

# Drugs

## Approved in 2014



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 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](mailto:HSA_productsafety@hsa.gov.sg)

NEW CHEMICAL /BIOLOGICAL ENTITY	PHARMACOTHERAPEUTIC GROUP
Azilsartan medoxomil 40 mg, 80 mg Edarbi® tablet	Antihypertensive agent (POM)
Bilastine 20 mg BILASTEN® tablet	Systemic antihistamine (POM)
Brentuximab Vedotin 50 mg/vial ADCETRIS® powder for concentrate for solution for infusion	Antineoplastic agent (POM)
Canagliflozin 100 mg, 300 mg INVOKANA™ film-coated tablet	Oral antidiabetic agent (POM)
Dapagliflozin 5 mg, 10 mg FORXIGA® film-coated tablet	Oral antidiabetic agent (POM)
Dexlansoprazole 30 mg DEXILANT® delayed-release capsule	Agent for peptic ulcer & gastro-oesophageal reflux disease (POM)
Dolutegravir 50 mg TIVICAY™ film-coated tablet	Systemic antiviral agent (POM)
Empagliflozin 10 mg, 25 mg JARDIANCE® film-coated tablet	Oral antidiabetic agent (POM)
Ipilimumab 5 mg/ml YERVOY® injection concentrate 5 mg/ml	Antineoplastic agent (POM)
Lacosamide 50 mg, 100 mg, 150 mg, 200 mg; Lacosamide 10 mg/ml Vimpat® film-coated tablet; Vimpat® solution for infusion	Antiepileptic agent (POM)
Lixisenatide 50 mcg/ml, 100 mcg/ml; Lixisenatide 50 mcg/ml & 100 mcg/ml Lyxumia® solution for injection in pre-filled pen 10 mcg, 20 mcg; Lyxumia® solution for injection in pre-filled pen 10 mcg & 20 mcg	Antidiabetic agent (POM)
Mirabegron 25 mg, 50 mg Betmiga® prolonged-release tablet	Agent for urinary frequency & incontinence (POM)
Ocriplasmin 0.5 mg/0.2 ml JETREA™ concentrate for solution for injection vial	Ophthalmological agent (POM)
Ofatumumab 20 mg/ml ARZERRA™ concentrate for solution for infusion 100 mg & 1000 mg	Antineoplastic agent (POM)
Olodaterol 2.5 mcg/actuation STRIVERDI® RESPIMAT® solution for inhalation	Agent for obstructive airway diseases (POM)
Omega-3-acid ethyl esters 90 1,000 mg [containing eicosapentaenoic acid (EPA) 460 mg & docosahexaenoic acid (DHA) 380 mg ethyl esters, & α-tocopherol 4 mg] OMACOR® soft capsule	Lipid modifying agent (POM)
Panitumumab 100 mg/vial Vectibix® concentrate for solution for infusion	Antineoplastic agent (POM)
Perampanel (anhydrous basis) 2 mg, 4 mg, 6 mg, 8 mg, 10 mg, 12 mg Fycompa® film-coated tablet	Antiepileptic agent (POM)
Pertuzumab 420 mg/14 ml PERJETA® concentrate for solution for infusion	Antineoplastic agent (POM)
Pomalidomide 1 mg, 2 mg, 3 mg, 4 mg POMALYST® capsule	Immunosuppressant (POM)
Pralatrexate 20 mg/ml Foloty® solution for infusion	Antineoplastic agent (POM)
Radium-223 chloride 1000 kBq/ml Xofigo® solution for injection	Therapeutic radiopharmaceutical agent (POM)
Retigabine 50 mg, 100 mg, 200 mg, 300 mg TROBALT™ film-coated tablet	Antiepileptic agent (POM)
Riociguat micronised 0.5 mg, 1 mg, 1.5 mg, 2 mg, 2.5 mg Adempas® film-coated tablet	Antihypertensive agent (POM)
Tapentadol 50 mg, 75 mg; Tapentadol 50 mg, 100 mg, 150 mg NUCYNTA® IR tablet; NUCYNTA® ER tablet	Systemic opioid analgesic (POM)
Tofacitinib 5 mg XELJANZ® film-coated tablet	Immunosuppressant (POM)
Trastuzumab emtansine 100 mg/vial, 160 mg/vial Kadcyla® powder for concentrate for solution for infusion	Antineoplastic agent (POM)
Vismodegib 150 mg ERIVEDGE® capsule	Antineoplastic agent (POM)
Vortioxetine 5 mg, 10 mg, 20 mg Brintellix® film-coated tablet	Antidepressant (POM)

