

## Marketing authorisations granted in June 2018

| PL Number     | Grant Date | MA Holder                           | Licensed Name(s)  | Active Ingredient                    | Quantity | Units                       | Legal Status |
|---------------|------------|-------------------------------------|---|--------------------------------------|----------|-----------------------------|--------------|
| PL 25215/0035 | 01/06/2018 | HAMELN PHARMA PLUS GMBH             | OXYCODONE HYDROCHLORIDE 10 MG/ML SOLUTION FOR INJECTION OR INFUSION         | OXYCODONE HYDROCHLORIDE              | 10       | MILLIGRAMMES                | POM          |
| PL 25215/0036 | 01/06/2018 | HAMELN PHARMA PLUS GMBH             | OXYCODONE HYDROCHLORIDE 50 MG/ML SOLUTION FOR INJECTION OR INFUSION         | OXYCODONE HYDROCHLORIDE              | 50       | MILLIGRAMMES                | POM          |
| PL 31980/0005 | 01/06/2018 | IDL INTERNATIONAL DRUG LICENSING    | PARACETAMOL AND CAFFEINE IDL 500 MG/65 MG FILM-COATED TABLETS               | CAFFEINE                             | 65.00    | MILLIGRAMMES                | GSL          |
| PL 31980/0005 | 01/06/2018 | IDL INTERNATIONAL DRUG LICENSING    | PARACETAMOL AND CAFFEINE IDL 500 MG/65 MG FILM-COATED TABLETS               | PARACETAMOL                          | 500.00   | MILLIGRAMMES                | GSL          |
| PL 37222/0040 | 01/06/2018 | HETERO EUROPE SL                    | ABACAVIR/LAMIVUDINE AMAROX 600 MG/300 MG FILM-COATED TABLETS                | ABACAVIR SULFATE                     | 702.762  | MILLIGRAMMES                | POM          |
| PL 37222/0040 | 01/06/2018 | HETERO EUROPE SL                    | ABACAVIR/LAMIVUDINE AMAROX 600 MG/300 MG FILM-COATED TABLETS                | LAMIVUDINE                           | 300.00   | MILLIGRAMMES                | POM          |
| PL 08801/0045 | 04/06/2018 | BIO PRODUCTS LABORATORY LIMITED     | GAMMAPLEX 10% 100 MG/ML SOLUTION FOR INFUSION                               | HUMAN NORMAL IMMUNOGLOBULIN          | 100      | GRAMMES PER LITRE           | POM          |
| PL 20692/0144 | 04/06/2018 | VALE PHARMACEUTICALS LIMITED        | MODAFINIL 100 MG TABLETS  | MODAFINIL                            | 100      | MILLIGRAMMES                | POM          |
| PL 20692/0145 | 04/06/2018 | VALE PHARMACEUTICALS LIMITED        | MODAFINIL 200 MG TABLETS  | MODAFINIL                            | 200      | MILLIGRAMMES                | POM          |
| PL 00240/0393 | 06/06/2018 | THORNTON & ROSS LIMITED             | CARE MAX STRENGTH COLD & FLU RELIEF 400MG/10MG FILM COATED TABLETS          | IBUPROFEN                            | 400      | MILLIGRAMMES                | POM          |
| PL 00240/0393 | 06/06/2018 | THORNTON & ROSS LIMITED             | CARE MAX STRENGTH COLD & FLU RELIEF 400MG/10MG FILM COATED TABLETS          | PHENYLEPHRINE HYDROCHLORIDE          | 10       | MILLIGRAMMES                | POM          |
| PL 43883/0001 | 06/06/2018 | IRE ELIT SA                         | GALLIAD, 0.74 -1.85 GBQ, RADIONUCLIDE GENERATOR                             | GALLIUM (GA 68) CHLORIDE             | 1.85     | GIGA BECQUEREL UNITS        | POM          |
