

| Tradename                       | Strength                       | Pharmaceutical form   | Marketing authorisation holder             |
|---------------------------------|--------------------------------|---|--|
| <b>Approved authorisations</b>  |                                |   |  |
| Acirasi                         | 125 mikrog + 50 mikrog / annos | nasal spray, suspension   | Adalvo Limited                             |
| Ampicillin STADA Nordic         | 1 g                            | powder for solution for injection/infusion                        | STADA Nordic ApS                           |
| Ampicillin STADA Nordic         | 2 g                            | powder for solution for injection/infusion                        | STADA Nordic ApS                           |
| Azacididine Hikma               | 25 mg/ml                       | powder for suspension for injection                               | Hikma Farmacêutica (Portugal) S.A.         |
| Carbidopa/Levodopa Orion        | 25 mg / 250 mg                 | tablet  | Orion Corporation                          |
| Cequa                           | 0.9 mg/ml                      | eye drops, solution in single-dose container                      | Sun Pharmaceutical Industries Europe B.V.  |
| Dapagliflozin Devatis           | 10 mg                          | film-coated tablet  | Devatis GmbH                               |
| Dapagliflozin Devatis           | 5 mg                           | film-coated tablet  | Devatis GmbH                               |
| Edoxaban Krka                   | 60 mg                          | film-coated tablet  | KRKA d.d. Novo mesto                       |
| Edoxaban Krka                   | 15 mg                          | film-coated tablet  | KRKA d.d. Novo mesto                       |
| Edoxaban Krka                   | 30 mg                          | film-coated tablet  | KRKA d.d. Novo mesto                       |
| Esomeprazol Hexal               | 20 mg                          | gastro-resistant tablet   | Hexal A/S                                  |
| Esomeprazol Hexal               | 40 mg                          | gastro-resistant tablet   | Hexal A/S                                  |
| Havrix                          | 1440 ELISA U/ml                | suspension for injection  | GlaxoSmithKline Biologicals SA             |
| Havrix                          | 720 ELISA U/0.5 ml             | suspension for injection in pre-filled syringe                    | GlaxoSmithKline Biologicals SA             |
| Ivermectin Glenmark             | 3 mg                           | tablet  | Glenmark Arzneimittel GmbH                 |
| Ivermectin Orion                | 3 mg                           | tablet  | Orion Corporation                          |
| Lanreotid Zentiva               | 90 mg                          | solution for injection in pre-filled syringe                      | Zentiva k.s.                               |
| Lanreotid Zentiva               | 60 mg                          | solution for injection in pre-filled syringe                      | Zentiva k.s.                               |
| Lanreotid Zentiva               | 120 mg                         | solution for injection in pre-filled syringe                      | Zentiva k.s.                               |
| Obupro                          | 4 mg/ml                        | eye drops, solution   | AGEPHA Pharma s.r.o                        |
| Rogaine                         | 50 mg/g                        | cutaneous foam  | McNeil / JNTL Consumer Health (Finland) Oy |
| Trelema                         | 10 mg/ml                       | solution for infusion   | G.L. Pharma GmbH                           |
| Vepesid                         | 50 mg                          | capsule, soft   | Abacus Medicine A/S                        |
| Waysus                          | 125 mikrog + 50 mikrog / annos | nasal spray, suspension   | Adalvo Limited                             |
| Zonisamide Desitin              | 20 mg/ml                       | oral suspension   | Desitin Arzneimittel GmbH                  |
| <b>Cancelled authorisations</b> |                                |   |  |
| Alfacalcidol Orifarm            | 0.5 microgram(s)               | capsule, soft   | Orifarm Generics A/S                       |
| Alfacalcidol Orifarm            | 0.25 microgram(s)              | capsule, soft   | Orifarm Generics A/S                       |
| Alfacalcidol Orifarm            | 1 microgram(s)                 | capsule, soft   | Orifarm Generics A/S                       |
| Amekrin                         | 75 mg / 1.5 ml                 | concentrate and solvent for concentrate for solution for infusion | Eurocept International BV                  |
| Anagrelide ratiopharm           | 0.5 mg                         | capsule, hard   | Teva B.V.                                  |
| Atenolol Sandoz                 | 25 mg                          | tablet  | Sandoz GmbH                                |
| Atenolol Sandoz                 | 50 mg                          | tablet  | Sandoz GmbH                                |
| Atorvastatin Viatris            | 10 mg                          | film-coated tablet  | Upjohn EESV                                |
| Atorvastatin Viatris            | 40 mg                          | film-coated tablet  | Upjohn EESV                                |
| Atorvastatin Viatris            | 80 mg                          | film-coated tablet  | Upjohn EESV                                |

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| Atorvastatin Viatris                   | 20 mg                        | film-coated tablet                    | Upjohn EESV  |
