

NEW DRUGS APPROVED IN 2010

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.

How to report

The ADR and Vaccine Adverse Event (VAE) reporting forms can be obtained at http://www.hsa.gov.sg/ae_online, from medical clinics, pharmacies, hospitals/health institutions or the Vigilance Branch of HSA. Online reporting is also available at the same website. Please send the completed forms to HSA either by post, email or fax to the Vigilance Branch.

Where to send your report

Vigilance Branch, 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_productsafety@hsa.gov.sg

New chemical / biological entity	Pharmacotherapeutic group
Agomelatine 25mg Valdoxan® tablet	Antidepressant (POM)
Azacitidine 100mg/vial Vidaza® powder for suspension for injection	Antineoplastic agent (POM)
Bendamustine 25mg, 100mg Symbenda® powder for concentrate for solution for infusion	Antineoplastic agent (POM)
Canakinumab 150mg Ilaris® powder for solution for injection	Immunosuppressant (POM)
Dapoxetine 30mg Priligy® tablet	Urological agent (POM)
Desvenlafaxine 100mg Pristiq® extended-release tablet	Antidepressant (POM)
Dienogest 2mg, micronized Visanne® tablet	Progestogen (POM)
Dronedarone 400mg Multaq® film-coated tablet	Antiarrhythmic agent (POM)
Epinastine 0.05% w/v Relestat® ophthalmic solution	Ophthalmological agent (POM)
Estradiol valerate, dienogest 1mg + 2mg + 3mg Qlaira® film-coated tablet	Systemic hormonal contraceptive (POM)
Idursulfase 6mg/vial Elaprase® solution for intravenous infusion	Enzyme (POM)
Imiglucerase 424U Cerezyme® powder for solution for injection	Enzyme (POM)
Liraglutide 6mg/ml Victoza® solution for injection in pre-filled pen	Anti-diabetic agent (POM)
Methylnaltrexone 12mg/0.6ml Relistor® solution for injection	Laxative (POM)

Moroctocog alfa 250IU, 500IU, 1000IU, 2000IU/vial Xyntha® powder and solvent for solution for injection	Antihemorrhagic agent (POM)
Nepafenac 1.0mg/ml Nevanac® eye drops suspension	Ophthalmological anti-inflammatory agent (POM)
Nonacog alfa 250IU, 500IU, 1000IU, 2000IU/vial BeneFIX® powder and solvent for solution for injection	Antihemorrhagic agent (POM)
Plerixafor 20mg/ml Mozobil® solution for injection	Immunostimulant (POM)
Pneumococcal polysaccharide conjugated Prevenar® 13 suspension for injection	Pneumococcal vaccine (POM)
Prasugrel 10mg Effient® tablet	Antithrombotic agent (POM)
Saxagliptin 5mg Onglyza® tablet	Anti-diabetic agent (POM)
Pneumococcal polysaccharide conjugated Synflorix® suspension for injection (prefilled syringe and vial)	Pneumococcal vaccine (POM)
Sugammadex 100mg Bridion® solution for injection	Antidote (POM)
Tafloprost 0.015mg/ml Taflotan® ophthalmic solution	Antiglaucoma preparation (POM)
New combination	Pharmacotherapeutic group
Adapalene 0.1%, Benzoyl peroxide 2.5% Epiduo® gel	Anti-acne preparation for topical use (POM)
Amlodipine, Perindopril Coveram® tablet 5mg/5mg, 10mg/10mg, 5mg/10mg, 10mg/5mg	Antihypertensive agent (POM)
Brinzolamide 10mg/ml, Timolol 5mg/ml Azarga® eye drops, suspension	Antiglaucoma preparation (POM)
Desloratadine micronized 2.5mg, Pseudoephedrine 120mg Aerius® D-12 modified release tablet	Antihistamine and decongestant for systemic use (POM)
Glycerol 9mg/ml, Sodium carboxymethylcellulose 1.75mg/ml (high viscosity) + 3.25mg/ml (medium viscosity) Optive® lubricant eye drop	Ophthalmological agent (GSL)
Hydrochlorothiazide, Valsartan, Amlodipine Exforge® HCT tablet 10mg/160mg/12.5mg, 10mg/160mg/25mg, 5mg/160mg/12.5mg, 5mg/160mg/25mg	Antihypertensive agent (POM)
Lidocaine topical: 20mg/ml; intracameral: 10mg/ml. Sodium hyaluronate topical: 3mg/ml; intracameral: 15mg/ml Visthesia® topical solution and Visthesia® intracameral solution	Ophthalmological agent (POM)