| PL 00289/2164 | 07/06/2018 | TEVA UK LIMITED                     | AGOMELATINE 25 MG FILM-COATED TABLETS                                       | AGOMELATINE UREA CO-CRYSTAL          | 31.171   | MILLIGRAMMES                | POM          |
| PL 30911/0003 | 07/06/2018 | IDIFARMA DESARROLLO FARMACEUTICO SL | BIMATOPROST IDIFARMA 0.3 MG/ML, EYE DROPS. SOLUTION                         | BIMATOPROST                          | 0.300    | MILLIGRAMMES PER MILLILITRE | POM          |
| PL 37039/0001 | 07/06/2018 | PRO.MED CS PRAHA AS                 | URSONORM 500MG FILM-COATED TABLET   | URSODEOXYCHOLIC ACID                 | 500      | MILLIGRAMMES                | POM          |
| PL 42069/0006 | 07/06/2018 | CADIASUN PHARMA GMBH                | IODIXANOL CADIASUN 320 MG I/ML SOLUTION FOR INJECTION                       | IODIXANOL                            | 652      | MILLIGRAMMES PER MILLILITRE | POM          |
| PL 01502/0103 | 08/06/2018 | HAMELN PHARMACEUTICALS LIMITED      | EPHEDRINE HYDROCHLORIDE 30 MG/ML SOLUTION FOR INJECTION                     | EPHEDRINE HYDROCHLORIDE              | 30       | MILLIGRAMMES                | POM          |
| PL 17780/0809 | 08/06/2018 | WINTHROP PHARMACEUTICALS UK LIMITED | AGOMELATINE ZENTIVA 25 MG FILM-COATED TABLETS                               | AGOMELATINE / CITRIC ACID CO-CRYSTAL | 44.739   | MILLIGRAMMES                | POM          |
| PL 20416/0243 | 11/06/2018 | CRESCENT PHARMA LIMITED             | ACICLOVIR 200MG TABLETS   | ACICLOVIR                            | 200.00   | MILLIGRAMMES                | POM          |
| PL 20416/0244 | 11/06/2018 | CRESCENT PHARMA LIMITED             | ACICLOVIR 400MG TABLETS   | ACICLOVIR                            | 400.00   | MILLIGRAMMES                | POM          |
| PL 20416/0245 | 11/06/2018 | CRESCENT PHARMA LIMITED             | ACICLOVIR 800MG TABLETS   | ACICLOVIR                            | 800.00   | MILLIGRAMMES                | POM          |
| PL 29906/0001 | 11/06/2018 | OMNIVISION GMBH                     | BRIMONIDINE OMNIVISION 2 MG/ML EYE DROPS, SOLUTION IN SINGLE-DOSE CONTAINER | BRIMONIDINE TARTRATE                 | 2        | MILLIGRAMMES PER MILLILITRE | POM          |
| PL 47848/0001 | 12/06/2018 | AXUNIO PHARMA GMBH                  | TENOFOVIR DISOPROXIL AXUNIO 245 MG FILM-COATED TABLETS                      | TENOFOVIR DISOPROXIL FUMARATE        | 300      | MILLIGRAMMES                | POM          |
| PL 15513/0395 | 13/06/2018 | MCNEIL PRODUCTS LIMITED             | NICORETTE QUICKMIST COOL BERRY 1MG/SPRAY MOUTHSPRAY                         | NICOTINE                             | 13.6     | MILLIGRAMMES PER MILLILITRE | GSL          |
| PL 22363/0023 | 13/06/2018 | KAPPLER PHARMA CONSULT GMBH         | AMLODIPINE/VALSARTAN KAPPLER 5 MG/80 MG FILM-COATED TABLETS                 | AMLODIPINE BESILATE                  | 6.934    | MILLIGRAMMES                | POM          |
| PL 22363/0023 | 13/06/2018 | KAPPLER PHARMA CONSULT GMBH         | AMLODIPINE/VALSARTAN KAPPLER 5 MG/80 MG FILM-COATED TABLETS                 | VALSARTAN                            | 80       | MILLIGRAMMES                | POM          |
