

Marketing authorisations granted in July 2018

PL Number	Grant Date	MA Holder	Licensed Name(s)	Active Ingredient	Quantity	Units	Legal Status
PL 08553/0626	02/07/2018	DR REDDY'S LABORATORIES (UK) LIMITED	EVEROLIMUS DR. REDDY'S 2.5 MG TABLETS	EVEROLIMUS	2.5	MILLIGRAMMES	POM
PL 08553/0627	02/07/2018	DR REDDY'S LABORATORIES (UK) LIMITED	EVEROLIMUS DR. REDDY'S 5 MG TABLETS	EVEROLIMUS	5	MILLIGRAMMES	POM
PL 08553/0628	02/07/2018	DR REDDY'S LABORATORIES (UK) LIMITED	EVEROLIMUS DR. REDDY'S 10 MG TABLETS	EVEROLIMUS	10	MILLIGRAMMES	POM
PL 04569/1717	03/07/2018	GENERICS (UK) LIMITED	PRAMIPEXOLE MYLAN 0.26 MG PROLONGED-RELEASE TABLETS	PRAMIPEXOLE DIHYDROCHLORIDE MONOHYDRATE	0.375	MILLIGRAMMES	POM
PL 04569/1718	03/07/2018	GENERICS (UK) LIMITED	PRAMIPEXOLE MYLAN 0.52 MG PROLONGED-RELEASE TABLETS	PRAMIPEXOLE DIHYDROCHLORIDE MONOHYDRATE	0.750	MILLIGRAMMES	POM
PL 04569/1719	03/07/2018	GENERICS (UK) LIMITED	PRAMIPEXOLE MYLAN 1.05 MG PROLONGED-RELEASE TABLETS	PRAMIPEXOLE DIHYDROCHLORIDE MONOHYDRATE	1.500	MILLIGRAMMES	POM
PL 04569/1720	03/07/2018	GENERICS (UK) LIMITED	PRAMIPEXOLE MYLAN 1.57 MG PROLONGED-RELEASE TABLETS	PRAMIPEXOLE DIHYDROCHLORIDE MONOHYDRATE	2.250	MILLIGRAMMES	POM
PL 04569/1721	03/07/2018	GENERICS (UK) LIMITED	PRAMIPEXOLE MYLAN 2.1 MG PROLONGED-RELEASE TABLETS	PRAMIPEXOLE DIHYDROCHLORIDE MONOHYDRATE	3.000	MILLIGRAMMES	POM
PL 04569/1722	03/07/2018	GENERICS (UK) LIMITED	PRAMIPEXOLE MYLAN 2.62 MG PROLONGED-RELEASE TABLETS	PRAMIPEXOLE DIHYDROCHLORIDE MONOHYDRATE	3.750	MILLIGRAMMES	POM
PL 04569/1723	03/07/2018	GENERICS (UK) LIMITED	PRAMIPEXOLE MYLAN 3.15 MG PROLONGED-RELEASE TABLETS	PRAMIPEXOLE DIHYDROCHLORIDE MONOHYDRATE	4.500	MILLIGRAMMES	POM
PL 16853/0147	03/07/2018	ALLIANCE PHARMACEUTICALS LIMITED	XONVEA 10MG/10MG GASTRO-RESISTANT TABLETS	DOXYLAMINE SUCCINATE	10	MILLIGRAMMES	POM
PL 16853/0147	03/07/2018	ALLIANCE PHARMACEUTICALS LIMITED	XONVEA 10MG/10MG GASTRO-RESISTANT TABLETS	PYRIDOXINE HYDROCHLORIDE	10	MILLIGRAMMES	POM
PL 20117/0295	03/07/2018	MORNINGSIDE HEALTHCARE LIMITED	PALONOSETRON 250 MICROGRAMS SOLUTION FOR INJECTION	PALONOSETRON HYDROCHLORIDE	0.281	MILLIGRAMMES	POM
PL 20416/0549	03/07/2018	CRESCENT PHARMA LIMITED	PAROXETINE 10MG FILM-COATED TABLETS	PAROXETINE HYDROCHLORIDE HEMIHYDRATE	11.379	MILLIGRAMMES	POM
PL 20416/0550	03/07/2018	CRESCENT PHARMA LIMITED	PAROXETINE 30MG FILM-COATED TABLETS	PAROXETINE HYDROCHLORIDE HEMIHYDRATE	34.137	MILLIGRAMMES	POM
