTHCARE LIMITED	ATOMOXETINE ACCORD, 60MG HARD CAPSULES	ATOMOXETINE HYDROCHLORIDE	68.5667	MILLIGRAMMES	POM
PL 20075/1178	13/11/2018	ACCORD HEALTHCARE LIMITED	ATOMOXETINE ACCORD, 80MG HARD CAPSULES	ATOMOXETINE HYDROCHLORIDE	91.4223	MILLIGRAMMES	POM
PL 20075/1179	13/11/2018	ACCORD HEALTHCARE LIMITED	ATOMOXETINE ACCORD, 100MG HARD CAPSULES	ATOMOXETINE HYDROCHLORIDE	114.2779	MILLIGRAMMES	POM
PL 12032/0023	14/11/2018	BRACCO IMAGING SPA	IOMERON 300, SOLUTION FOR INJECTION, MULTI-DOSE CONTAINER	IOMEPROL	612.4	MILLIGRAMMES PER MILLILITRE	POM
PL 12032/0024	14/11/2018	BRACCO IMAGING SPA	IOMERON 350, SOLUTION FOR INJECTION, MULTI-DOSE CONTAINER	IOMEPROL	714.4	MILLIGRAMMES PER MILLILITRE	POM
PL 12032/0025	14/11/2018	BRACCO IMAGING SPA	IOMERON 400, SOLUTION FOR INJECTION, MULTI-DOSE CONTAINER	IOMEPROL	816.5	MILLIGRAMMES PER MILLILITRE	POM
PL 39352/0436	14/11/2018	KOSEI PHARMA UK LIMITED	FEBUXOSTAT 80MG FILM-COATED TABLETS	FEBUXOSTAT HEMIHYDRATE	80	MILLIGRAMMES	POM
PL 39352/0437	14/11/2018	KOSEI PHARMA UK LIMITED	FEBUXOSTAT 120 MG FILM-COATED TABLETS	FEBUXOSTAT HEMIHYDRATE	120	MILLIGRAMMES	POM
PL 00173/0410	16/11/2018	DIOMED DEVELOPMENTS LIMITED	DIOMED HAEMORRHOIDS CUTANEOUS SPRAY	HYDROCORTISONE	0.2	PERCENT WEIGHT IN WEIGHT	P
PL 00173/0410	16/11/2018	DIOMED DEVELOPMENTS LIMITED	DIOMED HAEMORRHOIDS CUTANEOUS SPRAY	LIDOCAINE HYDROCHLORIDE	1.0	PERCENT WEIGHT IN WEIGHT	P
PL 20117/0299	16/11/2018	MORNINGSIDE HEALTHCARE LIMITED	AMANTADINE HYDROCHLORIDE 100MG CAPSULES	AMANTADINE HYDROCHLORIDE	100.00	MILLIGRAMMES	POM

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PL 34771/0233	16/11/2018	MACLEODS PHARMA UK LIMITED	PYRAZINAMIDE 500 MG TABLETS	PYRAZINAMIDE	500.00	MILLIGRAMMES	POM
PL 37222/0048	16/11/2018	HETERO EUROPE SL	VALGANCICLOVIR 450 MG FILM-COATED TABLETS	VALGANCICLOVIR HYDROCHLORIDE	496.3	MILLIGRAMMES	POM
PL 21344/0023	19/11/2018	AOP ORPHAN PHARMACEUTICALS AG	ANAGRELIDE AOP 0.5 MG HARD CAPSULES	ANAGRELIDE HYDROCHLORIDE	0.6	MILLIGRAMMES	POM
PL 31750/0118	21/11/2018	SUN PHARMACEUTICAL INDUSTRIES EUROPE BV	ABACAVIR/LAMIVUDINE SUN 600 MG/300 MG FILM-COATED TABLETS	ABACAVIR SULFATE	702.78	MILLIGRAMMES	POM
PL 31750/0118	21/11/2018	SUN PHARMACEUTICAL INDUSTRIES EUROPE BV	ABACAVIR/LAMIVUDINE SUN 600 MG/300 MG FILM-COATED TABLETS	LAMIVUDINE	300	MILLIGRAMMES	POM
PL 36722/0059	22/11/2018	SPECIAL CONCEPT DEVELOPMENT (UK) LIMITED	PROCYCLIDINE 5MG TABLETS	PROCYCLIDINE HYDROCHLORIDE	5.00	MILLIGRAMMES	POM
PL 00551/0236	23/11/2018	TYPHARM LIMITED	DOCUSATE SODIUM ADULT 50MG/5ML ORAL SOLUTION	DOCUSATE SODIUM	10	MILLIGRAMMES PER MILLILITRE	P
PL 00551/0237	23/11/2018	TYPHARM LIMITED	DOCUSATE SODIUM PAEDIATRIC 12.5MG/5ML ORAL SOLUTION	DOCUSATE SODIUM	2.5	MILLIGRAMMES PER MILLILITRE	P