| PL 22363/0024 | 13/06/2018 | KAPPLER PHARMA CONSULT GMBH         | AMLODIPINE/VALSARTAN KAPPLER 5 MG/160 MG FILM-COATED TABLETS                | AMLODIPINE BESILATE                  | 6.934    | MILLIGRAMMES                | POM          |
| PL 22363/0024 | 13/06/2018 | KAPPLER PHARMA CONSULT GMBH         | AMLODIPINE/VALSARTAN KAPPLER 5 MG/160 MG FILM-COATED TABLETS                | VALSARTAN                            | 160      | MILLIGRAMMES                | POM          |
| PL 22363/0025 | 13/06/2018 | KAPPLER PHARMA CONSULT GMBH         | AMLODIPINE/VALSARTAN KAPPLER 10 MG/160 MG FILM-COATED TABLETS               | AMLODIPINE BESILATE                  | 13.868   | MILLIGRAMMES                | POM          |
| PL 22363/0025 | 13/06/2018 | KAPPLER PHARMA CONSULT GMBH         | AMLODIPINE/VALSARTAN KAPPLER 10 MG/160 MG FILM-COATED TABLETS               | VALSARTAN                            | 160      | MILLIGRAMMES                | POM          |
| PL 34771/0205 | 13/06/2018 | MACLEODS PHARMA UK LIMITED          | COLCHICINE 500 MICROGRAM FILM-COATED TABLETS                                | COLCHICINE                           | 0.50     | MILLIGRAMMES                | POM          |

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| PL 34771/0206 | 13/06/2018 | MACLEODS PHARMA UK LIMITED   | COLCHICINE 1000 MICROGRAM FILM-COATED TABLETS  | COLCHICINE                    | 1.00     | MILLIGRAMMES                | POM          |
| PL 03551/0154 | 14/06/2018 | B BRAUN MELSUNGEN AG         | NUTRATAIN POWDER FOR SOLUTION FOR INFUSION   | ALL-RAC-ALPHA-TOCOPHEROL      | 9.1071   | MILLIGRAMMES                | POM          |
| PL 03551/0154 | 14/06/2018 | B BRAUN MELSUNGEN AG         | NUTRATAIN POWDER FOR SOLUTION FOR INFUSION   | ASCORBIC ACID                 | 200.00   | MILLIGRAMMES                | POM          |
| PL 03551/0154 | 14/06/2018 | B BRAUN MELSUNGEN AG         | NUTRATAIN POWDER FOR SOLUTION FOR INFUSION   | BIOTIN                        | 0.06     | MILLIGRAMMES                | POM          |
| PL 03551/0154 | 14/06/2018 | B BRAUN MELSUNGEN AG         | NUTRATAIN POWDER FOR SOLUTION FOR INFUSION   | COLECALCIFEROL                | 0.005    | MILLIGRAMMES                | POM          |
| PL 03551/0154 | 14/06/2018 | B BRAUN MELSUNGEN AG         | NUTRATAIN POWDER FOR SOLUTION FOR INFUSION   | CYANOCOBALAMIN                | 0.005    | MILLIGRAMMES                | POM          |
| PL 03551/0154 | 14/06/2018 | B BRAUN MELSUNGEN AG         | NUTRATAIN POWDER FOR SOLUTION FOR INFUSION   | DEXPANTHENOL                  | 14.0488  | MILLIGRAMMES                | POM          |
| PL 03551/0154 | 14/06/2018 | B BRAUN MELSUNGEN AG         | NUTRATAIN POWDER FOR SOLUTION FOR INFUSION   | FOLIC ACID                    | 0.60     | MILLIGRAMMES                | POM          |
| PL 03551/0154 | 14/06/2018 | B BRAUN MELSUNGEN AG         | NUTRATAIN POWDER FOR SOLUTION FOR INFUSION   | NICOTINAMIDE                  | 40.00    | MILLIGRAMMES                | POM          |
| PL 03551/0154 | 14/06/2018 | B BRAUN MELSUNGEN AG         | NUTRATAIN POWDER FOR SOLUTION FOR INFUSION   | PHYTOMENADIONE                | 0.15     | MILLIGRAMMES                | POM          |