PL 25298/0129	03/07/2018	BROWN & BURK UK LIMITED	AMITRIPTYLINE 10 MG FILM-COATED TABLETS	AMITRIPTYLINE HYDROCHLORIDE	10.00	MILLIGRAMMES	POM
PL 25298/0130	03/07/2018	BROWN & BURK UK LIMITED	AMITRIPTYLINE 25 MG FILM-COATED TABLETS	AMITRIPTYLINE HYDROCHLORIDE	25.00	MILLIGRAMMES	POM
PL 25298/0131	03/07/2018	BROWN & BURK UK LIMITED	AMITRIPTYLINE 50 MG FILM-COATED TABLETS	AMITRIPTYLINE HYDROCHLORIDE	50.00	MILLIGRAMMES	POM
PL 43461/0037	03/07/2018	FLAMINGO PHARMA (UK) LIMITED	THIAMINE HYDROCHLORIDE 50 MG TABLETS	THIAMINE HYDROCHLORIDE	50	MILLIGRAMMES	P
PL 43461/0038	03/07/2018	FLAMINGO PHARMA (UK) LIMITED	THIAMINE HYDROCHLORIDE 100 MG TABLETS	THIAMINE HYDROCHLORIDE	100	MILLIGRAMMES	P
PL 06831/0308	04/07/2018	GENUS PHARMACEUTICALS LIMITED	SOLIFENACIN 5 MG FILM-COATED TABLETS	SOLIFENACIN SUCCINATE	5	MILLIGRAMMES	POM
PL 06831/0309	04/07/2018	GENUS PHARMACEUTICALS LIMITED	SOLIFENACIN 10 MG FILM-COATED TABLETS	SOLIFENACIN SUCCINATE	10	MILLIGRAMMES	POM
PL 06934/0208	05/07/2018	ETHYPHARM	LINEVERO 2.5 MG TABLETS	EVEROLIMUS	2.5	MILLIGRAMMES	POM
PL 06934/0209	05/07/2018	ETHYPHARM	LINEVERO 5 MG TABLETS	EVEROLIMUS	5	MILLIGRAMMES	POM
PL 06934/0210	05/07/2018	ETHYPHARM	LINEVERO 10 MG TABLETS	EVEROLIMUS	10	MILLIGRAMMES	POM
PL 06934/0211	05/07/2018	ETHYPHARM	EVEROLIMUS ETHYPHARM 2.5MG TABLETS	EVEROLIMUS	2.50	MILLIGRAMMES	POM
PL 06934/0212	05/07/2018	ETHYPHARM	EVEROLIMUS ETHYPHARM 5MG TABLETS	EVEROLIMUS	5	MILLIGRAMMES	POM
PL 06934/0213	05/07/2018	ETHYPHARM	EVEROLIMUS ETHYPHARM 10MG TABLETS	EVEROLIMUS	10	MILLIGRAMMES	POM
PL 20395/0128	05/07/2018	RELONCHEM LIMITED	PARACETAMOL 500MG CAPSULES	PARACETAMOL	500.00	MILLIGRAMMES	GSL
PL 06464/3104	09/07/2018	WAYMADE PLC	VARDENAFIL WAYMADE 5 MG FILM-COATED TABLETS	VARDENAFIL HYDROCHLORIDE TRIHYDRATE	5.00	MILLIGRAMMES	POM
PL 06464/3105	09/07/2018	WAYMADE PLC	VARDENAFIL WAYMADE 10 MG FILM-COATED TABLETS	VARDENAFIL HYDROCHLORIDE TRIHYDRATE	10.00	MILLIGRAMMES	POM

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PL 06464/3106	09/07/2018	WAYMADE PLC	VARDENAFIL WAYMADE 20 MG FILM-COATED TABLETS	VARDENAFIL HYDROCHLORIDE TRIHYDRATE	20.00	MILLIGRAMMES	POM
PL 36722/0124	09/07/2018	SPECIAL CONCEPT DEVELOPMENT (UK) LIMITED	SENEASE 7.5MG TABLETS	CALCIUM SENNOSIDES 20%	37.50	MILLIGRAMMES	GSL
PL 01656/0244	10/07/2018	KRKA DD NOVO MESTO	EPLERENONE KRKA 25 MG FILM-COATED TABLETS	EPLERENONE	25.00	MILLIGRAMMES	POM
