

DRUGS APPROVED in 2015



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 and Compliance 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 and Compliance Branch.

WHERE TO SEND YOUR REPORT

Vigilance and Compliance 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
Alogliptin 6.25mg, 12.5mg, 25mg NESINA [®] tablet	Antidiabetic agent (POM)
Asunaprevir 100mg SUNVEPRA [™] capsule	Antiviral agent for systemic use (POM)
Ceritinib 150mg Zykadia [™] capsule	Antineoplastic agent (POM)
Chlormadinone acetate 2mg, Ethinylestradiol 0.03mg Belara [®] film-coated tablet 0.03mg/2mg	Hormonal contraceptive for systemic use (POM)
Cobicistat 150mg, Elvitegravir 150mg, Emtricitabine 200mg, Tenofovir disoproxil 245 mg Stribild [®] film-coated tablet 150mg/150mg/200mg/245mg	Antiviral agents for systemic use (POM)
Dabrafenib 50mg, 75mg TAFINLAR [™] hard capsule	Antineoplastic agent (POM)
Daclatasvir 30mg, 60mg DAKLINZA [™] tablet	Antiviral agent for systemic use (POM)
Dasabuvir tablet 250mg; Ombitasvir 12.5mg, Paritaprevir 75mg, Ritonavir 50mg VIEKIRA PAK [™] tablets	Antiviral agents for systemic use (POM)
Enzalutamide 40mg Xtandi [™] soft capsules	Antineoplastic & immunomodulating agent (POM)
Fampridine 10mg Fampyra [®] prolonged-release tablets	Agent for nervous system disease (POM)
Fluticasone furoate, Vilanterol RELVAR [™] ELLIPTA [™] inhalation powder 100mcg/25mcg, 200mcg/25mcg	Agents for obstructive airway diseases (POM)
Hydroxyprogesterone caproate 250mg/ml Proluton [®] Depot injection	Sex hormone & modulator of the genital system (POM)
Ibrutinib 140mg IMBRUVICA [™] capsule	Antineoplastic agent (POM)
Macitentan 10mg OPSUMIT [®] film-coated tablet	Antihypertensive agent (POM)
Methoxyflurane 99.9% PENTHROX [®] inhalation liquid	Analgesic agent (POM)
Nalmefene 18mg Selincro [®] film-coated tablets	Agent used in alcohol dependence (POM)
Obinutuzumab 1000mg/40ml GAZYVA [®] concentrate for solution for infusion	Antineoplastic agent (POM)
Pembrolizumab 25mg/ml KEYTRUDA [®] solution for infusion	Antineoplastic agent (POM)
Ranolazine 375mg, 500mg, 750mg Ranexa [®] prolonged-release tablet	Cardiac therapy agent (POM)
Rifaximin 550mg XIFAXAN [®] film-coated tablet	Intestinal anti-infective agent (POM)
<i>Saccharomyces boulardii</i> 250mg BIOFLOR [®] sachets	Antidiarrhoeal agent (P)
Secukinumab 150mg/vial; Secukinumab 150mg/ml Cosentyx [®] powder for solution for injection Cosentyx [®] solution for injection in pre-filled sensorready pen, Cosentyx [®] solution for injection in pre-filled syringe	Immunosuppressant (POM)
Siltuximab 100mg/vial, 400mg/vial SYLVANT [®] powder for concentrate for solution for infusion	Immunosuppressant (POM)
Sofosbuvir 400mg SOVALDI [®] tablet	Antiviral agent for systemic use (POM)
Sucroferric oxyhydroxide 2,500mg eqv Iron 500mg Velphoro [®] chewable tablets	Agent for treatment of hyperkalaemia & hyperphosphataemia (POM)
Tedizolid phosphate 200mg SIVEXTRO [™] film-coated tablet SIVEXTRO [™] lyophilized powder for solution for infusion 200mg/vial	Antibacterial agent for systemic use (POM)
Teriflunomide 14 mg AUBAGIO [®] film-coated tablets	Immunosuppressant (POM)
Umeclidinium 62.5mcg/dose INCRUSE [™] ELLIPTA [™] inhalation powder	Agent for obstructive airway diseases (POM)
Umeclidinium 62.5mcg, Vilanterol 25mcg ANORO [™] ELLIPTA [™] inhalation powder	Agents for obstructive airway diseases (POM)