| PL 03551/0154 | 14/06/2018 | B BRAUN MELSUNGEN AG         | NUTRATAIN POWDER FOR SOLUTION FOR INFUSION   | PYRIDOXINE HYDROCHLORIDE      | 7.30     | MILLIGRAMMES                | POM          |
| PL 03551/0154 | 14/06/2018 | B BRAUN MELSUNGEN AG         | NUTRATAIN POWDER FOR SOLUTION FOR INFUSION   | RIBOFLAVIN SODIUM PHOSPHATE   | 4.5746   | MILLIGRAMMES                | POM          |
| PL 03551/0154 | 14/06/2018 | B BRAUN MELSUNGEN AG         | NUTRATAIN POWDER FOR SOLUTION FOR INFUSION   | THIAMINE HYDROCHLORIDE        | 7.6255   | MILLIGRAMMES                | POM          |
| PL 03551/0154 | 14/06/2018 | B BRAUN MELSUNGEN AG         | NUTRATAIN POWDER FOR SOLUTION FOR INFUSION   | VITAMIN A                     | 1.815    | MILLIGRAMMES                | POM          |
| PL 35104/0021 | 14/06/2018 | PHOENIX LABS                 | CYCLIZINE LACTATE 50MG/ML INJECTION  | CYCLIZINE LACTATE             | 50.00    | MILLIGRAMMES PER MILLILITRE | POM          |
| PL 35533/0125 | 14/06/2018 | ASPIRE PHARMA LIMITED        | MEBEVERINE HYDROCHLORIDE 135MG FILM-COATED TABLETS                                     | MEBEVERINE HYDROCHLORIDE      | 135      | MILLIGRAMMES                | POM          |
| PL 42357/0243 | 14/06/2018 | AMNEAL PHARMA EUROPE LIMITED | EMTRICITABINE/TENOFOVIR DISOPROXIL AMNEAL 200 MG/245 MG FILM-COATED TABLETS            | EMTRICITABINE                 | 200      | MILLIGRAMMES                | POM          |
| PL 42357/0243 | 14/06/2018 | AMNEAL PHARMA EUROPE LIMITED | EMTRICITABINE/TENOFOVIR DISOPROXIL AMNEAL 200 MG/245 MG FILM-COATED TABLETS            | TENOFOVIR DISOPROXIL FUMARATE | 245      | MILLIGRAMMES                | POM          |
| PL 42765/0006 | 14/06/2018 | RENATA (UK) LIMITED          | DIPYRIDAMOLE 200 MG MODIFIED-RELEASE CAPSULES  | DIPYRIDAMOLE                  | 200      | MILLIGRAMMES                | POM          |
| PL 08215/0108 | 18/06/2018 | KENT PHARMACEUTICALS LIMITED | HYDROXOCOBALAMIN 1MG/ML SOLUTION FOR INJECTION   | HYDROXOCOBALAMIN ACETATE      | 1        | MILLIGRAMMES PER MILLILITRE | POM          |
| PL 34771/0224 | 18/06/2018 | MACLEODS PHARMA UK LIMITED   | RASAGILINE MACLEODS 1 MG TABLETS   | RASAGILINE MESYLATE           | 1.56     | MILLIGRAMMES                | POM          |
| PL 35667/0020 | 18/06/2018 | FARMALIDER SA                | IBUPROFEN AND PSEUDOEPHEDRINE HYDROCHLORIDE FARMALDIER 200MG/30MG/10ML ORAL SUSPENSION | IBUPROFEN                     | 20       | MILLIGRAMMES PER MILLILITRE | P            |
| PL 35667/0020 | 18/06/2018 | FARMALIDER SA                | IBUPROFEN AND PSEUDOEPHEDRINE HYDROCHLORIDE FARMALDIER 200MG/30MG/10ML ORAL SUSPENSION | PSEUDOEPHEDRINE HYDROCHLORIDE | 3        | MILLIGRAMMES PER MILLILITRE | P            |
| PL 36282/0014 | 18/06/2018 | RIA GENERICS LIMITED         | NEFOPAM HYDROCHLORIDE 30 MG FILM-COATED TABLETS  | NEFOPAM HYDROCHLORIDE         | 30       | MILLIGRAMMES                | POM          |
| PL 39307/0068 | 18/06/2018 | SYRI LIMITED                 | GABAPENTIN THAME 50MG/ML ORAL SOLUTION   | GABAPENTIN                    | 50.00    | MILLIGRAMMES                | POM          |
| PL 43707/0001 | 18/06/2018 | ESSENTIAL-HEALTHCARE LIMITED | CARBIMAZOLE 5 MG TABLETS   | CARBIMAZOLE                   | 5.000    | MILLIGRAMMES                | POM          |