NEW COMBINATION	PHARMACOTHERAPEUTIC GROUP
Azilsartan medoxomil, Chlortalidon Edarbyclor® tablet 40 mg/12.5 mg, 40 mg/25 mg	Antihypertensive agents (POM)
Fenofibrate 160 mg, Pravastatin sodium 40 mg Pravafen® hard capsule	Lipid modifying agents (POM)
Fluticasone propionate, Formoterol fumarate dihydrate Flutiform® pressurised inhalation, suspension 50 mcg/5 mcg per actuation, 125 mcg/5 mcg per actuation, 250 mcg/5 mcg per actuation	Agents for obstructive airway diseases (POM)
Glycopyrronium 50 mcg, Indacaterol (micronised) 110 mcg Ultibro® Breezhaler® inhalation powder hard capsule	Agents for obstructive airway diseases (POM)
Ibuprofen 150 mg, Paracetamol 500 mg Maxigesic® tablet 500 mg/150 mg	Systemic antiinflammatory & antirheumatic agents (POM)
NEW FORMULATION	PHARMACOTHERAPEUTIC GROUP
Adalimumab 40 mg/0.8 ml HUMIRA® solution for injection (vial)	Immunosuppressant (POM)
Aflibercept 25 mg/ml ZALTRAP® concentrate for solution for infusion	Antineoplastic agent (POM)
Aprotinin 2250 – 3750 KIU/ml, Calcium chloride 36 – 44 µmol/ml, Fibrinogen 72 – 110 mg/ml, Thrombin 400 – 625 IU/ml TISSEEL® fibrin sealant VH S/D (frozen)	Tissue adhesive & local haemostatic agent (POM)
Ciprofloxacin 2 mg/ml Cetraxal® ear drops solution	Otological agent (POM)
Ciprofloxacin 3 mg/ml, Fluocinolone acetonide 0.25 mg/ml Cetraxal Plus® ear drops solution	Otological agent (POM)
<i>Clostridium botulinum</i> neurotoxin type A (150 kD), free from complexing proteins 50 LD <sub>50</sub> units/vial, 100 LD <sub>50</sub> units/vial XEOMIN® powder for solution for injection	Peripherally acting muscle relaxant (POM)
Donepezil hydrochloride 23 mg Aricept® film-coated tablet	Antidementia agent (POM)
Guaifenesin 600 mg, 1200 mg Mucinex™ extended-release tablets	Cough & cold preparation (GSL)
Human hepatitis B immunoglobulin in 150 g/l human plasma protein (IgG ≥ 96%) 500 iu/ml; Human hepatitis B immunoglobulin in 50 mg/ml human plasma protein (IgG ≥ 96%) 50 iu/ml Zutectra® solution for injection; Hepatect® CP solution for infusion	Immunoglobulin (POM)
Hydroxocobalamin 1 mg/1ml HYDROXO-B12® solution for injection	Antianaemic preparation (P)
Interferon beta-1a 22 mcg/0.5 ml, 44 mcg/0.5 ml Rebif® solution for injection in pre-filled pen	Immunostimulant (POM)
Japanese encephalitis virus (live, attenuated, recombinant) 4.0 – 5.8 log PFU/dose IMOJEV® powder & diluent for suspension for injection	Viral vaccine (POM)
Leuprorelin acetate 7.5 mg, 22.5 mg, 45 mg ELIGARD® powder & solvent for solution for injection	Antineoplastic & immunomodulating agent (POM)
<i>Neisseria meningitidis</i> serogroups polysaccharide A, C, W-135 & Y 5 mcg/0.5 ml, Tetanus toxoid carrier protein ~ 44 mcg Nimenrix™ powder & solvent for solution for injection	Meningococcal vaccine (POM)
Paclitaxel 100 mg/vial Abraxane® for injectable suspension	Antineoplastic agent (POM)
Paracetamol 500 mg Panadol® with OPTIZORB caplet	Analgesic & antipyretic agent (GSL)
Raltegravir 25 mg, 100 mg ISENTRESS® chewable tablet	Systemic antiviral agent (POM)
Rivastigmine 13.3 mg/24 hr Exelon® patch 15	Antidementia agent (POM)
Romiplostim 250 mcg/vial Romiplostim® powder for solution for injection	Systemic haemostatic agent (POM)
Triptorelin 3.75 mg/vial, 11.25 mg/vial Diphereline® P.R. powder & solvent for suspension for injection	Antineoplastic & immunomodulating agent (POM)
Ulipristal acetate micronised 5 mg Esmya® tablet	Sex hormone & modulator of the genital system (POM)
Ursodeoxycholic acid 500 mg Ursofalk® film-coated tablet	Cholelitholytic agent (POM)
NEW DOSAGE FORM	PHARMACOTHERAPEUTIC GROUP
Amlodipine 5 mg, 10 mg NORVASC® ODT (orodispersible tablet)	Antihypertensive agent (POM)
Amoxicillin (as amoxicillin trihydrate) 562.5 mg (IR layer), Amoxicillin (as amoxicillin sodium) 437.5 mg (SR layer), Potassium clavulanate : Microcrystalline cellulose 1 : 1 blend 62.5 mg (IR layer) AUGMENTIN SR™ tablet 1000/62.5 mg	Systemic antibacterial agent (POM)
Ibuprofen 200 mg, 400 mg NUROFEN® EXPRESS® liquid capsule	Systemic antiinflammatory & antirheumatic agent (P, POM)
Paracetamol 10 mg/ml PARACETAMOL-AFT® solution for infusion	Analgesic & antipyretic agent (POM)
Prednisone 1 mg, 2 mg, 5 mg Lodotra® modified-release tablet	Systemic corticosteroid preparation (POM)
Sildenafil 50 mg VIAGRA™ ODT (orodispersible) tablet	Agent used in erectile dysfunction (POM)
Sitagliptin, Metformin hydrochloride JANUMET® XR tablet 50 mg/500 mg, 50 mg/1000 mg, 100 mg/1000 mg	Oral antidiabetic agent (POM)

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