

NEW DRUGS APPROVED IN 2006

Healthcare professionals are encouraged to report all serious and non-serious adverse drug reactions 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.

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 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,
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 chemical / biological entity	Pharmacotherapeutic group
Alefacept 7.5mg, 15mg Amevive® powder for solution for injection	Immunosuppressive agents (POM)
Duloxetine 30mg, 60mg Cymbalta® capsule	Antidepressants (POM)
Entecavir 0.5mg, 1mg, 0.05mg/ml Baraclude® film-coated tablet, oral solution	Antivirals (POM)
Erlotinib 25mg, 100mg, 150mg Tarceva® film-coated tablet	Antineoplastic agents (POM)
Everolimus 0.25mg, 0.5mg, 0.75mg, 1mg Certican® tablet Everolimus 0.1mg, 0.25mg Certican® dispersible tablet	Immunosuppressive agents (POM)
Fulvestrant 250mg/5ml Faslodex® solution for injection	Anti-oestrogens (POM)
Human papillomavirus (types 6,11,16,18) Gardasil® pre-filled syringe, solution for injection	Viral vaccines (POM)
Omalizumab 75mg, 100mg Xolair® powder for solution for injection	Agents for obstructive airway diseases (POM)
Pegaptanib 0.3mg/90µl Macugen® solution for injection	Ophthalmologic agents (POM)
Pegfilgrastim 6mg/0.6ml Neulastim® pre-filled syringe	Immunostimulating agents – colony stimulating factors (POM)
Strontium ranelate (anhydrous) 2000mg Protos® granules for oral suspension	Agents affecting bone structure and mineralisation (POM)
Zoledronic acid 5mg/100ml Aclasta® solution for infusion	Bisphosphonates (POM)
New combination	
Ciprofloxacin 0.3% and dexamethasone 0.1% Cilodex® otic suspension	Otologicals – corticosteroids and anti-infectives in combination (POM)
Measles virus, mumps virus, rubella virus and varicella virus ProQuad® powder for solution for injection	Viral vaccines, combination (POM)
New formulation	
Levetiracetam 100mg/ml Keppra® oral solution	Anti-epileptics (POM)

POM: Prescription only medicine