

Drugs

Approved in 2012



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, #11-01, Helios, Singapore 138667

Tel: +65-6866 3538 Fax: +65-6478 9069 Email: HSA_productsafety@hsa.gov.sg

NEW CHEMICAL /BIOLOGICAL ENTITY	PHARMACOTHERAPEUTIC GROUP
Abiraterone 250mg ZYTIGA® tablet	Antineoplastic agent (POM)
Apixaban 2.5mg ELIQUIS® tablet	Antithrombotic agent (POM)
Belimumab 120mg, 400mg BENLYSTA™ powder for solution for infusion	Antineoplastic agent (POM)
Boceprevir 200mg VICTRELIS® capsule	Antiviral agent (POM)
Ceftaroline fosamil 600mg/vial ZINFORO™ powder for concentrate for solution for infusion	Systemic antibiotic (POM)
Crizotinib 200mg, 250mg XALKORI® capsule	Antineoplastic agent (POM)
Eculizumab 300mg/vial SOLIRIS® concentrate for solution for infusion	Antineoplastic agent (POM)
Emtricitabine 200mg, Tenofovir disoproxil fumarate 300mg TRUVADA® tablet	Anti- human immunodeficiency virus agents (POM)
Fingolimod 0.5mg GILENYA™ capsule	Antineoplastic agent (POM)
Golimumab 50mg/0.5ml SIMPONI® solution for injection in pre-filled syringe	Antineoplastic agent (POM)
Japanese Encephalitis, attenuated strain SA ₁₄ -14-2 6mcg/0.5ml IXIARO® suspension for injection in pre-filled syringe	Viral vaccine (POM)
Linagliptin 5mg TRAJENTA® film-coated tablet	Antidiabetic agent (POM)
Meningococcal Group A,C,W,Y conjugated vaccine MENVEO® powder and solution for injection	Meningococcal vaccine (POM)
Nomegestrol acetate 2.5mg, Estradiol 1.5mg ZOELY® film-coated tablet	Systemic hormonal contraceptive (POM)
Parecoxib 40mg DYNASTAT® powder for solution for injection; DYNASTAT® powder & solvent for solution for injection	Antiinflammatory & antirheumatic agent (POM)
Prucalopride 1mg, 2mg RESOLOR™ film-coated tablet	Agent for functional gastrointestinal disorders (POM)
Romiplostim 250mcg/vial NPLATE® powder for solution for injection	Antihaemorrhagic agent (POM)
Rotigotine 2mg/24hours, 4mg/24hours, 6mg/24hours, 8mg/24hours NEUPRO® transdermal patch	Antiparkinson agent (POM)
Rupatadine 10mg RUPAFIN® tablet	Systemic antihistamine (POM)
Ticagrelor 90mg BRILINTA™ tablet	Antithrombotic agent (POM)
Vernakalant HCl 20mg/ml BRINAVESS® concentrate for solution for infusion	Antiarrhythmic agent (POM)
Vinflunine 25mg/ml JAVLOR® concentrate for solution for infusion	Antineoplastic agent (POM)
NEW COMBINATION	PHARMACOTHERAPEUTIC GROUP
Aliskiren, Amlodipine RASILAMLO® film coated tablet 150mg/5mg, 150mg/10mg, 300mg/5mg, 300mg/10mg	Agents acting on the renin-angiotensin system (POM)
Amlodipine, Losartan potassium COZAAR® XQ® tablet 5mg/50mg, 5mg/100mg	Agents acting on the renin-angiotensin system (POM)
Dutasteride 0.5mg, Tamsulosin HCl 0.4mg DUODART™ capsule	Agents used in benign prostatic hypertrophy (POM)
Guaiphenesin 100mg, Paracetamol 250mg, Phenylephrine HCl 5mg PANADOL® cough & cold caplet	Cough & cold preparation (GSL)
Micronised glimepiride, Metformin HCl AMARYL® M film coated tablet 1/250mg, 2/500mg; AMARYL® M SR film coated tablet 2/500mg	Antidiabetic agent (POM)