PL 01656/0245	10/07/2018	KRKA DD NOVO MESTO	EPLERENONE KRKA 50 MG FILM-COATED TABLETS	EPLERENONE	50.00	MILLIGRAMMES	POM
PL 11311/0561	10/07/2018	TILLOMED LABORATORIES LIMITED	PREGABALIN TILLOMED 25 MG CAPSULE, HARD	PREGABALIN	25	MILLIGRAMMES	POM
PL 11311/0562	10/07/2018	TILLOMED LABORATORIES LIMITED	PREGABALIN TILLOMED 50 MG CAPSULE, HARD	PREGABALIN	50	MILLIGRAMMES	POM
PL 11311/0563	10/07/2018	TILLOMED LABORATORIES LIMITED	PREGABALIN TILLOMED 75MG CAPSULE, HARD	PREGABALIN	75	MILLIGRAMMES	POM
PL 11311/0564	10/07/2018	TILLOMED LABORATORIES LIMITED	PREGABALIN TILLOMED 100MG CAPSULE, HARD	PREGABALIN	100	MILLIGRAMMES	POM
PL 11311/0565	10/07/2018	TILLOMED LABORATORIES LIMITED	PREGABALIN TILLOMED 150MG CAPSULE, HARD	PREGABALIN	150	MILLIGRAMMES	POM
PL 11311/0566	10/07/2018	TILLOMED LABORATORIES LIMITED	PREGABALIN TILLOMED 200MG CAPSULE, HARD	PREGABALIN	200	MILLIGRAMMES	POM
PL 11311/0567	10/07/2018	TILLOMED LABORATORIES LIMITED	PREGABALIN TILLOMED 225MG CAPSULE, HARD	PREGABALIN	225	MILLIGRAMMES	POM
PL 11311/0568	10/07/2018	TILLOMED LABORATORIES LIMITED	PREGABALIN TILLOMED 300MG CAPSULE, HARD	PREGABALIN	300	MILLIGRAMMES	POM
PL 20075/0540	10/07/2018	ACCORD HEALTHCARE LIMITED	ATOSIBAN ACCORD 6.75 MG SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE	ATOSIBAN ACETATE	7.5	MILLIGRAMMES	POM
PL 16363/0476	12/07/2018	MILPHARM LIMITED	TRANEXAMIC ACID 100 MG/ML SOLUTION FOR INJECTION	TRANEXAMIC ACID	100	MILLIGRAMMES PER MILLILITRE	POM
PL 16363/0541	13/07/2018	MILPHARM LIMITED	ZOPICLONE 3.75 MG FILM-COATED TABLETS	ZOPICLONE	3.85	MILLIGRAMMES	POM
PL 16363/0542	13/07/2018	MILPHARM LIMITED	ZOPICLONE 7.5 MG FILM-COATED TABLETS	ZOPICLONE	7.50	MILLIGRAMMES	POM
PL 20416/0543	13/07/2018	CRESCENT PHARMA LIMITED	ETORICOXIB 30MG FILM-COATED TABLETS	ETORICOXIB	30	MILLIGRAMMES	POM
PL 20416/0544	13/07/2018	CRESCENT PHARMA LIMITED	ETORICOXIB 60MG FILM-COATED TABLETS	ETORICOXIB	60	MILLIGRAMMES	POM
PL 20416/0545	13/07/2018	CRESCENT PHARMA LIMITED	ETORICOXIB 90MG FILM-COATED TABLETS	ETORICOXIB	90.00	MILLIGRAMMES	POM
PL 20416/0546	13/07/2018	CRESCENT PHARMA LIMITED	ETORICOXIB 120MG FILM-COATED TABLETS	ETORICOXIB	120.00	MILLIGRAMMES	POM
PL 21562/0031	13/07/2018	DISTRQUIMICA S.A.	RIVAROXABAN 2.5 MG FILM-COATED TABLETS	RIVAROXABAN	2.500	MILLIGRAMMES	POM
PL 21562/0032	13/07/2018	DISTRQUIMICA S.A.	RIVAROXABAN 10MG FILM-COATED TABLETS	RIVAROXABAN	10.00	MILLIGRAMMES	POM
