

### Marketing authorisations granted in September 2018

| PL Number     | Grant Date | MA Holder                               | Licensed Name(s)  | Active Ingredient   | Quantity | Units        | Legal Status |
|---------------|------------|---|---|---|----------|--------------|--------------|
| PL 11311/0592 | 04/09/2018 | TILLOMED LABORATORIES LIMITED           | FLECAINIDE ACETATE 50 MG TABLETS                        | FLECAINIDE ACETATE  | 50       | MILLIGRAMMES | POM          |
| PL 11311/0593 | 04/09/2018 | TILLOMED LABORATORIES LIMITED           | FLECAINIDE ACETATE 100 MG TABLETS                       | FLECAINIDE ACETATE  | 100      | MILLIGRAMMES | POM          |
| PL 31750/0137 | 04/09/2018 | SUN PHARMACEUTICAL INDUSTRIES EUROPE BV | EPOPROSTENOL 0.5 MG POWDER FOR SOLUTION FOR INFUSION    | EPOPROSTENOL SODIUM   | 0.531    | MILLIGRAMMES | POM          |
| PL 31750/0138 | 04/09/2018 | SUN PHARMACEUTICAL INDUSTRIES EUROPE BV | EPOPROSTENOL 1.5 MG POWDER FOR SOLUTION FOR INFUSION    | EPOPROSTENOL SODIUM   | 1.593    | MILLIGRAMMES | POM          |
| PL 44124/0005 | 04/09/2018 | PANPHARMA                               | FLUCLOXACILLIN 500MG, POWDER FOR SOLUTION FOR INJECTION | FLUCLOXACILLIN SODIUM   | 544.00   | MILLIGRAMMES | POM          |
| PL 44124/0010 | 04/09/2018 | PANPHARMA                               | FLUCLOXACILLIN 250MG, POWDER FOR SOLUTION FOR INJECTION | FLUCLOXACILLIN SODIUM   | 272.00   | MILLIGRAMMES | POM          |
| PL 44124/0011 | 04/09/2018 | PANPHARMA                               | FLUCLOXACILLIN 1G, POWDER FOR SOLUTION FOR INJECTION    | FLUCLOXACILLIN SODIUM   | 1.08     | GRAMMES      | POM          |
| PL 00010/0665 | 05/09/2018 | BAYER PLC                               | RENNIE 680MG/80MG ORAL POWDER                           | CALCIUM CARBONATE   | 680      | MILLIGRAMMES | GSL          |
| PL 00010/0665 | 05/09/2018 | BAYER PLC                               | RENNIE 680MG/80MG ORAL POWDER                           | MAGNESIUM CARBONATE HEAVY   | 80       | MILLIGRAMMES | GSL          |
| PL 20416/0540 | 05/09/2018 | CRESCENT PHARMA LIMITED                 | OLMESARTAN MEDOXOMIL 10MG FILM COATED-TABLETS           | OLMESARTAN MEDOXOMIL  | 10       | MILLIGRAMMES | POM          |
| PL 20416/0541 | 05/09/2018 | CRESCENT PHARMA LIMITED                 | OLMESARTAN MEDOXOMIL 20MG FILM COATED-TABLETS           | OLMESARTAN MEDOXOMIL  | 20       | MILLIGRAMMES | POM          |
| PL 20416/0542 | 05/09/2018 | CRESCENT PHARMA LIMITED                 | OLMESARTAN MEDOXOMIL 40MG FILM COATED-TABLETS           | OLMESARTAN MEDOXOMIL  | 40       | MILLIGRAMMES | POM          |
| PL 25258/0277 | 05/09/2018 | GLENMARK PHARMACEUTICALS EUROPE LIMITED | GEFITINIB GLENMARK 250 MG FILM-COATED TABLETS           | GEFITINIB   | 250.00   | MILLIGRAMMES | POM          |
| PL 04416/1523 | 06/09/2018 | SANDOZ LIMITED                          | LENALIDOMIDE SANDOZ 2.5 MG HARD CAPSULES                | LENALIDOMIDE  | 2.50     | MILLIGRAMMES | POM          |
