

NEW DRUGS APPROVED IN 2007

Healthcare professionals are encouraged to report all serious and non-serious suspected 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 Products Regulation Group
Health Sciences Authority
11 Biopolis Way #11-03 Helios
Singapore 138667
Tel : +65- 6866 3538
Fax : +65- 6478 9069
Email : HSA_drugsafety@hsa.gov.sg

New chemical / biological entity	Pharmacotherapeutic group
Ciclesonide 80mcg or 160mcg/actuation Alvesco® inhaler	Agents for obstructive airway diseases — glucocorticoids (POM)
Darbepoetin alfa 20mcg/0.5ml, 30mcg/0.3ml, 40mcg/0.4ml, 100mcg/0.5ml Aranesp® pre-filled syringe for injection	Antianaemic preparations (POM)
Dasatinib 20mg, 50mg, 70mg Sprycel® film-coated tablet	Antineoplastic agents (POM)
Gadoxetic acid, disodium 181.43mg (0.25mmol/ml) Primovist® solution for injection	Contrast media (POM)
Histrelin 50mg Vantas® implant	Gonadotropin-releasing hormones (POM)
Human papillomavirus (types 16, 18) Cervarix® vial, pre-filled syringe, suspension for injection	Viral vaccines (POM)
Lapatinib 250mg Tykerb® film-coated tablet	Antineoplastic agents (POM)
Laronidase 2.9mg/5ml Aldurazyme® injection	Alimentary tract and metabolism — enzymes (POM)
Nitric oxide 800ppm Inomax® gas	Stimulants for respiratory system(POM)
Paliperidone 3mg, 6mg, 9mg, 12mg Invega® extended-release tablet	Antipsychotics (POM)
Perflutren or perfluoropropane gas 6.52mg/ml Definity® liquid-encapsulated microbubbles for injection	Contrast media (POM)
Propiverine 15mg Mictionorm® tablet	Urinary antispasmodics (POM)
Rotavirus, live attenuated (human-bovine) RotaTeq® oral solution	Viral vaccines (POM)
Sitagliptin 25mg, 50mg, 100mg Januvia® tablet	Antidiabetics (POM)
Sorafenib 200mg Nexavar® film-coated tablet	Antineoplastic agents (POM)
Sunitinib 12.5mg, 25mg, 50mg Sutent® capsule	Antineoplastic agents (POM)
Telbivudine 600mg Sebivo® film-coated tablet	Antivirals — nucleoside and nucleotide reverse transcriptase inhibitors (POM)
Tigecycline 50mg Tygacil® injection	Antibiotics — tetracyclines (POM)
Trospium chloride 20mg Spasmolyt® film-coated tablet	Urinary antispasmodics (POM)
Urea (¹³ C) 100mg Ubit® film-coated tablet	Diagnostic agents (POM)
Varenicline 1mg Champix® film-coated tablet	Drugs used in nicotine dependence (POM)
Varenicline 0.5mg and 1mg Champix® starter pack	
New combination	Pharmacotherapeutic group
Abacavir 600mg, lamivudine 300mg Kivexa® tablet	Antivirals (POM)
Clindamycin 1%w/w, benzoyl peroxide 5%w/w Clindoxyl® gel	Antibiotics, combinations (POM)
Hydrochlorothiazide, olmesartan medoxomil 12.5/20, 12.5/40, 25/40mg Olmetec Plus® film-coated tablet	Thiazide diuretics and angiotensin II antagonists (POM)
New formulation	Pharmacotherapeutic group
Busulfan 60mg Busulfex® concentrate solution for injection	Antineoplastic agents (POM)
Carmustine 7.7mg Gliadel® wafer	Antineoplastic agents (POM)
Clobetasol propionate 0.05%w/v Clobex® lotion, shampoo	Corticosteroids (POM)
Paricalcitol 1mcg, 2mcg, 4mcg Zemplar® capsule	Vitamin D and analogues (POM)
Others	Pharmacotherapeutic group
Sildenafil 20mg Revatio® film-coated tablets	Peripheral vasodilator (POM)