PL 21562/0033	13/07/2018	DISTRQUIMICA S.A.	RIVAROXABAN 15MG FILM-COATED TABLETS	RIVAROXABAN	15.00	MILLIGRAMMES	POM
PL 21562/0034	13/07/2018	DISTRQUIMICA S.A.	RIVAROXABAN 20MG FILM-COATED TABLETS	RIVAROXABAN	20.00	MILLIGRAMMES	POM
PL 48221/0001	13/07/2018	FARMA INDUSTRI AS	VENTIZOLVE 1.26 MG NASAL SPRAY, SOLUTION IN SINGLE-DOSE CONTAINER	NALOXONE HYDROCHLORIDE DIHYDRATE	15.4	MILLIGRAMMES PER MILLILITRE	POM
PL 21597/0054	16/07/2018	G L PHARMA GMBH	ESLICARBAZEPINE G.L. 200 MG TABLETS	ESLICARBAZEPINE ACETATE	200	MILLIGRAMMES	POM
PL 21597/0055	16/07/2018	G L PHARMA GMBH	ESLICARBAZEPINE G.L. 400MG TABLETS	ESLICARBAZEPINE ACETATE	400	MILLIGRAMMES	POM
PL 21597/0056	16/07/2018	G L PHARMA GMBH	ESLICARBAZEPINE G.L. 600MG TABLETS	ESLICARBAZEPINE ACETATE	600	MILLIGRAMMES	POM
PL 21597/0057	16/07/2018	G L PHARMA GMBH	ESLICARBAZEPINE G.L. 800MG TABLETS	ESLICARBAZEPINE ACETATE	800	MILLIGRAMMES	POM
PL 00240/0407	17/07/2018	THORNTON & ROSS LIMITED	ARIPIPRAZOLE THORNTON & ROSS 10MG ORODISPERSIBLE TABLETS	ARIPIPRAZOLE	10	MILLIGRAMMES	POM
PL 00240/0408	17/07/2018	THORNTON & ROSS LIMITED	ARIPIPRAZOLE THORNTON & ROSS 15MG ORODISPERSIBLE TABLETS	ARIPIPRAZOLE	15	MILLIGRAMMES	POM

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PL 06831/0292	17/07/2018	GENUS PHARMACEUTICALS LIMITED	ATOMOXETINE 10 MG HARD CAPSULES	ATOMOXETINE HYDROCHLORIDE	11.430	MILLIGRAMMES	POM
PL 06831/0293	17/07/2018	GENUS PHARMACEUTICALS LIMITED	ATOMOXETINE 18 MG HARD CAPSULES	ATOMOXETINE HYDROCHLORIDE	20.574	MILLIGRAMMES	POM
PL 06831/0294	17/07/2018	GENUS PHARMACEUTICALS LIMITED	ATOMOXETINE 25 MG HARD CAPSULES	ATOMOXETINE HYDROCHLORIDE	28.575	MILLIGRAMMES	POM
PL 06831/0295	17/07/2018	GENUS PHARMACEUTICALS LIMITED	ATOMOXETINE 40 MG HARD CAPSULES	ATOMOXETINE HYDROCHLORIDE	45.720	MILLIGRAMMES	POM
PL 06831/0296	17/07/2018	GENUS PHARMACEUTICALS LIMITED	ATOMOXETINE 60 MG HARD CAPSULES	ATOMOXETINE HYDROCHLORIDE	68.580	MILLIGRAMMES	POM
PL 06831/0297	17/07/2018	GENUS PHARMACEUTICALS LIMITED	ATOMOXETINE 80 MG HARD CAPSULES	ATOMOXETINE HYDROCHLORIDE	91.440	MILLIGRAMMES	POM
PL 06831/0298	17/07/2018	GENUS PHARMACEUTICALS LIMITED	ATOMOXETINE 100 MG HARD CAPSULES	ATOMOXETINE HYDROCHLORIDE	114.300	MILLIGRAMMES	POM
PL 20046/0300	17/07/2018	FOCUS PHARMACEUTICALS LIMITED	TRIFLUOPERAZINE 5 MG/5 ML ORAL SOLUTION	TRIFLUOPERAZINE HYDROCHLORIDE	1.18	MILLIGRAMMES PER MILLILITRE	POM
