

# Drugs APPROVED IN 2011



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](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, #11-01, Helios, Singapore 138667

Tel: +65-6866 3538 Fax: +65-6478 9069 Email: [HSA\\_productsafety@hsa.gov.sg](mailto:HSA_productsafety@hsa.gov.sg)

NEW CHEMICAL / BIOLOGICAL ENTITY	PHARMACOTHERAPEUTIC GROUP
Anthrax antigen protein 50mcg Biothrax® (Anthrax vaccine adsorbed) suspension for injection	Anthrax vaccine (POM)
Asenapine 5mg, 10mg Saphris® sublingual tablet	Antipsychotic (POM)
Besifloxacin 6mg/ml Besivance® ophthalmic suspension	Antibacterial ophthalmological agent (POM)
Cabazitaxel 60mg/1.5ml Jevtana® concentrate and solvent for solution for infusion	Antineoplastic agent (POM)
Cinacalcet 25mg Regpara® tablet	Antiparathyroid agent (POM)
Clofarabine 1mg/ml Evoltra® concentrate solution for infusion	Antineoplastic agent (POM)
Corifollitropin alfa 100mcg/0.5ml, 150mcg/0.5ml Elonva® solution for injection	Gonadotropin (POM)
Denosumab 60mg/ml Prolia® solution for injection (prefilled syringe)	Agent affecting bone metabolism (POM)
Eltrombopag 25mg, 50mg Revolade® tablet	Antihemorrhagic agent (POM)
Eribulin 0.5mg/ml Halaven® solution for injection	Antineoplastic agent (POM)
Ferric carboxymaltose 50mg/ml Ferinject® solution for injection	Antianaemic preparation (POM)
Indacaterol 150mcg, 300mcg Onbrez® Breezhaler® powder for inhalation hard capsule	Preparation for Chronic Obstructive Pulmonary Disease (POM)
Melatonin 2mg Circadin® prolonged release tablet	Hypnotic & sedative (POM)
Palonosetron 250mcg/5ml Aloxi® solution for injection	Antiemetic & anti-nauseant (POM)
Pancreatic powder 150mg Creon® 10000 capsule, coated pellets	Enzyme (POM)
Pazopanib 200mg, 400mg Votrient® tablet	Antineoplastic agent (POM)
Tenofovir 300mg Viread® tablet	Antiviral agent (POM)
Ulipristal 30mg Ella® tablet	Systemic hormonal contraceptive (POM)
Ustekinumab 45mg/0.5ml, 90mg/1ml Stelara® solution for injection in pre-filled syringe; Stelara® solution for injection	Immunosuppressant (POM)

NEW COMBINATION	PHARMACOTHERAPEUTIC GROUP
Diphtheria toxoid, Meningococcal polysaccharide conjugated Menactra® solution for injection	Meningococcal vaccine (POM)
Follitropin alfa 150IU, Lutropin alfa 75IU Pergoveris® powder & solvent for solution for injection	Gonadotropin (POM)
Guaifenesin 100mg/5ml, Phenylephrine 5mg/5ml Robitussin PE® syrup	Cough & cold preparation (GSL)
Human fibrinogen 50-90mg/ml & human thrombin 800-1200IU/ml Evicel® fibrin sealant (human) solution	Antihemorrhagic agent (POM)
Naproxen 500mg, esomeprazole 20mg Vimovo® tablet	Anti-inflammatory analgesic & anti-ulcerant (POM)
Olmesartan, Amlodipine Azoren® film-coated tablet 20mg/5mg, 40mg/10mg, 40mg/5mg	Antihypertensive agent (POM)
Oxycodone, Naloxone Targin® prolonged release tablet 5mg/2.5mg, 10mg/5mg, 20mg/10mg, 40mg/20mg	Opioid analgesic (POM)
Telmisartan, Amlodipine Twynsta® tablet 40mg/5mg, 40mg/10mg, 80mg/5mg, 80mg/10mg	Antihypertensive agent (POM)

