

New Drugs Approved In 2004



The Pharmacovigilance Unit of the Centre for Drug Administration, HSA encourages the reporting of all suspected adverse drug reactions to the new drugs listed below. 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
Alemtuzumab 10 mg/ml Mabcampath [®] concentrate for solution for infusion	Antineoplastics (POM)
Anagrelide 0.5 mg Agrylin [®] capsule	Antithrombotics - platelet aggregation inhibitor (POM)
Aripiprazole 2 mg, 5 mg, 10 mg, 15mg, 20 mg, 30 mg Abilify [®] tablet	Antipsychotics (POM)
Atazanavir 100 mg, 150 mg, 200 mg capsule Reyataz [®] capsule	Antivirals (POM)
Bosentan 62.5 mg, 125 mg Tracleer [®] film-coated tablet	Antihypertensives - endothelin-receptor antagonist (POM)
Fluoro-2-deoxy-D-glucose 5 mCi-20 mCi/dose Fludeoxyglucose F 18 [®] injection	Diagnostic radiopharmaceuticals (POM)
Gadobenate dimeglumine 529 mg/ml Multihance [®] solution for injection	Contrast media - magnetic resonance imaging (POM)
Loteprednol 0.5% w/v Lotemax [®] ophthalmic suspension	Ophthalmologicals - glucocorticoids (POM)
Olmesartan 10 mg, 20 mg, 40 mg Olmotec [®] film-coated tablet	Angiotensin II antagonists (POM)
Pemetrexed 500 mg Alimta [®] powder for solution for infusion	Antineoplastics - folic acid analogues (POM)
Tazarotene 0.1% w/w Avage [®] cream	Dermatologicals - antipsoriatics (POM)
Teriparatide 750 mcg/3 ml Forteo [®] solution for injection	Parathyroid hormones and analogues (POM)
Zofenopril 30 mg Bifil [®] film-coated tablet	Angiotensin-converting enzyme inhibitors (POM)

How to report:

The ADR reporting form can be obtained at http://www.hsa.gov.sg/adr_form, from pharmacies, hospitals/health institutions or Pharmacovigilance Unit, Centre for Drug Administration. Please send the completed ADR reporting form either by mail, email or fax to the Pharmacovigilance Unit. Online ADR reporting is available at http://www.hsa.gov.sg/adr_online.

Where to send your report:

Pharmacovigilance Unit,
Centre for Drug Administration
Health Sciences Authority
11 Biopolis Way #11-03
Singapore 138667
Tel: 65 6866 3538
Fax: 65 6478 9069
Email: HSA_drugsafety@hsa.gov.sg

New dosage form	Pharmacotherapeutic group
Desloratadine 0.5 mg/ml Aerius [®] syrup Desalex [®] syrup	Antihistamines (POM)
Esomeprazole 40 mg Nexium [®] powder for solution for injection & infusion	Proton pump inhibitors (POM)
Galantamine 8 mg, 16 mg, 24 mg Reminyl [®] prolonged release capsule	Antidementia agents (POM)
Gatifloxacin 3 mg/ml 0.3% w/v Zymar [®] ophthalmic solution	Ophthalmologicals - fluoroquinolones (antibiotics) (POM)
Moxifloxacin 5 mg/ml or 0.5% w/v Vigamox [®] ophthalmic solution	Ophthalmologicals - fluoroquinolones (antibiotics) (POM)
Nicotine 2 mg, 4 mg Nicorette [®] chewing gum Nicotinell [®] chewing gum	Drugs used in nicotine dependence (P)
Nicotinic acid 375 mg, 500 mg, 750 mg, 1000 mg Niaspan [®] prolonged release tablet	Serum lipid reducing agents (POM)
Olanzapine 10 mg Zyprexa [®] intramuscular injection	Antipsychotics (POM)
Oseltamivir 12 mg/ml Tamiflu [®] powder for oral suspension	Antivirals (POM)
Sodium chloride 5% w/w Oftalmolosa Cusi Antiedema [®] eye ointment	Ophthalmologicals (POM)
Tacrolimus 0.03% w/w, 0.1% w/w Protopic [®] ointment	Dermatologicals - immunosuppressants (POM)
Vinorelbine 20 mg, 30 mg, 40 mg Navelbine [®] soft capsule	Antineoplastics - vinca alkaloids and analogues (POM)
Voriconazole 40 mg/ml Vfend [®] powder for oral suspension	Antifungals (POM)
New combination	Pharmacotherapeutic group
Ethambutol 275 mg, isoniazid 75 mg, pyrazinamide 400 mg, rifampicin 150 mg Merip [®] film-coated tablet	Antituberculous agents (POM)
Ezetimibe, simvastatin 10/10, 10/20, 10/40, 10/80 Vytorin [®] tablet	Antihyperlipidaemic agents (POM)
Fluocinolone 0.1 mg/g, hydroquinone 40 mg/g, tretinoin 0.5 mg/g Tri-luma [®] cream	Dermatologicals - corticosteroids and retinoids (POM)

POM: Prescription only medicines; P: Pharmacy only medicines

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.