Polyethylene glycol 400 0.4 % w/v, Propylene glycol 0.3 % w/v Systane® ultra lubricant eye drop and lubricant eye drop (preservative free)	Ophthalmological agent (GSL)
Risedronate 35mg, Calcium 1000mg, Cholecalciferol 880IU Actonel® Plus Calcium D tablet and powder	Agents affecting bone metabolism (POM)
New formulation	Pharmacotherapeutic group
Bimatoprost 0.3mg/ml Latisse® ophthalmic solution	Antiglaucoma preparation (POM)
Budesonide micronized 0.2mg/actuation Budair® pressurised inhalation solution	Inhaled Corticosteroid (POM)
Cetylpyridinium 1.33mg, Pholcodine 5.5mg Duro-Tuss® lemon dry cough lozenges	Locally acting anti-bacterial agent and cough suppressant (P)
Everolimus 5mg, 10mg Afinitor® tablet	Antineoplastic (POM)
Hepatitis A virus 80U/0.5ml Avaxim® paediatric, suspension for injection in prefilled syringe	Viral vaccine (POM)
Human normal immunoglobulin 100mg/ml Kiovig® solution for infusion	Immunoglobulin (POM)
Nicotine 2mg, 4mg Nicotinell® liquorice chewing gum	Agent used in nicotine dependence (P)
Orlistat 60mg, milled Alli® capsule	Antiobesity preparation (P)
Ropinirole 2mg, 4mg, 8mg Requip PD 24 Hour® prolonged release tablet	Anti-parkinson agent (POM)
Sodium hyaluronate 40mg/2 ml Arthrum® H injection	Agent for disorder of musculo-skeletal system (POM)
Sodium hyaluronate 15mg/ml Gelbag Plus®	Ophthalmological agent (POM)
Sodium hyaluronate 15mg/ml Survisc® injection	Ophthalmological agent (POM)
Sodium hyaluronate 16.5mg/ml, Chondroitin 40mg/ml Discovisc® ophthalmic viscosurgical device	Ophthalmological agent (POM)
Tramadol 100mg, 200mg Durotram® XR tablet	Opioid analgesic (POM)
New dosage form	Pharmacotherapeutic group
Aprotinin 2250-3750KIU/ml, Calcium chloride 36-44µmol/ml, Factor XIII 0.6-5IU/ml, Fibrinogen 72-110mg/ml, Thrombin 400-625 IU/ml Tisseel® Lyo, powder for solution	Antihemorrhagic agents (POM)
Betamethasone 0.5mg/g, Calcipotriol 50mcg/g Xamiol® gel	Topical antipsoriatic (POM)
Etanercept 50mg/ml Enbrel® solution for injection in pre-filled syringe	Immunosuppressant (POM)
Formoterol 0.012mg/inhalation Atimos® pressurised inhalation solution	Antiasthmatic preparation (POM)
Gadobutrol 1mmol/ml Gadovist® pre-filled syringes 5ml and 7.5ml	Contrast media (POM)
Lidocaine 0.7g/plaster Lignopad® medicated plaster	Local anaesthetic (POM)
Temozolomide 100mg/vial Temodal® powder for solution for infusion	Antineoplastic agent (POM)