| PL 04416/1524 | 06/09/2018 | SANDOZ LIMITED                          | LENALIDOMIDE SANDOZ 5 MG HARD CAPSULES                  | LENALIDOMIDE  | 5.00     | MILLIGRAMMES | POM          |
| PL 04416/1525 | 06/09/2018 | SANDOZ LIMITED                          | LENALIDOMIDE SANDOZ 7.5MG HARD CAPSULES                 | LENALIDOMIDE  | 7.50     | MILLIGRAMMES | POM          |
| PL 04416/1526 | 06/09/2018 | SANDOZ LIMITED                          | LENALIDOMIDE SANDOZ 10 MG HARD CAPSULES                 | LENALIDOMIDE  | 10.00    | MILLIGRAMMES | POM          |
| PL 04416/1527 | 06/09/2018 | SANDOZ LIMITED                          | LENALIDOMIDE SANDOZ 15 MG HARD CAPSULES                 | LENALIDOMIDE  | 15.00    | MILLIGRAMMES | POM          |
| PL 04416/1528 | 06/09/2018 | SANDOZ LIMITED                          | LENALIDOMIDE SANDOZ 20 MG HARD CAPSULES                 | LENALIDOMIDE  | 20.00    | MILLIGRAMMES | POM          |
| PL 04416/1529 | 06/09/2018 | SANDOZ LIMITED                          | LENALIDOMIDE SANDOZ 25 MG HARD CAPSULES                 | LENALIDOMIDE  | 25.00    | MILLIGRAMMES | POM          |
| PL 15072/0018 | 06/09/2018 | APOGEPHA ARZNEIMITTEL GMBH              | APONORM XL 45 MG MODIFIED-RELEASE CAPSULES              | PROPIVERINE HYDROCHLORIDE   | 45       | MILLIGRAMMES | POM          |
| PL 16363/0540 | 06/09/2018 | MILPHARM LIMITED                        | CO-AMOXICLAV 250MG/125MG FILM-COATED TABLETS            | AMOXICILLIN TRIHYDRATE  | 286.960  | MILLIGRAMMES | POM          |
| PL 16363/0540 | 06/09/2018 | MILPHARM LIMITED                        | CO-AMOXICLAV 250MG/125MG FILM-COATED TABLETS            | POTASSIUM CLAVULANATE (1:1) MIXTURE WITH CELLULOSE MICROCRYSTALLINE | 297.620  | MILLIGRAMMES | POM          |
| PL 40739/0171 | 06/09/2018 | ENNOGEN HEALTHCARE LIMITED              | VITAMIN B COMPOUND TABLETS BPC                          | NICOTINAMIDE  | 15       | MILLIGRAMMES | P            |
| PL 40739/0171 | 06/09/2018 | ENNOGEN HEALTHCARE LIMITED              | VITAMIN B COMPOUND TABLETS BPC                          | RIBOFLAVIN  | 1        | MILLIGRAMMES | P            |
| PL 40739/0171 | 06/09/2018 | ENNOGEN HEALTHCARE LIMITED              | VITAMIN B COMPOUND TABLETS BPC                          | THIAMINE HYDROCHLORIDE  | 1        | MILLIGRAMMES | P            |
| PL 00289/2202 | 07/09/2018 | TEVA UK LIMITED                         | MELATONIN TEVA XL 2 MG PROLONGED RELEASE TABLETS        | MELATONIN   | 2.00     | MILLIGRAMMES | POM          |
| PL 00289/2203 | 07/09/2018 | TEVA UK LIMITED                         | CELTON XL 2 MG PROLONGED-RELEASE TABLETS                | MELATONIN   | 2.00     | MILLIGRAMMES | POM          |
| PL 20075/1167 | 07/09/2018 | ACCORD HEALTHCARE LIMITED               | FEBUXOSTAT ACCORD 80 MG FILM-COATED TABLETS             | FEBUXOSTAT  | 80.00    | MILLIGRAMMES | POM          |
| PL 20075/1168 | 07/09/2018 | ACCORD HEALTHCARE LIMITED               | FEBUXOSTAT ACCORD 120 MG FILM-COATED TABLET             | FEBUXOSTAT  | 120.00   | MILLIGRAMMES | POM          |