| Bafucin                                |                              | lozenge                               | McNeil / JNTL Consumer Health (Finland) Oy                 |
| Bafucin Mint                           |                              | lozenge                               | McNeil / JNTL Consumer Health (Finland) Oy                 |
| Bio-E-Vitamin                          | 350 mg                       | capsule, soft                         | Pharma Nord ApS  |
| Ditekipol                              |                              | suspension for injection              | AJ Vaccines A/S  |
| Felden                                 | 0.5 percent                  | gel                                   | Pfizer Oy  |
| Fluvastatin Viatris                    | 80 mg                        | prolonged-release tablet              | Viatris Limited  |
| GalliaPharm                            | 0.74-1.85 GBq                | radionuclide generator                | Eckert & Ziegler Radiopharma GmbH                          |
| Hippomectin                            | 12 mg/g                      | oral gel                              | Le Vet. B.V.   |
| Ibuprofen Accord                       | 400 mg                       | film-coated tablet                    | Accord Healthcare B.V.                                     |
| Ibuprofen Accord                       | 600 mg                       | film-coated tablet                    | Accord Healthcare B.V.                                     |
| Iloprost Zentiva                       | 10 microgram(s)/millilitre   | nebuliser solution                    | Zentiva, k.s.  |
| Iloprost Zentiva                       | 20 microgram(s)/millilitre   | nebuliser solution                    | Zentiva, k.s.  |
| Indometin                              | 50 mg                        | capsule, hard                         | Orion Corporation  |
| Lopinavir/Ritonavir Accord             | 200 mg / 50 mg               | film-coated tablet                    | Accord Healthcare B.V.                                     |
| Losarstad                              | 100 mg                       | film-coated tablet                    | STADA Arzneimittel AG                                      |
| Losarstad                              | 12.5 mg                      | film-coated tablet                    | STADA Arzneimittel AG                                      |
| Losarstad                              | 50 mg                        | film-coated tablet                    | STADA Arzneimittel AG                                      |
| Losarstad Comp                         | 50 mg / 12.5 mg              | film-coated tablet                    | STADA Arzneimittel AG                                      |
| Losarstad Comp                         | 100 mg / 25 mg               | film-coated tablet                    | STADA Arzneimittel AG                                      |
| Methadone Martindale Pharma            | 2 mg/ml                      | oral solution                         | Ethypharm  |
| Nuvaring                               | 0.120 mg / 0.015 mg per 24 h | vaginal delivery system               | Orifarm Oy   |
| Olmesartan medoxomil/Amlodipine Accord | 20 mg / 5 mg                 | film-coated tablet                    | Accord Healthcare B.V.                                     |
| Olmesartan medoxomil/Amlodipine Accord | 40 mg / 10 mg                | film-coated tablet                    | Accord Healthcare B.V.                                     |
| Oramorph                               | 2 mg/ml                      | oral solution in single-dose ampoule  | L.Molteni & C.dei F.Ili Alitti Società di Esercizio S.p.A. |
| Oramorph                               | 6 mg/ml                      | oral solution in single-dose ampoule  | L.Molteni & C.dei F.Ili Alitti Società di Esercizio S.p.A. |
| Oramorph                               | 20 mg/ml                     | oral solution in single-dose ampoule  | L.Molteni & C.dei F.Ili Alitti Società di Esercizio S.p.A. |
| Otimectin vet.                         | 1 mg/g                       | ear gel                               | Le Vet. B.V.   |
| Rybrila                                | 160 microgram(s)/millilitre  | oral solution                         | Clinigen Healthcare B.V.                                   |
| Silotoc                                | 50 mg                        | film-coated tablet                    | Opella Healthcare France SAS                               |
| Sporanox                               | 10 mg/ml                     | oral solution                         | Janssen-Cilag Oy   |
| Tenofovir disoproxil Accordpharma      | 245 mg                       | film-coated tablet                    | Accord Healthcare B.V.                                     |
| Tolterodin Viatris                     | 2 mg                         | prolonged-release capsule, hard       | Upjohn EESV  |
| Tolterodin Viatris                     | 2 mg                         | film-coated tablet                    | Upjohn EESV  |
| Tolterodin Viatris                     | 1 mg                         | film-coated tablet                    | Upjohn EESV  |
| Tsoledronihappo Hameln                 | 4 mg / 5 ml                  | concentrate for solution for infusion | Hameln Pharma GmbH   |
| Venlafaxin ratiopharm                  | 150 mg                       | prolonged-release capsule, hard       | Teva B.V.  |
| Venlafaxin ratiopharm                  | 75 mg                        | prolonged-release capsule, hard       | Teva B.V.  |
| Venlafaxin ratiopharm                  | 37.5 mg                      | prolonged-release capsule, hard       | Teva B.V.  |