PL 30684/0265	17/07/2018	DAWA LIMITED	CELECOXIB 100MG CAPSULES, HARD	CELECOXIB	100.00	MILLIGRAMMES	POM
PL 30684/0266	17/07/2018	DAWA LIMITED	CELECOXIB 200 MG CAPSULES, HARD	CELECOXIB	200.00	MILLIGRAMMES	POM
PL 34096/0015	17/07/2018	MITHRA PHARMACEUTICALS SA	MYDONARING 0.120 MG/0.015 MG PER 24 HOURS, VAGINAL DELIVERY SYSTEM	ETHINYLESTRADIOL	2.7	MILLIGRAMMES	POM
PL 34096/0015	17/07/2018	MITHRA PHARMACEUTICALS SA	MYDONARING 0.120 MG/0.015 MG PER 24 HOURS, VAGINAL DELIVERY SYSTEM	ETONOGESTREL	11.7	MILLIGRAMMES	POM
PL 34424/0034	17/07/2018	KEY PHARMACEUTICALS LIMITED	SERTRALINE 50MG FILM-COATED TABLETS	SERTRALINE HYDROCHLORIDE	55.96	MILLIGRAMMES	POM
PL 34424/0035	17/07/2018	KEY PHARMACEUTICALS LIMITED	SERTRALINE 100MG FILM-COATED TABLETS	SERTRALINE HYDROCHLORIDE	111.92	MILLIGRAMMES	POM
PL 14434/0037	18/07/2018	LABORATOIRE AGUETTANT	LIDOCAINE 10 MG/ML (1% W/V) SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE	LIDOCAINE HYDROCHLORIDE	100	MILLIGRAMMES	POM
PL 14434/0038	18/07/2018	LABORATOIRE AGUETTANT	LIDOCAINE 20 MG/ML (2% W/V) SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE	LIDOCAINE HYDROCHLORIDE	20	MILLIGRAMMES	POM
PL 14903/0003	19/07/2018	TEMMLER PHARMA GMBH & CO KG	NAPRADIOL 75 MG / 20 MG MODIFIED-RELEASE HARD CAPSULES	DICLOFENAC SODIUM	75	MILLIGRAMMES	POM
PL 14903/0003	19/07/2018	TEMMLER PHARMA GMBH & CO KG	NAPRADIOL 75 MG / 20 MG MODIFIED-RELEASE HARD CAPSULES	OMEPRAZOLE	20	MILLIGRAMMES	POM
PL 31603/0018	19/07/2018	APOLLO GENERICS LIMITED	PARACETAMOL 500MG EFFERVESCENT TABLETS	PARACETAMOL	500.00	MILLIGRAMMES	GSL
PL 31603/0019	19/07/2018	APOLLO GENERICS LIMITED	PARACETAMOL 500MG EFFERVESCENT TABLETS	PARACETAMOL	500.00	MILLIGRAMMES	P
PL 00037/0678	20/07/2018	ABBOTT LABORATORIES LIMITED	IBUPROFEN 600MG EFFERVESCENT GRANULES	IBUPROFEN	600	MILLIGRAMMES	POM
PL 31603/0021	20/07/2018	APOLLO GENERICS LIMITED	PARACETAMOL 1000MG EFFERVESCENT TABLETS	PARACETAMOL	1000.00	MILLIGRAMMES	P
PL 22363/0018	23/07/2018	KAPPLER PHARMA CONSULT GMBH	LINEZOLID 600 MG FILM-COATED TABLETS	LINEZOLID	600	MILLIGRAMMES	POM
PL 30322/0034	23/07/2018	ALISSA HEALTHCARE RESEARCH LIMITED	QUETIAPINE 25 MG FILM-COATED TABLETS	QUETIAPINE FUMARATE	28.78	MILLIGRAMMES	POM
PL 30322/0035	23/07/2018	ALISSA HEALTHCARE RESEARCH LIMITED	QUETIAPINE 100 MG FILM-COATED TABLETS	QUETIAPINE FUMARATE	115.12	MILLIGRAMMES	POM