PL 20075/0539	26/11/2018	ACCORD HEALTHCARE LIMITED	ANIDULAFUNGIN 100 MG POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION	ANIDULAFUNGIN	100	MILLIGRAMMES	POM
PL 48468/0001	26/11/2018	VIVALABS EUROPE LIMITED	ACRIVASTINE 8 MG CAPSULES, HARD	ACRIVASTINE	8.00	MILLIGRAMMES	P
PL 48468/0002	26/11/2018	VIVALABS EUROPE LIMITED	BROWN & BURK ALLERGY RELIEF 8MG CAPSULES, HARD	ACRIVASTINE	8	MILLIGRAMMES	GSL
PL 11243/0025	27/11/2018	MEDICE ARZNEIMITTEL PUTTER GMBH & CO KG	ATOMOXETINE 10MG FILM-COATED TABLETS	ATOMOXETINE HYDROCHLORIDE	11.43	MILLIGRAMMES	POM
PL 11243/0026	27/11/2018	MEDICE ARZNEIMITTEL PUTTER GMBH & CO KG	ATOMOXETINE 18MG FILM-COATED TABLETS	ATOMOXETINE HYDROCHLORIDE	20.57	MILLIGRAMMES	POM
PL 11243/0027	27/11/2018	MEDICE ARZNEIMITTEL PUTTER GMBH & CO KG	ATOMOXETINE 25MG FILM-COATED TABLETS	ATOMOXETINE HYDROCHLORIDE	28.57	MILLIGRAMMES	POM
PL 11243/0028	27/11/2018	MEDICE ARZNEIMITTEL PUTTER GMBH & CO KG	ATOMOXETINE 40MG FILM-COATED TABLETS	ATOMOXETINE HYDROCHLORIDE	45.71	MILLIGRAMMES	POM
PL 11243/0029	27/11/2018	MEDICE ARZNEIMITTEL PUTTER GMBH & CO KG	ATOMOXETINE 60MG FILM-COATED TABLETS	ATOMOXETINE HYDROCHLORIDE	68.56	MILLIGRAMMES	POM
PL 11243/0030	27/11/2018	MEDICE ARZNEIMITTEL PUTTER GMBH & CO KG	ATOMOXETINE 80MG FILM-COATED TABLETS	ATOMOXETINE HYDROCHLORIDE	91.42	MILLIGRAMMES	POM
PL 11243/0031	27/11/2018	MEDICE ARZNEIMITTEL PUTTER GMBH & CO KG	ATOMOXETINE 100MG FILM-COATED TABLETS	ATOMOXETINE HYDROCHLORIDE	114.30	MILLIGRAMMES	POM
PL 31750/0115	27/11/2018	SUN PHARMACEUTICAL INDUSTRIES EUROPE BV	ESOMEPRAZOLE 20 MG GASTRO-RESISTANT CAPSULES, HARD	ESOMEPRAZOLE MAGNESIUM AMORPHOUS	22.25	MILLIGRAMMES	POM
PL 31750/0116	27/11/2018	SUN PHARMACEUTICAL INDUSTRIES EUROPE BV	ESOMEPRAZOLE 40 MG GASTRO-RESISTANT CAPSULES, HARD	ESOMEPRAZOLE MAGNESIUM AMORPHOUS	44.50	MILLIGRAMMES	POM
PL 42765/0001	28/11/2018	RENATA (UK) LIMITED	PROPYLTHIOURACIL 50MG TABLETS	PROPYLTHIOURACIL	50.00	MILLIGRAMMES	POM
PL 20117/0317	29/11/2018	MORNINGSIDE HEALTHCARE LIMITED	HYDROXYZINE HYDROCHLORIDE 10 MG FILM-COATED TABLETS	HYDROXYZINE HYDROCHLORIDE	10	MILLIGRAMMES	POM
PL 20117/0318	29/11/2018	MORNINGSIDE HEALTHCARE LIMITED	HYDROXYZINE HYDROCHLORIDE 25 MG FILM-COATED TABLETS	HYDROXYZINE HYDROCHLORIDE	25	MILLIGRAMMES	POM
PL 31603/0022	29/11/2018	APOLLO GENERICS LIMITED	PARACETAMOL AND CAFFEINE 500MG/50MG SOLUBLE TABLETS	CAFFEINE	50.00	MILLIGRAMMES	POM
PL 31603/0022	29/11/2018	APOLLO GENERICS LIMITED	PARACETAMOL AND CAFFEINE 500MG/50MG SOLUBLE TABLETS	PARACETAMOL	500.00	MILLIGRAMMES	POM
PL 48037/0017	30/11/2018	PASSAUER PHARMA GMBH	RIZATRIPTAN PASSAUER 5 MG ORODISPERSIBLE TABLETS	RIZATRIPTAN BENZOATE	7.265	MILLIGRAMMES	POM
PL 48037/0018	30/11/2018	PASSAUER PHARMA GMBH	RIZATRIPTAN PASSAUER 10 MG ORODISPERSIBLE TABLETS	RIZATRIPTAN BENZOATE	14.53	MILLIGRAMMES	POM