Mometasone furoate, Formoterol fumarate dihydrate ZENHALE® pressurized inhalation aerosol 50/5mcg, 100/5mcg, 200/5mcg (per actuation)	Antiasthmatic preparation (POM)
Saxagliptin, Metformin HCl KOMBIGLYZE XR® tablet 5mg/500mg, 2.5mg/1000mg, 5mg/1000mg	Antidiabetic agent (POM)
NEW FORMULATION	PHARMACOTHERAPEUTIC GROUP
Acellular pertussis, reduced diphtheria toxoid & tetanus toxoid adsorbed ADACEL® suspension for injection	Bacterial & viral vaccines (POM)
Calcium carbonate 187.5mg, Sodium alginate 250mg, Sodium bicarbonate 106.5mg GAVISCON® double action tablet	Antacid (GSL)
Darbepoetin alfa 20mcg, 30mcg, 40mcg, 120mcg NESP® injection syringe	Antianaemic preparation (POM)
Denosumab 120mg/vial XGEVA® solution for injection	Agent for disorders of the musculo-skeletal system (POM)
Desloratadine, micronised 2.5mg, 5mg AERIUS® REDITABS® tablet	Systemic antihistamine (POM)
Docetaxel 20mg/ml, 80mg/4ml TAXOTERE® concentrate for solution for infusion	Antineoplastic agent (POM)
Etonogestrel 68mg IMPLANON NXT® implant	Systemic hormonal contraceptive (POM)
Everolimus 2.5mg AFINITOR® tablet	Antineoplastic agent (POM)
Filgrastim 120mcg/0.2ml, 300mcg/0.5ml, 480mcg/0.5ml NIVESTIM® solution for injection/infusion	Immunostimulant (POM)
Human albumin 200g/L Human Albumin solution for infusion 20% Behring®	Blood substitute & perfusion solution (POM)
Human normal immunoglobulin 50g/L INTRATECT® solution for infusion	Immunoglobulin (POM)
Ketorolac tromethamine 0.45%w/v ACUVAIL™ (ketorolac tromethamine ophthalmic solution)	Ophthalmological agent (POM)
Loratadine 10mg CLARITYN™ tablet	Systemic antihistamine (GSL)
Meloxicam 7.5mg, 15mg NULOX® orodispersible tablet	Antiinflammatory & antirheumatic agent (POM)
Minoxidil 5% MEN'S REGAINE® extra strength, minoxidil topical foam	Dermatological preparation (P)
Pandemic Influenza A virus -A/VIETNAM/1203/2004 (H5N1) Pandemic Influenza Vaccine H5N1 Baxter® suspension for injection	Pandemic vaccine (POM)
Perindopril arginine 2.5mg, 5mg, 10mg COVERSYL® orodispersible tablet	Agent acting on the renin-angiotensin system (POM)
Sodium molybdate (99Mo), Sodium pertechnetate (99mTc) ULTRATECHNEKOW® FM generator	Diagnostic agent (POM)
Tacrolimus anhydrous 0.5mg, 1mg, 5mg ADVAGRAF® prolonged release hard capsules	Immunosuppressant (POM)
Vardenafil 10mg LEVITRA® orodispersible tablet	Agent for erectile dysfunction (POM)
NEW DOSAGE FORM	PHARMACOTHERAPEUTIC GROUP
Budesonide 2mg/dose BUDENOFALK® rectal foam	Intestinal antiinflammatory agent (POM)
Desmopressin 60mcg, 120mcg MINIRIN® Melt	Systemic hormonal preparation (POM)
Etamsylate 500mg DICYNONE® capsule	Antihaemorrhagic agent (POM)
Fexofenadine HCl 6mg/ml Telfast® oral suspension	Systemic antihistamine (POM)
Ibuprofen 400mg SPEDIFEN® film coated tablet	Antiinflammatory analgesic (POM)
Oxycodone HCl 1mg/ml; Oxycodone HCl 10mg/ml OXYNORM® oral solution; OXYNORM® concentrate oral solution	Opioid analgesic (POM)
Terlipressin acetate 0.1mg/ml GLYPRESSIN® solution for injection	Systemic hormonal preparation (POM)
<p>POM: Prescription only medicine P: Pharmacy-only medicine GSL: General Sales List</p>	