

Drugs

Approved in 2013



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
Afatinib 20mg, 30mg, 40mg, 50mg Giotrif® film-coated tablet	Antineoplastic agent (POM)
Aflibercept 2mg/0.05ml EYLEA® solution for injection in vial; EYLEA® solution for injection in prefilled syringe	Ophthalmological agent (POM)
Alcaftadine 2.5mg/ml LASTACFT™ (alcaftadine ophthalmic solution) 0.25%	Ophthalmological agent (POM)
Axitinib 1mg, 5mg INLYTA® tablet	Antineoplastic agent (POM)
Calfactant 35mg/ml INFASURF® intratracheal suspension	Lung surfactant (POM)
Certolizumab pegol 200mg/ml CIMZIA® solution for injection in prefilled syringe	Immunosuppressant (POM)
Cisatracurium 5mg/2.5ml, 150mg/30ml NIMBEX™ injection, NIMBEX™ forte injection	Muscle relaxant (POM)
Citric acid (anhydrous) 12g, Magnesium oxide (light) 3.5g, Sodium picosulfate 10mg PICOPREP® powder for oral solution	Laxative (POM)
Degarelix 80mg, 120mg FIRMAGON® powder and solvent for solution for injection	Antineoplastic & immunomodulating agent (POM)
Emedastine 0.5mg/ml EMADINE® sterile ophthalmic solution 0.05%	Ophthalmological agent (POM)
Glycopyrronium 50mcg Seebri™ Breezhaler® inhalation powder, hard capsule	Preparation for obstructive airway disease (POM)
Influenza virus surface antigens A/VIETNAM/1194/2004 (H5N1) – like strain used (NIBRG – 14) Aflunov® suspension for injection 0.5ml in prefilled syringe; Novartis prepandemic influenza vaccine® (H5N1) suspension for injection 0.5ml in prefilled syringe	Pandemic vaccine (POM)
Micafungin 50mg/vial MYCAMINE® powder for solution for infusion	Systemic antimycotic agent (POM)
Natalizumab 300mg/15ml TYSABRI® concentrate for solution for infusion	Immunosuppressant (POM)
Pasireotide 0.3mg/ml, 0.6mg/ml, 0.9mg/ml Signifor® solution for injection	Systemic hormonal preparation (POM)
Racecadotril 10mg, 30mg Hidrasec® infants granules for oral suspension, Hidrasec® children granules for oral suspension	Antidiarrhoeal agent (POM)
Regorafenib 40mg Stivarga® tablet	Antineoplastic agent (POM)
Rilpivirine 25mg EDURANT® film-coated tablet	Antiviral agent (POM)
Ruxolitinib 5mg, 15mg, 20mg Jakavi® tablet	Antineoplastic agent (POM)
Sodium fluoride F18 10-200mCi/ml SODIUM FLUORIDE F18® injection	Diagnostic radiopharmaceutical agent (POM)
Vemurafenib 240mg ZELBORAF® tablet	Antineoplastic agent (POM)
NEW COMBINATION	PHARMACOTHERAPEUTIC GROUP
Linagliptin, Metformin HCl Trajenta Duo® film-coated tablet 2.5mg/500mg, 2.5mg/850mg, 2.5mg/1000mg	Antidiabetic agent (POM)
Omeprazole, Sodium bicarbonate PIRSECT™ capsule 20mg/1100mg, 40mg/1100mg	Agents for peptic ulcer & gastroesophageal reflux disease (POM)
NEW FORMULATION	PHARMACOTHERAPEUTIC GROUP
Abatacept 125mg/ml ORENCIA® injection in prefilled syringe	Antineoplastic & immunomodulating agent (POM)
Alanine 7.1g, Arginine 6.1g, Fish oil 5.7g, Glucose monohydrate 127g, Glycine 5.6g, Histidine 1.5g, Isoleucine 2.5g, Leucine 3.8g,	Blood substitute & perfusion solution (POM)