PL 30322/0036	23/07/2018	ALISSA HEALTHCARE RESEARCH LIMITED	QUETIAPINE 150 MG FILM-COATED TABLETS	QUETIAPINE FUMARATE	172.68	MILLIGRAMMES	POM
PL 30322/0037	23/07/2018	ALISSA HEALTHCARE RESEARCH LIMITED	QUETIAPINE 200 MG FILM-COATED TABLETS	QUETIAPINE FUMARATE	230.24	MILLIGRAMMES	POM
PL 30322/0038	23/07/2018	ALISSA HEALTHCARE RESEARCH LIMITED	QUETIAPINE 300 MG FILM-COATED TABLETS	QUETIAPINE FUMARATE	345.36	MILLIGRAMMES	POM
PL 35533/0133	23/07/2018	ASPIRE PHARMA LIMITED	CETRAXAL PLUS 3 MG/ML + 0.25 MG/ML EAR DROPS SOLUTION IN SINGLE-DOSE CONTAINER	CIPROFLOXACIN HYDROCHLORIDE	872.5	MICROGRAMMES	POM
PL 35533/0133	23/07/2018	ASPIRE PHARMA LIMITED	CETRAXAL PLUS 3 MG/ML + 0.25 MG/ML EAR DROPS SOLUTION IN SINGLE-DOSE CONTAINER	FLUCCINOLONE ACETONIDE	62.5	MICROGRAMMES	POM
PL 04569/1743	24/07/2018	GENERICS (UK) LIMITED	EVEROLIMUS MYLAN 2.5 MG TABLETS	EVEROLIMUS	2.5	MILLIGRAMMES	POM

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PL 04569/1744	24/07/2018	GENERICIS (UK) LIMITED	EVEROLIMUS MYLAN 5 MG TABLETS	EVEROLIMUS	5	MILLIGRAMMES	POM
PL 04569/1745	24/07/2018	GENERICIS (UK) LIMITED	EVEROLIMUS MYLAN 10 MG TABLETS	EVEROLIMUS	10	MILLIGRAMMES	POM
PL 43552/0003	25/07/2018	PAXVAX LIMITED	VIVOTIF	SALMONELLA TYPHI TY 21A ATTENUATED	2000.00	MEGA UNITS	POM
PL 11311/0570	26/07/2018	TILLOMED LABORATORIES LIMITED	EPLERENONE TILLOMED 25 MG FILM-COATED TABLETS	EPLERENONE	25	MILLIGRAMMES	POM
PL 11311/0571	26/07/2018	TILLOMED LABORATORIES LIMITED	EPLERENONE TILLOMED 50 MG FILM-COATED TABLETS	EPLERENONE	50	MILLIGRAMMES	POM
PL 08553/0611	31/07/2018	DR REDDY'S LABORATORIES (UK) LIMITED	DARUNAVIR DR. REDDY'S 75 MG FILM-COATED TABLETS	DARUNAVIR PROPYLENE GLYCOLATE	85.42	MILLIGRAMMES	POM
PL 08553/0612	31/07/2018	DR REDDY'S LABORATORIES (UK) LIMITED	DARUNAVIR DR. REDDY'S 150 MG FILM-COATED TABLETS	DARUNAVIR PROPYLENE GLYCOLATE	170.84	MILLIGRAMMES	POM
PL 08553/0613	31/07/2018	DR REDDY'S LABORATORIES (UK) LIMITED	DARUNAVIR DR. REDDY'S 400 MG FILM-COATED TABLETS	DARUNAVIR PROPYLENE GLYCOLATE	455.55	MILLIGRAMMES	POM
PL 08553/0614	31/07/2018	DR REDDY'S LABORATORIES (UK) LIMITED	DARUNAVIR DR. REDDY'S 600 MG FILM-COATED TABLETS	DARUNAVIR PROPYLENE GLYCOLATE	683.33	MILLIGRAMMES	POM
PL 08553/0615	31/07/2018	DR REDDY'S LABORATORIES (UK) LIMITED	DARUNAVIR DR. REDDY'S 800 MG FILM-COATED TABLETS	DARUNAVIR PROPYLENE GLYCOLATE	911.10	MILLIGRAMMES	POM