

DRUGS APPROVED in 2017



Healthcare professionals are encouraged to report all serious and non-serious suspected adverse drug reactions (ADRs) 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 webpage. Please send the completed forms to Vigilance and Compliance Branch, HSA either by post, email or fax.

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 1111 • Fax: +65-6478 9069 • Email: HSA_productsafety@hsa.gov.sg

NEW CHEMICAL/ BIOLOGICAL ENTITY	PHARMACOTHERAPEUTIC GROUP
Acclidinium 322 mcg/delivered dose (343 mcg/metered dose) Ekliira® Genuair® inhalation powder	Agent for obstructive airway diseases (POM)
Alectinib 150 mg Alecensa® hard capsule	Antineoplastic agent (POM)
Alirocumab 75 mg/ml, 150 mg/ml Praluent® solution for injection in a pre-filled syringe & pen	Lipid modifying agent (POM)
Aminolevulinic acid hydrochloride 30 mg/ml GLIOLAN® powder for oral solution	Surgical visualisation aid (POM)
Apremilast 30 mg Apremilast 10 mg, Apremilast 20 mg & Apremilast 30 mg; OTEZLA® tablet starter pack; OTEZLA® tablet	Immunosuppressant (POM)
Carfilzomib 60 mg/vial KYPROLIS® powder for solution for infusion	Antineoplastic agent (POM)
Ceftolozane 1000 mg, Tazobactam 500 mg ZERBAXA® powder for solution for injection 1 g/0.5 g	Antibacterial agents for systemic use (POM)
Cobicistat 150 mg, Elvitegravir 150 mg, Emtricitabine 200 mg, Tenofovir alafenamide 10 mg GENVOYA® film-coated tablet 150 mg/150 mg/200 mg/10 mg	Antiviral agents for systemic use (POM)
Cobimetinib 20 mg Cotellic® film-coated tablet	Antineoplastic agent (POM)
Cyclizine hydrochloride 50 mg NausiCalm® tablet	Antihistamine for systemic use (POM)
Doxylamine succinate 10 mg, Pyridoxine hydrochloride 10 mg DICLECTIN® delayed release tablet 10 mg/10 mg	Antihistamine for systemic use (POM)
Evolocumab 140 mg/ml Repatha® solution for injection in pre-filled syringe; Repatha® solution for injection in pre-filled auto injector	Lipid modifying agent (POM)
Fimasartan potassium 60 mg, 120 mg Kanarb® tablet	Agent acting on the renin-angiotensin system (POM)
Ioflupane (123I) 74 MBq/ml at reference time DaTSCAN® solution for injection	Diagnostic radiopharmaceutical agent (POM)
Ixazomib 2.3 mg, 3 mg, 4 mg NINLARO® capsule	Antineoplastic agent (POM)
Lubiprostone (fill solution) 8 mcg, 24 mcg Amitiza® capsule	Agent for treatment of constipation (POM)
Mepolizumab 100 mg/vial NUCALA™ powder for solution for injection 100 mg	Agent for obstructive airway diseases (POM)
Necitumumab 16 mg/ml Portrazza® concentrate for solution for infusion 800 mg/50 ml	Antineoplastic agent (POM)
Rasagiline 1 mg AZILECT® tablet	Antiparkinsonism agent (POM)
Rufinamide 200 mg Inovelon® film-coated tablet	Antiepileptic agent (POM)
Selexipag 0.2 mg, 0.4 mg, 0.6 mg, 0.8 mg, 1.0 mg, 1.2 mg, 1.4 mg, 1.6 mg UPTRAVI® film-coated tablet 200 mcg, 400 mcg, 600 mcg, 800 mcg, 1000 mcg, 1200 mcg, 1400 mcg, 1600 mcg	Platelet aggregation inhibitor (POM)
Sofosbuvir 400 mg, Velpatasvir 100 mg EPCLUSIA® tablet 400 mg/100 mg	Antiviral agents for systemic use (POM)
Trametinib 0.5 mg, 2 mg Mekinist® film-coated tablet	Antineoplastic agent (POM)
Venetoclax 10 mg, 50 mg, 100 mg VENCLEXTA™ film-coated tablet	Antineoplastic agent (POM)
NEW COMBINATION	PHARMACOTHERAPEUTIC GROUP
Acclidinium 340 mcg/delivered dose, Formoterol fumarate dihydrate 11.8 mcg/delivered dose (12 mcg/metered dose) Duaklir® Genuair® inhalation powder 340/12 mcg/dose	Agents for obstructive airway diseases (POM)
Azelastine hydrochloride 0.1% w/w, Fluticasone propionate 0.0365 % w/w DYMISTA® nasal spray; SYNAZE® nasal spray	Antihistamine & corticosteroid for topical use (POM)
Bisoprolol fumarate, Perindopril arginine Cosyrele® film-coated tablet 5 mg/5 mg, 5 mg/10 mg, 10 mg/5 mg, 10 mg/10 mg	Agents for cardiovascular diseases (POM)
Empagliflozin, Linagliptin Glyxambi® film-coated tablet 10 mg/5 mg, 25 mg/5 mg	Antidiabetic agents (POM)