| PL 40800/0021 | 10/09/2018 | DEVELCO PHARMA GMBH                     | FOCUSIM XL 10 MG MODIFIED-RELEASE HARD CAPSULES         | METHYLPHENIDATE HYDROCHLORIDE                                       | 10.00    | MILLIGRAMMES | POM          |

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| PL 40800/0022 | 10/09/2018 | DEVELCO PHARMA GMBH             | FOCUSIM XL 20 MG MODIFIED-RELEASE HARD CAPSULES                        | METHYLPHENIDATE HYDROCHLORIDE | 20.00    | MILLIGRAMMES                | POM          |
| PL 40800/0023 | 10/09/2018 | DEVELCO PHARMA GMBH             | FOCUSIM XL 30 MG MODIFIED-RELEASE HARD CAPSULES                        | METHYLPHENIDATE HYDROCHLORIDE | 30.00    | MILLIGRAMMES                | POM          |
| PL 40800/0024 | 10/09/2018 | DEVELCO PHARMA GMBH             | FOCUSIM XL 40 MG MODIFIED-RELEASE HARD CAPSULES                        | METHYLPHENIDATE HYDROCHLORIDE | 40.00    | MILLIGRAMMES                | POM          |
| PL 20162/0027 | 11/09/2018 | LABORATOIRES THEA               | CARTEOLOL HYDROCHLORIDE THEA 20MG/ML, EYE DROPS, SOLUTION              | CARTEOLOL HYDROCHLORIDE       | 20       | MILLIGRAMMES PER MILLILITRE | POM          |
| PL 20416/0489 | 11/09/2018 | CRESCENT PHARMA LIMITED         | LOSARTAN POTASSIUM 25MG FILM-COATED TABLETS                            | LOSARTAN POTASSIUM            | 25.00    | MILLIGRAMMES                | POM          |
| PL 20416/0490 | 11/09/2018 | CRESCENT PHARMA LIMITED         | LOSARTAN POTASSIUM 50MG FILM-COATED TABLETS                            | LOSARTAN POTASSIUM            | 50.00    | MILLIGRAMMES                | POM          |
| PL 20416/0565 | 11/09/2018 | CRESCENT PHARMA LIMITED         | LOSARTAN POTASSIUM 100MG FILM-COATED TABLETS                           | LOSARTAN POTASSIUM            | 100.00   | MILLIGRAMMES                | POM          |
| PL 30684/0248 | 11/09/2018 | DAWA LIMITED                    | CARBIMAZOLE 5MG TABLETS  | CARBIMAZOLE                   | 5        | MILLIGRAMMES                | POM          |
| PL 30684/0249 | 11/09/2018 | DAWA LIMITED                    | CARBIMAZOLE 20MG TABLETS   | CARBIMAZOLE                   | 20       | MILLIGRAMMES                | POM          |
| PL 39541/0009 | 11/09/2018 | ASCOT LABORATORIES LIMITED      | METHADONE HYDROCHLORIDE 5 MG TABLETS                                   | METHADONE HYDROCHLORIDE       | 5        | MILLIGRAMMES                | POM          |
| PL 40546/0022 | 11/09/2018 | ARISTO PHARMA GMBH              | METHOCARBAMOL ARISTO 750 MG FILM-COATED TABLETS                        | METHOCARBAMOL                 | 750.00   | MILLIGRAMMES                | POM          |
| PL 40546/0039 | 11/09/2018 | ARISTO PHARMA GMBH              | METHOCARBAMOL 750 MG FILM-COATED TABLETS                               | METHOCARBAMOL                 | 750.00   | MILLIGRAMMES                | POM          |