| PL 43707/0002 | 18/06/2018 | ESSENTIAL-HEALTHCARE LIMITED | CARBIMAZOLE 20 MG TABLETS  | CARBIMAZOLE                   | 20.000   | MILLIGRAMMES                | POM          |
| PL 08828/0272 | 19/06/2018 | FRESENIUS KABI LIMITED       | LIDOCAINE HYDROCHLORIDE 1% SOLUTION FOR INJECTION                                      | LIDOCAINE HYDROCHLORIDE       | 50.00    | MILLIGRAMMES                | POM          |
| PL 08828/0273 | 19/06/2018 | FRESENIUS KABI LIMITED       | LIDOCAINE HYDROCHLORIDE 2% SOLUTION FOR INJECTION                                      | LIDOCAINE HYDROCHLORIDE       | 100.00   | MILLIGRAMMES                | POM          |
| PL 34424/0001 | 19/06/2018 | KEY PHARMACEUTICALS LIMITED  | ERYTHROMYCIN 250MG FILM COATED TABLETS   | ERYTHROMYCIN STEARATE         | 346.90   | MILLIGRAMMES                | POM          |
| PL 34424/0002 | 19/06/2018 | KEY PHARMACEUTICALS LIMITED  | ERYTHROMYCIN 500MG FILM COATED TABLETS   | ERYTHROMYCIN STEARATE         | 693.80   | MILLIGRAMMES                | POM          |

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| PL 19907/0019 | 20/06/2018 | BIOORGANICS BV                 | RASAGILINE 1 MG TABLETS   | RASAGILINE TARTRATE              | 1.44     | MILLIGRAMMES                | POM          |
| PL 00240/0409 | 21/06/2018 | THORNTON & ROSS LIMITED        | ATORVASTATIN 30MG FILM-COATED TABLETS                             | ATORVASTATIN CALCIUM TRIHYDRATE  | 32.4712  | MILLIGRAMMES                | POM          |
| PL 00240/0410 | 21/06/2018 | THORNTON & ROSS LIMITED        | ATORVASTATIN 60MG FILM-COATED TABLETS                             | ATORVASTATIN CALCIUM TRIHYDRATE  | 64.942   | MILLIGRAMMES                | POM          |
| PL 15764/0119 | 21/06/2018 | STRANDHAVEN LIMITED            | DULOXETINE 30 MG GASTRO-RESISTANT HARD CAPSULES                   | DULOXETINE HYDROCHLORIDE         | 33.650   | MILLIGRAMMES                | POM          |
| PL 15764/0120 | 21/06/2018 | STRANDHAVEN LIMITED            | DULOXETINE 60 MG GASTRO-RESISTANT HARD CAPSULES                   | DULOXETINE HYDROCHLORIDE         | 67.30    | MILLIGRAMMES                | POM          |
| PL 40546/0023 | 21/06/2018 | ARISTO PHARMA GMBH             | ETHOSUXIMIDE ARISTO 50 MG/ML ORAL SOLUTION                        | ETHOSUXIMIDE                     | 50       | MILLIGRAMMES PER MILLILITRE | POM          |
| PL 40546/0041 | 21/06/2018 | ARISTO PHARMA GMBH             | ETHOSUXIMIDE ARISTO PHARMA 50 MG/ML ORAL SOLUTION                 | ETHOSUXIMIDE                     | 50       | MILLIGRAMMES PER MILLILITRE | POM          |
| PL 20416/0487 | 22/06/2018 | CRESCENT PHARMA LIMITED        | ESOMEPRAZOLE 20MG GASTRO-RESISTANT TABLETS                        | ESOMEPRAZOLE MAGNESIUM AMORPHOUS | 22.264   | MILLIGRAMMES                | POM          |
| PL 20416/0488 | 22/06/2018 | CRESCENT PHARMA LIMITED        | ESOMEPRAZOLE 40MG GASTRO-RESISTANT TABLETS                        | ESOMEPRAZOLE MAGNESIUM AMORPHOUS | 44.528   | MILLIGRAMMES                | POM          |
| PL 20568/0083 | 22/06/2018 | CLARIS LIFESCIENCES UK LIMITED | SUCROFER 20 MG IRON/ML, SOLUTION FOR INJECTION /INFUSION          | IRON SUCROSE                     | 20.000   | MILLIGRAMMES PER MILLILITRE | POM          |
