

NEW DRUGS APPROVED IN 2008

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	New formulation	Pharmacotherapeutic group
Abatacept 250mg Orencia® injection	Immunosuppressants (POM)	Azithromycin 2g Zmax® granule for suspension, extended release	Macrolides (POM)
Alglucosidase alfa 50mg Myozyme® powder for solution for infusion	Enzymes (POM)	Measles, mumps, rubella, varicella viruses ProQuad® refridgerator stable formulation	Viral vaccines (POM)
Aliskiren 150mg, 300mg Rasilez® film coated tablet	Agents acting on the renin-angiotensin system (POM)	Mesalazine 1g/satchet Pentasa® prolonged release granules	Intestinal anti-inflammatory (POM)
Anidulafungin 100mg Eraxis® injection	Antimycotics for systemic use (POM)	Omeprazole 20mg Losec® capsules, enteric coated pellets	Proton pump inhibitors (POM)
Daptomycin 500mg Cubicin® injection	Antibacterials for systemic use (POM)	Quetiapine 50mg, 200mg, 300mg, 400mg Seroquel XR® tablet	Antipsychotics (POM)
Darunavir 300mg Prezista® tablet	Protease inhibitors (POM)	Terbinafine 1% (10mg/g) Lamisil Once® film forming solution	Antifungals for topical use (GSL)
Deferasirox 125mg, 250mg, 500mg Exjade® dispersible tablet	Iron chelating agents (POM)		
Exenatide 5mcg, 10mcg Byetta® solution for injection	Blood glucose lowering drugs (POM)	New dosage form	Pharmacotherapeutic group
Human Anti-D immunoglobulin 600IU (120mcg), 1500IU (300mcg), 5000IU (1000mcg) Winrho® SDF injection	Immunoglobulins (POM)	Fluocinolone 0.59mg Retisert® intravitreal implant	Anti-inflammatory agents (POM)
Methoxy polyethylene glycol-epoetin beta 1000mcg/ml, 100mcg/ml, 200mcg/ml, 300mcg/ml, 50mcg/ml, 100mcg/0.3ml, 150mcg/0.3ml, 200mcg/0.3ml, 250mcg/0.3ml, 50mcg/0.3ml, 75mcg/0.3ml, 800mcg/0.6ml Mircera® solution for injection vial & pre-filled syringe	Antianaemic preparations (POM)	Ibandronic acid 50mg Bondronate® tablet	Bisphosphonates (POM)
Methyl 5-aminolevulinate hydrochloride 20% w/w Metvix® cream	Antineoplastic agents (POM)	Levocetirizine 5mg/ml Xyzal® oral drops	Antihistamines (POM)
Nilotinib 200mg Tasigna® capsule	Antineoplastic agents (POM)	Rivastigmine 9mg/5cm ² , 18mg/10cm ² Exelon® transdermal patch	Anti-dementia drugs (POM)
Purified tetanus toxoid (= 40IU/ 0.5ml dose) Tetavax® Vaccine	Bacterial vaccines (POM)	Others	Pharmacotherapeutic group
Raltegravir 400mg Isentress® tablet	Antivirals for systemic use (POM)	Glucagon 1mg/ml Glucagen® hypokit for injection	Pancreatic hormones (POM)
Ranibizumab 3mg/0.3ml Lucentis® solution for injection	Ocular vascular disorder agents (POM)	Hepatitis B immune globulin (human) 0.5ml, 1ml HyperHEP B S/D® pre-filled syringe	Immune sera & immunoglobulins (POM)
Recombinant antihemophilic factor VIII octocog Alfa 250IU, 500IU, 1000IU, 1500 IU Advate® powder and solvent for solution for injection	Antihemorrhagics (POM)	Influenza virus A & B FluLaval® suspension for injection	Influenza vaccines (POM)
Rivaroxaban micronized 10mg Xarelto® film coated tablet	Antithrombotic agents (POM)	Insulin glargine 100IU/ml Lantus SoloStar® solution for injection in a pre-filled pen	Insulins & analogues (POM)
Varicella-zoster virus, live attenuated Oka/Merck strain 19,400 PFU Zostavax® injection (frozen and refrigerator stable formulation)	Viral vaccines (POM)	Insulin glulisine 100units/ml Apidra SoloStar® solution for injection in a pre-filled pen	Insulins & analogues (POM)
Vildagliptin 50mg Galvus® tablet	Blood glucose lowering drugs (POM)		
New combination	Pharmacotherapeutic group		
Amlodipine, valsartan 5/80, 5/160, 10/160mg Exforge® film-coated tablet	Agents acting on the renin-angiotensin system (POM)		
Brimonidine (2mg/ml), timolol (5mg/ml) Combigan® ophthalmic solution	Antiglaucoma preparations and miotics (POM)		
Glimepiride, rosiglitazone 1/4, 2/4, 4/4mg Avandaryl® tablet	Combinations of oral blood glucose lowering drugs (POM)		
Losartan 100mg, hydrochlorothiazide 12.5mg Hyzaar® Plus tablet	Angiotensin II antagonists & diuretics (POM)		
Metformin, sitagliptin 500/50, 850/50, 1000/50mg Janumet® tablet	Combinations of oral blood glucose lowering drugs (POM)		

POM: Prescription only medicine

GSL: General Sales List

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) Branch of the HSA. Please send the completed ADR reporting form either by mail, email or fax to the PV Branch. Online ADR reporting is available at http://www.hsa.gov.sg/adr_online

Where to send your report:

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