| PL 46788/0014 | 11/09/2018 | ALTAN PHARMA LIMITED            | LEVOBUPIVACAINE ALTAN 0.625 MG/ML SOLUTION FOR INFUSION                | LEVOBUPIVACAINE HYDROCHLORIDE | 0.7041   | MILLIGRAMMES PER MILLILITRE | POM          |
| PL 46788/0015 | 11/09/2018 | ALTAN PHARMA LIMITED            | LEVOBUPIVACAINE ALTAN 1.25 MG/ML SOLUTION FOR INFUSION                 | LEVOBUPIVACAINE HYDROCHLORIDE | 1.41     | MILLIGRAMMES PER MILLILITRE | POM          |
| PL 46788/0016 | 11/09/2018 | ALTAN PHARMA LIMITED            | LEVOBUPIVACAINE ALTAN 2.5 MG/ML SOLUTION FOR INJECTION/INFUSION        | LEVOBUPIVACAINE HYDROCHLORIDE | 2.618    | MILLIGRAMMES PER MILLILITRE | POM          |
| PL 46788/0017 | 11/09/2018 | ALTAN PHARMA LIMITED            | LEVOBUPIVACAINE ALTAN 5 MG/ML SOLUTION FOR INJECTION/INFUSION          | LEVOBUPIVACAINE HYDROCHLORIDE | 5.633    | MILLIGRAMMES PER MILLILITRE | POM          |
| PL 46788/0018 | 11/09/2018 | ALTAN PHARMA LIMITED            | LEVOBUPIVACAINE ALTAN 7.5 MG/ML SOLUTION FOR INJECTION/INFUSION        | LEVOBUPIVACAINE HYDROCHLORIDE | 8.449    | MILLIGRAMMES PER MILLILITRE | POM          |
| PL 20075/1225 | 12/09/2018 | ACCORD HEALTHCARE LIMITED       | ETORICOXIB 30 MG FILM-COATED TABLETS                                   | ETORICOXIB                    | 30       | MILLIGRAMMES                | POM          |
| PL 20075/1226 | 12/09/2018 | ACCORD HEALTHCARE LIMITED       | ETORICOXIB 60 MG FILM-COATED TABLETS                                   | ETORICOXIB                    | 60       | TABLETS                     | POM          |
| PL 20075/1239 | 12/09/2018 | ACCORD HEALTHCARE LIMITED       | ETORICOXIB 90 MG FILM-COATED TABLETS                                   | ETORICOXIB                    | 90       | TABLETS                     | POM          |
| PL 20075/1240 | 12/09/2018 | ACCORD HEALTHCARE LIMITED       | ETORICOXIB 120 MG FILM-COATED TABLETS                                  | ETORICOXIB                    | 120      | MILLIGRAMMES                | POM          |
| PL 35533/0128 | 12/09/2018 | ASPIRE PHARMA LIMITED           | BIMATOPROST ASPIRE 0.3MG/ML EYE DROPS, SOLUTION, SINGLE-DOSE CONTAINER | BIMATOPROST                   | 0.30     | MILLIGRAMMES PER MILLILITRE | POM          |
| PL 17509/0088 | 13/09/2018 | INTRAPHARM LABORATORIES LIMITED | LEVETIRACETAM 100 MG/ML CONCENTRATE FOR SOLUTION FOR INFUSION          | LEVETIRACETAM                 | 100.00   | MILLIGRAMMES PER MILLILITRE | POM          |
| PL 25298/0145 | 13/09/2018 | BROWN & BURK UK LIMITED         | AZELASTINE HYDROCHLORIDE 0.5MG/ML EYE DROPS, SOLUTION                  | AZELASTINE HYDROCHLORIDE      | 0.500    | MILLIGRAMMES PER MILLILITRE | POM          |
| PL 31603/0020 | 13/09/2018 | APOLLO GENERICS LIMITED         | CO-CODAMOL 30/500MG EFFERVESCENT TABLETS                               | CODEINE PHOSPHATE HEMIHYDRATE | 30       | MILLIGRAMMES                | POM          |
| PL 31603/0020 | 13/09/2018 | APOLLO GENERICS LIMITED         | CO-CODAMOL 30/500MG EFFERVESCENT TABLETS                               | PARACETAMOL                   | 500      | MILLIGRAMMES                | POM          |
