

NEW DRUGS APPROVED IN 2005

Healthcare professionals are encouraged to report all suspected adverse drug reactions (both serious and non-serious) to new drugs. Your active participation in the adverse drug reaction monitoring programme will provide valuable support to the ongoing post-marketing surveillance on drug safety.

New Chemical/Biological Entity	Pharmacotherapeutic Group
Atomoxetine 10 mg, 18 mg, 25 mg, 40 mg, 60 mg Strattera [®] capsule	Agents for attention deficit hyperactivity disorder (POM)
Bevacizumab 25 mg/ml Avastin [®] concentrate for infusion	Antineoplastic agents (POM)
Bicisate 0.9 mg Neurolite [®] kit for preparation of technetium Tc99m bicisate injection	Diagnostic radiopharmaceuticals (POM)
Bortezomib 3.5 mg Velcade [®] powder for solution for injection	Antineoplastic agents (POM)
Butoconazole 2% w/w Gynofort [®] vaginal cream	Imidazole antifungal agents (P)
Cetuximab 2 mg/ml Erbix [®] solution for injection	Antineoplastic agents (POM)
Dexketoprofen 25 mg Kettese [®] film-coated tablet	Nonsteroidal anti-inflammatory agents (POM)
Efalizumab 125 mg/1.25 ml Raptiva [®] powder for solution for injection	Immunosuppressive agents (POM)
Enfuvirtide 90 mg/ml Fuzeon [®] powder for solution for injection	Antivirals (POM)
Eplerenone 25 mg, 50 mg Inspra [®] coated tablet	Potassium-sparing diuretics (POM)
Iloprost 0.01 mg/ml Ventavis [®] solution for nasal inhalation	Prostaglandins (POM)
Insulin detemir 100 iu/ml Levemir Flexpen [®] , Levemir Penfill [®]	Drugs used in diabetes (POM)
Insulin glulisine 100 iu/ml Apidra [®] solution for injection in cartridge/OptiSet/vial	Drugs used in diabetes (POM)
Oxycodone 5 mg, 10 mg, 20 mg Oxynorm [®] capsule	Opioid analgesics (POM)
Oxycodone 5 mg, 10 mg, 20 mg, 40 mg, 80 mg Oxycontin [®] film-coated prolonged release tablet	Opioid analgesics (POM)
Pegvisomant 10 mg, 15 mg, 20 mg Somavert [®] powder for solution for injection	Anterior pituitary lobe hormone and analogues (POM)
Pregabalin 25 mg, 50 mg, 75 mg, 100 mg, 150 mg, 200 mg, 300 mg Lyrica [®] capsule	Anti-epileptics (POM)
Rotavirus, live attenuated Rotarix [®] powder for oral suspension	Vaccines (POM)
Tetrakis copper tetrafluoroborate Cardiolite [®] kit for preparation of technetium Tc99m sestamibi injection	Diagnostic radiopharmaceuticals (POM)
Thyrotropin alfa 1.1 mg Thyrogen [®] powder for solution for injection	Diagnostic agents - thyroid function (POM)

New Combination	Pharmacotherapeutic Group
Alendronic acid 70 mg, colecalciferol 70 mcg eqv to Vitamin D (2800 iu) Fosamax Plus [®] tablet	Bisphosphonate and calcium (POM)
Amlodipine and atorvastatin 5/10, 5/20, 5/40, 5/80, 10/10, 10/20, 10/40, 10/80 mg Caduet [®] film-coated tablet	Calcium channel blocker and HMG CoA reductase inhibitor combination (POM)
Carbidopa, entacapone and levodopa, 12.5/200/50, 25/200/100, 37.5/200/150 mg Stalevo [®] film-coated tablet	Antiparkinson agents (POM)
Carbomer and carbopol 0.25% w/w Siccafluid [®] eye gel	Ophthalmologicals - artificial tears (GSL)
Etonogestrel 11.7 mg, ethinylestradiol 2.7 mg Nuvaring [®] intrauterine device	Hormonal contraceptives (POM)
New Formulation	Pharmacotherapeutic Group
Dexpanthenol (precursor of vitamin B5) 5% w/w Bepanthen [®] ointment	Preparations for treatment of wounds (GSL)
Ibandronic acid 2.5 mg Bonviva [®] film-coated tablet	Bisphosphonates (POM)
Phenytoin 125 mg/5 ml Dilantin [®] oral suspension	Anti-epileptics (POM)
Sirolimus 2 mg Rapamune [®] sugar-coated tablet	Immunosuppressive agents (POM)
Testosterone 1% w/w AndroGel [®] gel	Androgens (POM)
Varicella zoster virus, live attenuated Varivax [®] refrigerated injection	Vaccines (POM)

POM: Prescription only medicines; **P:** Pharmacy only medicines;

GSL: General sale list

Drugs are listed under the pharmacotherapeutic groups as defined by the Anatomical Therapeutic Chemical (ATC) classification produced by the WHO Collaborating Centre for Drug Statistics Methodology.

How to report:

The ADR reporting form can be obtained at http://www.hsa.gov.sg/adr_form, from medical clinics, pharmacies, hospitals/health institutions or the Pharmacovigilance (PV) Unit of the HSA. Please send the completed ADR reporting form either by mail, email or fax to the PV Unit. Online ADR reporting is available at http://www.hsa.gov.sg/adr_online

Where to send your report:

Pharmacovigilance Unit
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