

NEW DRUGS APPROVED IN 2009



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.

New chemical / biological entity	Pharmacotherapeutic group
Agalsidase beta 35mg Fabrazyme® powder for solution for injection	α-galactosidase A enzyme (POM)
Dabigatran 75mg Pradaxa® hard capsule	Antithrombotic agent (POM)
Doripenem 500mg Doribax® powder for injection	Antibiotic (POM)
Etravirine 100mg Intence® tablet	Antiviral agent (POM)
H1N1 Pandemic Influenza A (2009) virus Pandemrix® H1N1 injection	Pandemic vaccine (POM)
H1N1 Pandemic Influenza A (2009) virus Panvax® H1N1 Vaccine/Panvax® H1N1 Vaccine Junior	Pandemic vaccine (POM)
Hydromorphone 32mg Jurnista® prolonged release tablet	Opioid analgesic (POM)
*Hydroquinone 4% w/w Eldopaque Forte® cream, Eldoquin Forte® cream	Dermatological agent (POM)
H5N1 Influenza virus Prepandrix® injection	Pandemic vaccine (POM)
Ixabepilone 45mg Ixempra® for injection	Antineoplastic agent (POM)
Lanthanum 250mg Fosrenol® chewable tablet	Agent for treatment of hyperphosphataemia (POM)
Lenalidomide 5mg Revlimid® capsule	Antineoplastic agent (POM)
Maraviroc 150mg Celsentri® film-coated tablet	Antiviral (POM)
Niacin, Laropiprant 1gm/20mg Tredaptive® tablet	Lipid Modifying agent (POM)
Retapamulin 1% w/w Altargo® ointment	Topical antibiotic (POM)
Sevelamer 800mg Renvela® tablet	Agent for treatment of hyperphosphataemia (POM)
Solifenacin 5mg Vesicare® tablet	Urinary antispasmodic agent (POM)
Tamsulosin 400mcg Harnal OCAS® prolonged release film-coated tablet	Agent used in benign prostatic hypertrophy (POM)
Tegafur, Oteracil, Gimeracil 20mg/19.6mg/5.8mg TS-ONE® capsule	Antineoplastic agent (POM)
Temsirolimus 25 mg/ml Torisel® concentrate for injection	Antineoplastic agent (POM)
Tocilizumab 20 mg/ml Actemra® concentrate for solution for infusion	Immunosuppressant (POM)
Trabectedin 1mg Yondelis® powder for injection	Antineoplastic agent (POM)
Ustekinumab 45mg/0.5 ml Stelara® solution for injection	Immunosuppressant (POM)
Vaccinia virus, ACAM2000® injection, powder, lyophilized, for solution	Pandemic vaccine (POM)
<i>*Previously regulated as a cosmetic product</i>	
New combination	Pharmacotherapeutic group
Aliskiren 150mg, Hydrochlorothiazide 12.5 mg Rasilez HCT® tablet	Antihypertensive agent (POM)
Bromhexine 0.8mg/ml, pseudoephedrine 4mg/ml Duro-Tuss® chesty cough liquid plus nasal decongestant	Cough & cold preparation (P)
Benzylamine 3mg, Cetylpyridinium 1.33mg, Diffiam® eucalyptus & menthol sugar free lozenges	Locally acting oral anti-inflammatory and anti-bacterial agent (P)

Benzylamine 1.5mg, Cetylpyridinium 1.33mg, Pholcodine 5.5mg Diffiam® blackcurrant sugar free cough lozenges	Locally acting oral anti-inflammatory, anti-bacterial agent and cough suppressant (P)
Calcium carbonate 160mg, Sodium alginate 500mg, Sodium bicarbonate 267mg per tablet/per ml Gaviscon® extra strength 500 peppermint tablets, Gaviscon® liquid sachets	Agent for gastro-oesophageal reflux disease (GSL)
Hepatitis A virus, Salmonella typhi Vi polysaccharide Vivaxim® vaccine	Bacterial & viral vaccines (POM)
Timolol 5mg/ml, Travoprost 40ug/ml DuoTrav® eye drops, solution	Antiglaucoma preparation (POM)
Measles, mumps, rubella, varicella viruses Priorix-Tetra® injection, powder, lyophilized, for solution	Viral vaccines (POM)
Vildagliptin 50mg, metformin 850mg Galvusmet® tablet	Anti-diabetic agent (POM)
New formulation	Pharmacotherapeutic group
Antithrombin III, human 500 iu/10 ml Anbinex® powder for injection	Antithrombotic agent (POM)
*Budesonide 200mcg/dose Pulmicort® HFA pressurised metered dose inhaler	Corticosteroid (POM)
Ciprofloxacin 500mg Cipro XR® film-coated tablet	Antibiotic (POM)
Fenofibrate 145mg Lipanthyl penta® film coated tablet	Lipid modifying agent (POM)
Fluticasone furoate 27.5mcg/spray Avamys® nasal spray	Corticosteroid (POM)
<i>*CFC-free formulation</i>	
New dosage form	Pharmacotherapeutic group
Benzylamine 1.5mg/ml Diffiam® anti-inflammatory throat spray	Locally acting oral anti-inflammatory agent (P)
Escitalopram 20mg/ml Lexapro® oral drops	Antidepressant (POM)
Insulin lispro 100iu/ml Humalog® pen solution for injection	Insulin analogue (POM)
Levetiracetam 100mg/ml Keppra® concentrate for solution for infusion	Antiepileptic agent (POM)
Mannitol 0mg, 5mg, 10mg, 20mg, 40mg Aridol® mannitol powder for inhalation composite pack	Diagnostic agent (POM)
Oxycodone 10 mg/ml OxyNorm® sterile solution for injection or infusion	Opioid analgesic (POM)
Rotavirus, (human) Rotarix® oral suspension	Viral vaccine (POM)
Sodium hyaluronate 30mg/ml Healon D® solution for intraocular application	Ophthalmological agent (POM)
Topotecan 0.25mg, 1mg Hycamtin® hard capsules	Antineoplastic agent (POM)
Biosimilar	Pharmacotherapeutic group
Somatropin Scitropin A® powder for solution & injection 1.3mg/ml (4IU) & 5mg/ml (15IU), solution for injection 5mg/1.5ml (15IU) & 10mg/1.5ml (30IU)	Growth hormone (POM)

POM: Prescription only medicine

P: Pharmacy-only medicine

GSL: General Sales List

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
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