| PL 34424/0028 | 22/06/2018 | KEY PHARMACEUTICALS LIMITED    | PRAVASTATIN SODIUM 10MG TABLETS                                   | PRAVASTATIN SODIUM               | 10       | MILLIGRAMMES                | POM          |
| PL 34424/0029 | 22/06/2018 | KEY PHARMACEUTICALS LIMITED    | PRAVASTATIN SODIUM 20MG TABLETS                                   | PRAVASTATIN SODIUM               | 20       | MILLIGRAMMES                | POM          |
| PL 34424/0030 | 22/06/2018 | KEY PHARMACEUTICALS LIMITED    | PRAVASTATIN SODIUM 40MG TABLETS                                   | PRAVASTATIN SODIUM               | 40       | MILLIGRAMMES                | POM          |
| PL 11311/0579 | 26/06/2018 | TILLOMED LABORATORIES LIMITED  | GABAPENTIN TILLOMED 100 MG HARD CAPSULES                          | GABAPENTIN                       | 100.00   | MILLIGRAMMES                | POM          |
| PL 11311/0580 | 26/06/2018 | TILLOMED LABORATORIES LIMITED  | GABAPENTIN TILLOMED 300 MG HARD CAPSULES                          | GABAPENTIN                       | 300      | MILLIGRAMMES                | POM          |
| PL 11311/0581 | 26/06/2018 | TILLOMED LABORATORIES LIMITED  | GABAPENTIN TILLOMED 400 MG HARD CAPSULES                          | GABAPENTIN                       | 400      | MILLIGRAMMES                | POM          |
| PL 43461/0033 | 26/06/2018 | FLAMINGO PHARMA (UK) LIMITED   | TRAZODONE HYDROCHLORIDE 150 MG FILM-COATED TABLETS                | TRAZODONE HYDROCHLORIDE          | 150.00   | MILLIGRAMMES                | POM          |
| PL 41947/0036 | 27/06/2018 | ELC GROUP SRO                  | ERTAPENEM ELC 1G POWDER FOR CONCENTRATE FOR SOLUTION FOR INFUSION | ERTAPENEM SODIUM                 | 1.046    | GRAMMES                     | POM          |
| PL 20416/0500 | 29/06/2018 | CRESCENT PHARMA LIMITED        | SILDENAFIL CRESCENT 25MG FILM-COATED TABLETS                      | SILDENAFIL CITRATE               | 35.121   | MILLIGRAMMES                | POM          |
| PL 20416/0501 | 29/06/2018 | CRESCENT PHARMA LIMITED        | SILDENAFIL CRESCENT 50MG FILM-COATED TABLETS                      | SILDENAFIL CITRATE               | 70.241   | MILLIGRAMMES                | POM          |
| PL 20416/0502 | 29/06/2018 | CRESCENT PHARMA LIMITED        | SILDENAFIL CRESCENT 100MG FILM-COATED TABLETS                     | SILDENAFIL CITRATE               | 140.482  | MILLIGRAMMES                | POM          |
| PL 35501/0017 | 29/06/2018 | HCS BVBA                       | EVEROLIMUS HCS 2.5 MG TABLETS                                     | EVEROLIMUS                       | 2.5      | MILLIGRAMMES                | POM          |
| PL 35501/0018 | 29/06/2018 | HCS BVBA                       | EVEROLIMUS HCS 5 MG TABLETS                                       | EVEROLIMUS                       | 5        | MILLIGRAMMES                | POM          |
| PL 35501/0019 | 29/06/2018 | HCS BVBA                       | EVEROLIMUS HCS 10 MG TABLETS                                      | EVEROLIMUS                       | 10       | MILLIGRAMMES                | POM          |