| PL 44710/0025 | 13/09/2018 | KINEDEXE UK LIMITED             | SIMVASTATIN 20MG GRANULES FOR ORAL SUSPENSION IN SACHET                | SIMVASTATIN                   | 20.000   | MILLIGRAMMES                | POM          |
| PL 44710/0026 | 13/09/2018 | KINEDEXE UK LIMITED             | SIMVASTATIN 40MG GRANULES FOR ORAL SUSPENSION IN SACHET                | SIMVASTATIN                   | 40.000   | MILLIGRAMMES                | POM          |
| PL 17277/0380 | 14/09/2018 | PHARMATHEN SA                   | ELSTABYA 80 MG FILM-COATED TABLET                                      | FEBUXOSTAT                    | 80.00    | MILLIGRAMMES                | POM          |
| PL 17277/0381 | 14/09/2018 | PHARMATHEN SA                   | ELSTABYA 120MG FILM-COATED TABLETS                                     | FEBUXOSTAT                    | 120.00   | MILLIGRAMMES                | POM          |
| PL 17780/0825 | 14/09/2018 | ZENTIVA PHARMA UK LIMITED       | ATOMOXETINE 10 MG HARD CAPSULES  | ATOMOXETINE HYDROCHLORIDE     | 11.42    | MILLIGRAMMES                | POM          |

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| PL 17780/0826 | 14/09/2018 | ZENTIVA PHARMA UK LIMITED   | ATOMOXETINE 18 MG HARD CAPSULES   | ATOMOXETINE HYDROCHLORIDE | 20.55    | MILLIGRAMMES                | POM          |
| PL 17780/0827 | 14/09/2018 | ZENTIVA PHARMA UK LIMITED   | ATOMOXETINE 25 MG HARD CAPSULES   | ATOMOXETINE HYDROCHLORIDE | 28.55    | MILLIGRAMMES                | POM          |
| PL 17780/0828 | 14/09/2018 | ZENTIVA PHARMA UK LIMITED   | ATOMOXETINE 40 MG HARD CAPSULES   | ATOMOXETINE HYDROCHLORIDE | 45.68    | MILLIGRAMMES                | POM          |
| PL 17780/0829 | 14/09/2018 | ZENTIVA PHARMA UK LIMITED   | ATOMOXETINE 60 MG HARD CAPSULES   | ATOMOXETINE HYDROCHLORIDE | 68.52    | MILLIGRAMMES                | POM          |
| PL 17780/0830 | 14/09/2018 | ZENTIVA PHARMA UK LIMITED   | ATOMOXETINE 80 MG HARD CAPSULES   | ATOMOXETINE HYDROCHLORIDE | 91.36    | MILLIGRAMMES                | POM          |
| PL 17780/0831 | 14/09/2018 | ZENTIVA PHARMA UK LIMITED   | ATOMOXETINE 100 MG HARD CAPSULES  | ATOMOXETINE HYDROCHLORIDE | 114.2    | MILLIGRAMMES                | POM          |
| PL 19156/0141 | 18/09/2018 | JUBILANT PHARMACEUTICALS NV | CANDESARTAN CILEXETIL JUBILANT 4 MG TABLETS                             | CANDESARTAN CILEXETIL     | 4        | MILLIGRAMMES                | POM          |
| PL 19156/0142 | 18/09/2018 | JUBILANT PHARMACEUTICALS NV | CANDESARTAN CILEXETIL JUBILANT 8 MG TABLETS                             | CANDESARTAN CILEXETIL     | 8        | MILLIGRAMMES                | POM          |
| PL 19156/0143 | 18/09/2018 | JUBILANT PHARMACEUTICALS NV | CANDESARTAN CILEXETIL JUBILANT 16 MG TABLETS                            | CANDESARTAN CILEXETIL     | 16       | MILLIGRAMMES                | POM          |