NEW COMBINATION	PHARMACOTHERAPEUTIC GROUP
Alogliptin, Metformin hydrochloride NESINA MET [®] film-coated tablet 12.5mg/500mg, 12.5mg/1000mg	Antidiabetic agents (POM)
Indapamide, Amlodipine NATRIXAM [®] modified-release tablet 1.5mg/5mg, 1.5mg/10mg	Antihypertensive agents (POM)
Lidocaine 7% w/w, Tetracaine 7% w/w PLIAGLIS [®] cream 70mg/g + 70mg/g	Local anaesthetic agents (POM)
NEW FORMULATION	PHARMACOTHERAPEUTIC GROUP
Aprotinin 2250 – 3750 kiu/ml, Calcium chloride 36 – 44 umol/ml, Human fibrinogen 72 – 110mg/ml, Human thrombin 3.2 – 5 iu/ml ARTISS [®] solutions for sealant, deep frozen	Tissue adhesive & local haemostatic agent (POM)
Brimonidine 3mg/g MIRVASO [®] gel	Dermatological preparation (POM)
Caffeine 65mg, Paracetamol 500mg Panadol [®] Extra Effervescent tablet Panadol [®] Extra with OPTIZORB [®] caplets	Analgesic & antipyretic agents (GSL)
Cetirizine dihydrochloride 10mg ZYRTEC [®] -R film-coated tablet	Antihistamine for systemic use (GSL)
Clotrimazole 1g/100g, Hydrocortisone 1g/100g Canesten [®] Plus cream	Topical antifungal preparation (P)
Coal tar solution 12% w/w, Salicylic acid 2% w/w, Sulphur 4% w/w CERA-SCALP [®] ointment	Dermatological preparation (GSL)
Darbepoetin alfa 10mcg/0.5ml, 20mcg/0.5ml, 30mcg/0.5ml, 40mcg/0.5ml, 60mcg/0.5ml, 120 mcg/0.5 ml, 180mcg/0.5ml NESP [®] injection plastic syringe	Antianaemic preparation (POM)
Diphtheria toxoid ≥ 30 IU/0.5ml, Filamentous haemagglutinin 25mcg/0.5ml, <i>Haemophilus influenzae</i> type b polysaccharide conjugated to 18 – 30mcg Tetanus protein 10mcg/0.5ml, Pertussis toxoid 25mcg/0.5ml, Poliomyelitis virus Type 1 (inactivated) 40 DU/0.5 ml, Poliomyelitis virus Type 2 (inactivated) 8 DU/0.5 ml, Poliomyelitis virus Type 3 (inactivated) 32 DU/0.5 ml, Tetanus toxoid ≥ 40 IU/0.5ml PENTAXIM [®] vaccine	Bacterial & viral vaccines (POM)
Diphtheria toxoid ≥ 20 IU/0.5ml, Filamentous haemagglutinin 25 mcg/0.5ml, <i>Haemophilus influenzae</i> type b polysaccharide conjugated to 22 – 36mcg Tetanus protein 12mcg/0.5ml, Hepatitis B surface antigen 10mcg/0.5ml, Pertussis toxoid 25mcg/0.5ml, Poliomyelitis virus Type 1 (inactivated) 40 DU/0.5ml, Poliomyelitis virus Type 2 (inactivated) 8 DU/0.5ml, Poliomyelitis virus Type 3 (inactivated) 32 DU/0.5ml, Tetanus toxoid ≥ 40 IU/0.5ml Hexaxim [®] suspension for injection in pre-filled syringe	Bacterial & viral vaccines (POM)
Estradiol 10mcg Vagifem [®] vaginal tablet	Sex hormone & modulator of the genital system (POM)
Filgrastim, recombinant 30 MU/0.5ml Zarzio [®] solution for injection/infusion in pre-filled syringe	Immunostimulant (POM)
Golimumab 12.5mg/1ml in 4ml vial Golimumab 100mg/1ml SIMPONI [®] I.V. concentrate for solution for infusion SIMPONI [®] solution for injection in pre-filled syringe	Immunosuppressant (POM)
Influenza virus, monovalent inactivated split - virion: A/H1N1 15mcg haemagglutinin, A/H3N2 15mcg haemagglutinin, B strain (Victoria lineage) 15mcg haemagglutinin, B strain (Yamagata lineage) 15mcg haemagglutinin per 0.5ml Fluarix [™] Tetra suspension for injection in pre-filled syringe	Influenza vaccine (POM)
Methylphenidate hydrochloride 5mg, 10mg, 20mg, 30mg, 40mg MEDIKINET [®] MR capsules	Psychostimulant (POM)
Oxycodone hydrochloride 10mg, 20mg, 40mg, 60mg, 80mg OxyContin [®] Neo controlled-release tablets	Opioid analgesic agent (POM)
Paracetamol 10mg/ml Paracetamol B. Braun [®] solution for infusion	Analgesic & antipyretic agent (POM)
Ranibizumab 1.65mg/0.165ml Lucentis [®] solution for injection in pre-filled syringe	Ophthalmological agent (POM)
Tafuprost 0.015mg TAFLOTAN [®] -S ophthalmic solution 0.0015%	Ophthalmological agent (POM)
Tocilizumab 162mg/0.9ml Actemra [®] 162mg solution for injection in pre-filled syringe	Immunosuppressant (POM)
Trastuzumab 600mg Herceptin [®] solution for injection 600mg/5ml	Antineoplastic agent (POM)
NEW DOSAGE FORM	PHARMACOTHERAPEUTIC GROUP
Buprenorphine 5mg/patch, 10mg/patch, 20mg/patch Sovenor [®] transdermal patch 5mcg/h, 10mcg/h, 20mcg/h	Opioid analgesic agent (POM)
Dexketoprofen 25mg KETESSE [®] granules for oral solution 25mg/sachet	Anti-inflammatory & antirheumatic agent (POM)
Rupatadine 1mg/ml Rupafin [®] oral solution	Antihistamine for systemic use (POM)

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