NEW FORMULATION	PHARMACOTHERAPEUTIC GROUP
Beclometasone 100mcg, Formoterol 6mcg Foster® pressurised inhalation solution	Antiasthmatic preparation (POM)
Calcium carbonate 325mg/10ml, sodium alginate 500mg/10ml, sodium bicarbonate 213mg/10ml; calcium carbonate 80mg, sodium alginate 250mg, sodium bicarbonate 133.5mg Gaviscon® double action liquid, suspension; Gaviscon® peppermint tablet	Antacid (GSL)
Calcium chloride dihydrate 0.2205g/1000ml, glucose monohydrate 1.1g/1000ml, magnesium chloride hexahydrate 0.1017g/1000ml, sodium chloride 6.136g/1000ml, sodium hydrogen carbonate 2.94g/1000ml MultiBic® potassium-free solution for haemofiltration	Blood substitute & perfusion solution (GSL)
Calcium chloride 0.3675g, hydroxyethyl starch 60g/100g, L-malic acid 0.671g, magnesium chloride 0.2033g, potassium chloride 0.2984g, sodium acetate 3.266g, sodium chloride 6.252g per 1000ml (6% & 10%) Tetraspan® solution for infusion	Blood substitute & perfusion solution (GSL)
Ciclesonide 50mcg Omnaris® nasal spray	Inhaled Corticosteroid (POM)
Clarithromycin 200mg Monoclarium® prolonged release capsule	Systemic antibiotic (POM)
Dexamethasone 0.7mg Ozurdex® intravitreal implant	Ophthalmological agent (POM)
Diclofenac 50mg Voltfast® powder for oral solution	Anti-inflammatory analgesic (POM)
Dinoprostone 10mg Cervidil® vaginal delivery system	Oxytocic (POM)
Eptacog alfa (activated)/rFVIIa 1mg, 2mg Novoseven® powder & solvent for solution for injection	Antihemorrhagic agent (POM)
Human albumin 200g/l Uman® albumin solution for infusion	Blood substitute & perfusion solution (POM)
Human anti-hepatitis B immunoglobulin 250iu/ml; Human anti-hepatitis B immunoglobulin 600iu/2.4ml, 1000iu/4ml Niulivia® solution for infusion; Niuliva® solution for infusion in pre-filled syringe	Immunoglobulin (POM)
Human coagulation factor VIII 250iu/vial, 500iu/vial Haemotin® SDH for injection	Antihemorrhagic agent (POM)
Human normal immunoglobulin 50mg/ml Flebogamma® DIF solution for infusion	Immunoglobulin (POM)
Human normal immunoglobulin 50mg/ml Ig Vena® solution for infusion	Immunoglobulin (POM)
Hyaluronic acid 20mg/ml Durolane® injection	Agent for disorders of the musculo-skeletal system (POM)
Influenza viruses 9mcg/dose, 15mcg/dose Intanza® suspension for injection	Influenza vaccine (POM)
Insulin glargine 100units/ml Podevta® solution for injection (cartridge and vial)	Antidiabetic agent (POM)
Interferon beta-1a 22mcg/0.5ml, 44mcg/0.5ml Rebif® pre-filled syringe; Rebif® solution for injection in cartridge	Immunostimulant (POM)
Leuprorelin 5mg/ml; depot for injection 3.75mg, 11.25mg, 30mg Lucrin® injection; Lucrin® depot for injection PDS	Antineoplastic agent (POM)
Olopatadine 0.2% Pataday® sterile ophthalmic solution	Ophthalmological agent (POM)
Paliperidone 1.5mg, 3mg, 6mg, 9mg, 12mg; Paliperidone 25mg/0.25ml, 50mg/0.5ml, 75mg/0.75ml, 100mg/1ml, 150mg/1.5ml Invega® extended-release tablet; INVEGA Sustenna® prolonged release suspension for IM injection	Antipsychotic (POM)
Polysaccharide Salmonella Typhi 0.025mg/0.5ml Typhim VI® solution for injection in multidose	Typhoid vaccine (POM)
Pramipexole 0.125mg, 0.25mg, 1mg; Pramipexole 0.375mg, 0.75mg, 1.5mg Sifrol® tablet; Sifrol® extended release tablet	Antiparkinson agent (POM)
Raltegravir 400mg ISENTRESS-G® tablet	Antiviral (POM)
Risedronate 150mg Actonel® once-a-month film coated tablet	Agent affecting bone metabolism (POM)

NEW DOSAGE FORM	PHARMACOTHERAPEUTIC GROUP
Diclofenac 60mg/12g Panamax® patch	Topical analgesic & anti-inflammatory (GSL)

POM: Prescription only medicine P: Pharmacy-only medicine GSL: General Sales List