| PL 19156/0144 | 18/09/2018 | JUBILANT PHARMACEUTICALS NV | CANDESARTAN CILEXETIL JUBILANT 32 MG TABLETS                            | CANDESARTAN CILEXETIL     | 32       | MILLIGRAMMES                | POM          |
| PL 26351/0004 | 19/09/2018 | BIOPROJET PHARMA            | HIDRASEC 175MG FILM-COATED TABLETS                                      | RACECADOTRIL              | 175      | MILLIGRAMMES                | POM          |
| PL 40739/0041 | 20/09/2018 | ENNOGEN HEALTHCARE LIMITED  | ISOTRETINOIN 10 MG CAPSULES, SOFT                                       | ISOTRETINOIN              | 10       | MILLIGRAMMES                | POM          |
| PL 42852/0016 | 24/09/2018 | GENERIC PARTNERS UK LIMITED | MELATONIN GENERIC PARTNERS 2 MG PROLONGED-RELEASE TABLETS               | MELATONIN                 | 2        | MILLIGRAMMES                | POM          |
| PL 40546/0061 | 25/09/2018 | ARISTO PHARMA GMBH          | FEBUXOSTAT ARISTO 80MG FILM-COATED TABLETS                              | FEBUXOSTAT                | 80.00    | MILLIGRAMMES                | POM          |
| PL 40546/0062 | 25/09/2018 | ARISTO PHARMA GMBH          | FEBUXOSTAT ARISTO 120MG FILM-COATED TABLETS                             | FEBUXOSTAT                | 120.00   | MILLIGRAMMES                | POM          |
| PL 41987/0016 | 25/09/2018 | HEC PHARM GMBH              | ENTACAPONE HEC 200 MG FILM-COATED TABLETS                               | ENTACAPONE                | 200      | MILLIGRAMMES                | POM          |
| PL 35533/0139 | 26/09/2018 | ASPIRE PHARMA LIMITED       | SOLIFENACIN SUCCINATE 5 MG FILM-COATED TABLETS                          | SOLIFENACIN SUCCINATE     | 5        | MILLIGRAMMES                | POM          |
| PL 35533/0140 | 26/09/2018 | ASPIRE PHARMA LIMITED       | SOLIFENACIN SUCCINATE 10 MG FILM-COATED TABLETS                         | SOLIFENACIN SUCCINATE     | 10       | MILLIGRAMMES                | POM          |
| PL 30684/0267 | 27/09/2018 | DAWA LIMITED                | HALOPERIDOL 5MG/ML SOLUTION FOR INJECTION                               | HALOPERIDOL               | 5.00     | MILLIGRAMMES                | POM          |
| PL 48278/0010 | 27/09/2018 | EYWA PHARMA LIMITED         | TRAZODONE HYDROCHLORIDE 50MG HARD CAPSULES                              | TRAZODONE HYDROCHLORIDE   | 50       | MILLIGRAMMES                | POM          |
| PL 48278/0011 | 27/09/2018 | EYWA PHARMA LIMITED         | TRAZODONE HYDROCHLORIDE 100MG HARD CAPSULES                             | TRAZODONE HYDROCHLORIDE   | 100      | MILLIGRAMMES                | POM          |
| PL 43801/0055 | 28/09/2018 | SCIECURE PHARMA LIMITED     | CISATRACURIUM BESILATE SCIECURE 2 MG/ML SOLUTION FOR INJECTION/INFUSION | CISATRACURIUM BESILATE    | 26.765   | MILLIGRAMMES                | POM          |
| PL 43801/0056 | 28/09/2018 | SCIECURE PHARMA LIMITED     | CISATRACURIUM BESILATE SCIECURE 5 MG/ML SOLUTION FOR INJECTION/INFUSION | CISATRACURIUM BESILATE    | 200.737  | MILLIGRAMMES PER MILLILITRE | POM          |