Emtricitabine, Tenofovir alafenamide DESCOVY® film-coated tablet 200 mg/10 mg, 200 mg/25 mg	Antiviral agents for systemic use (POM)
Ibuprofen 200 mg, Paracetamol 500 mg NUROMOL® film-coated tablet 200 mg/500 mg	Antiinflammatory & analgesic agents (GSL)
Metoprolol tartrate, Ivabradine Implicor® film-coated tablet 25 mg/5 mg, 25 mg/7.5 mg, 50 mg/5 mg, 50 mg/7.5 mg	Antianginal agents (POM)
Tramadol hydrochloride 75 mg, Dexketoprofen 25 mg SKUDEXA® film-coated tablet 75 mg/25 mg	Analgesic agents (POM)
NEW FORMULATION	PHARMACOTHERAPEUTIC GROUP
Adalimumab 40 mg Humira® solution for injection 40 mg/0.4 ml (syringe & pen)	Immunosuppressant (POM)
Calcium chloride dihydrate 0.15 g/1000 ml, Magnesium chloride hexahydrate 0.2 g/1000 ml, Potassium chloride 0.3 g/1000 ml, Sodium acetate trihydrate 3.27 g/1000 ml, Sodium chloride 5.55 g/1000 ml, Succinylated gelatine 40 g/1000 ml Gelaspan® solution for infusion	Blood substitute & perfusion solution (POM)
Carbetocin 100 mcg/ml DURATOCIN® RTS solution for injection	Uterotonic agent (POM)
Human albumin 50 g/1000 ml, 200 g/1000 ml, 250 g/1000 ml Alburnorm® solution for infusion 5 %, 20 %, 25 %	Blood substitute & perfusion solution (POM)
Irinotecan (anhydrous free base) 4.33 mg/ml ONIVYDE™ (irinotecan liposome) injection 43 mg/10 ml	Antineoplastic agent (POM)
Ketoprofen 30 mg/sheet KefenTech® Air	Antiinflammatory agent for topical use (GSL)
Olopatadine 0.7 % Pazeo® ophthalmic solution	Antihistamine for topical use (POM)
Paliperidone 175 mg/0.875 ml, 263 mg/1.315 ml, 350 mg/1.75 ml, 525 mg/2.625 ml INVEGA® TRINZA™ prolonged release suspension for IM injection	Antipsychotic agent (POM)
Pasireotide 20 mg, 40 mg, 60 mg Signifor® LAR powder & solvent for suspension for injection	Systemic hormonal preparation (POM)
Split influenza virus, inactivated A/Vietnam/1194/2004 (H5N1) 3.75 mcg haemagglutinin/dose Adjupanrix™ pandemic influenza vaccine (split virion, inactivated, AS03 adjuvanted)	Influenza vaccine (POM)
Ticagrelor 60 mg BRILINTA® tablet	Antithrombotic agent (POM)
Travoprost 0.03 mg/ml TRAVATAN® C eye drop solution 30 mcg/ml	Antiglaucoma agent (POM)
NEW DOSAGE FORM	PHARMACOTHERAPEUTIC GROUP
Alendronic acid 70 mg Buffered Binosto® effervescent tablet	Agent for treatment of bone diseases (POM)
Aripiprazole anhydrous 400 mg/vial Abilify Maintena® powder & solvent for prolonged release suspension for injection 400 mg	Antipsychotic agent (POM)
Beclomethasone dipropionate anhydrous (micronised) 100 mcg/dose, Formoterol fumarate dihydrate (micronised) 6 mcg/dose Foster® NEXThaler® inhalation powder 100 mcg/6 mcg per dose	Agents for obstructive airway diseases (POM)
Budesonide micronised 9 mg CORTIMENT™ MMX™ prolonged release tablet	Intestinal antiinflammatory agent (POM)
Cholecalciferol 25,000 IU D-Cure® oral solution	Agent for prevention of vitamin deficiency & treatment of bone diseases (POM)
Ciclosporin 1 mg/ml IKERVIS® eye drops, emulsion	Intraocular antiinflammatory agent (POM)
Clobetasol propionate 0.05 % w/w Clobex® spray	Corticosteroid for topical use (POM)
Deferasirox 90 mg, 180 mg, 360 mg Jadenu® film-coated tablet	Iron chelating agent (POM)
Fentanyl 100 mcg, 200 mcg, 300 mcg, 400 mcg, 600 mcg, 800 mcg Abstral® sublingual tablet	Opioid analgesic agent (POM)
Flurbiprofen 8.748 mg/dose Strepsils® Max Pro Direct Spray 8.75 mg per dose	Antiinflammatory agent for topical use (P)
Interferon beta-1a 30 mcg/0.5 ml AVONEX® solution for injection in pre-filled pen; AVONEX® solution for injection in pre-filled syringe	Immunostimulant (POM)
Ivermectin 10 mg/g Soolantra® cream	Antiinflammatory agent for topical use (POM)
Minocycline 20 mg/g Perioclina® periodontal ointment 2 % w/w	Antiinfective agent for stomalogical use (POM)
Palonosetron 0.5 mg ALOXI® soft capsules 500 mcg	Antiemetic & anti-nauseant agent (POM)
Povidone iodine 0.45 % w/w BETADINE® sore throat spray	Antiseptic agent for topical use (GSL)
Povidone iodine 10 % w/w BETADINE® vaginal gel	Gynaecological antiinfective & antiseptic preparation (GSL)
NEW INDICATION	PHARMACOTHERAPEUTIC GROUP
Dutasteride 0.5 mg NUVANIV™ soft capsule	Agent for treatment of hair loss (POM)
Liraglutide 6 mg/ml Saxenda® solution for injection in pre-filled pen	Agent for regulating appetite (POM)
Tenofovir alafenamide 25 mg VEMLIDY® film-coated tablet	Antiviral agent for systemic use (POM)

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