Lysine acetate 3.4g, Methionine 2.2g, Olive oil 9.5g, Phenylalanine 2.6g, Proline 5.7g, Serine 3.3g, Soya bean oil 11.4g, Taurine 0.5g, Threonine 2.2g, Triglycerides 11.4g, Tryptophan 1g, Tyrosine 0.2g, Valine 3.1g (Per 1000ml) SmofKabiven® Electrolyte Free emulsion for infusion; SmofKabiven® Electrolyte Free emulsion for infusion + Calcium chloride dihydrate 0.28g, Magnesium sulphate heptahydrate 0.61g, Potassium chloride 2.3g, Sodium acetate trihydrate 1.7g, Sodium glycerophosphate hydrate 2.1g, Zinc sulphate heptahydrate 0.0066g (Per 1000ml) SmofKabiven® emulsion for infusion; Alanine 4.4g, Arginine 3.8g, Calcium chloride dihydrate 0.18g, Fish oil 4.2g, Glucose monohydrate 71g, Glycine 3.5g, Histidine 0.93g, Isoleucine 1.6g, Leucine 2.3g, Lysine acetate 2.1g, Magnesium sulphate heptahydrate 0.38g, Methionine 1.3g, Olive oil 7g, Phenylalanine 1.6g, Potassium chloride 1.4g, Proline 3.5g, Serine 2.1g, Sodium acetate trihydrate 1.1g, Sodium glycerophosphate hydrate 1.3g, Soya bean oil 8.5g, Taurine 0.32g, Threonine 1.4g, Triglycerides 8.5g, Tryptophan 0.63g, Tyrosine 0.12g, Valine 2g, Zinc sulphate heptahydrate 0.004g (Per 1000ml) SmofKabiven® Peripheral emulsion for infusion	
Apixaban 5mg ELIQUIS® tablet	Antithrombotic agent (POM)
Bimatoprost 0.01% LUMIGAN® (bimatoprost ophthalmic solution)	Ophthalmological agent (POM)
Cefuroxime 125mg Zinnat™ granule for oral suspension	Systemic antibacterial agent (POM)
Desogestrel 75mcg CERAZETTE® tablet	Systemic hormonal contraceptive (POM)
Etanercept 50mg ENBREL® solution for injection in a prefilled pen	Immunosuppressant (POM)
Fenofibric acid 45mg, 135mg Trilipix® modified release capsule	Lipid modifying agent (POM)
Flurbiprofen 8.75mg Strepsils® MaxPro honey and lemon lozenges	Throat preparation (POM)
Human Cytomegalovirus Immunoglobulin 100U/ml Megalotect CP® solution for infusion	Immunoglobulin (POM)
Ibuprofen Lysine 342mg, 684mg NUROFEN® Express caplet	Systemic anti-inflammatory & anti-rheumatic agent (P, POM)
Lanreotide 60mg, 90mg, 120mg Somatuline® Autogel® prolonged release solution for injection in a prefilled syringe	Systemic hormonal preparation (POM)
Mucopolysaccharide polysulphate 445mg/100g Hirudoid® forte cream	Topical antivaricose preparation (GSL)
Nicotine 2mg, 4mg Nicorette® icy mint gum	Agent used in nicotine dependence (P)
Ritonavir 100mg NORVIR® tablet	Antiviral agent (POM)
Rivaroxaban 2.5mg Xarelto® film-coated tablet	Antithrombotic agent (POM)
Somatropin 4mg, 10mg ZOMACTON® powder and solvent for solution for injection Somatropin 6mg/ml, 12mg/ml, 20mg/ml Saizen® solution for injection	Systemic hormonal preparation (POM)
Triptorelin 3.75mg, 11.25mg, 22.5mg Pamorelin® powder for suspension for injection	Antineoplastic & immunomodulating agent (POM)
Urofollitropin 75IU BRAVELLE® powder and solvent for solution for injection	Gonadotropin (POM)
Zoledronic acid 4mg/100ml Zometa® solution for infusion	Agent affecting bone metabolism (POM)
NEW DOSAGE FORM	PHARMACOTHERAPEUTIC GROUP
Calcipotriol 50mcg/g, Betamethasone 0.5mg/g Daivobet® gel	Topical antipsoriatic preparation (POM)
Granisetron 34.3mg/patch SANCUSO® transdermal system 3.1mg/24hours	Antiemetic & anti-nauseant preparation (POM)
Human fibrinogen 5.5mg/cm ² , Human thrombin 2iu/cm ² TACHOSIL® medicated sponge	Antihemorrhagic agent (POM)
Mesalazine 500mg/sachet, 1g/sachet, 1.5g/sachet, 3g/sachet Salofalk® gastro-resistant prolonged-release granules	Intestinal anti-inflammatory agent (POM)
Nevirapine anhydrous 100mg, 400mg VIRAMUNE® XR extended-release tablet	Antiviral agent (POM)
Nicotine 10mg/16 hours, 15mg/16 hours, 25mg/16 hours Nicorette® invisipatch	Agent used in nicotine dependence (P)

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