

DRUGS APPROVED in 2016



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

NEW CHEMICAL/ BIOLOGICAL ENTITY	PHARMACOTHERAPEUTIC GROUP
Ambrisentan 5 mg, 10 mg VOLIBRIS™ film-coated tablet	Antihypertensive agent (POM)
Blinatumomab 55 mcg/ml BLINCYTO® powder for infusion 35 mcg/vial	Antineoplastic agent (POM)
CYD dengue virus serotype 1 4.5 - 6.0 log ₁₀ CCID ₅₀ /dose, CYD dengue virus serotype 2 4.5 - 6.0 log ₁₀ CCID ₅₀ /dose, CYD dengue virus serotype 3 4.5 - 6.0 log ₁₀ CCID ₅₀ /dose, CYD dengue virus serotype 4 4.5 - 6.0 log ₁₀ CCID ₅₀ /dose, Dengvaxia®, powder & solvent for suspension for injection; Dengvaxia MD®, powder & solvent for suspension for injection	Viral vaccine (POM)
Daratumumab 20 mg/ml DARZALEX™ concentrate for solution for infusion 100 mg/5 ml, 400 mg/20 ml	Antineoplastic agent (POM)
Dimethyl fumarate 120 mg, 240 mg Tecfidera® gastro-resistant hard capsules	Agent for nervous system (POM)
Dulaglutide 0.75 mg/0.5 ml, 1.5 mg/0.5 ml Trulicity® injection	Antidiabetic agent (POM)
Factor II 280 – 760 IU/vial, Factor IX 500 IU/vial, Factor VII 180 – 480 IU/vial, Factor X 360 – 600 IU/vial, Protein C 260 – 620 IU/vial, Protein S 240 – 640 IU/vial Octaplex® powder & solvent for solution for injection 500 IU	Antihæmorrhagic agent (POM)
Febuxostat 80 mg FEBURIC® film-coated tablets	Antigout agent (POM)
Human Papillomavirus (HPV) Type 11 L1 Protein 40 mcg, HPV Type 16 L1 Protein 60 mcg, HPV Type 18 L1 Protein 40 mcg, HPV Type 31 L1 Protein 20 mcg, HPV Type 33 L1 Protein 20 mcg, HPV Type 45 L1 Protein 20 mcg, HPV Type 52 L1 Protein 20 mcg, HPV Type 58 L1 Protein 20 mcg, HPV Type 6 L1 Protein 30 mcg GARDASIL® 9 suspension for injection	Viral vaccine (POM)
Idarucizumab 50 mg/ml Praxbind® solution for injection/ infusion	Antidote (POM)
Idelalisib 100 mg, 150 mg ZYDELIG® film-coated tablet	Antineoplastic agent (POM)
Ledipasvir 90 mg, Sofosbuvir 400 mg HARVONI® tablet 90 mg/400 mg	Antiviral agents for systemic use (POM)
Lenvatinib 4 mg, 10 mg Lenvima® hard capsule	Antineoplastic agent (POM)
Lurasidone hydrochloride 40 mg, 80 mg LATUDA® tablet	Antipsychotic agent (POM)
Netupitant 300 mg, Palonosetron 0.5 mg AKYNZEO® capsules 300 mg/0.5 mg	Antiemetic & anti-nauseant agent (POM)
Nintedanib 100 mg, 150 mg Ofev® soft capsules	Antineoplastic agent (POM)
Nivolumab 10 mg/ml OPDIVO® concentrate for solution for infusion	Antineoplastic agent (POM)
Olaparib 50 mg Lynparza® hard capsules	Antineoplastic agent (POM)
Osimertinib 40 mg, 80 mg TAGRISSO® tablet	Antineoplastic agent (POM)
Palbociclib 75 mg, 100 mg, 125 mg IBRANCE® capsule	Antineoplastic agent (POM)
Panobinostat 10 mg, 15 mg, 20 mg Farydak® hard gelatin capsule	Antineoplastic agent (POM)
Pirfenidone 267 mg ESBRIET® hard capsule	Immunosuppressant (POM)
Ramucirumab 10 mg/ml Cyramza® concentrate for solution for infusion 100 mg/10 ml, 500 mg/50 ml	Antineoplastic agent (POM)
Sacubitril/Valsartan free anhydrous acid Entresto® film-coated tablets 50 mg (24.3 mg/25.7 mg), 100 mg (48.6 mg/51.4 mg), 200 mg (97.2 mg/102.8 mg)	Agents acting on the renin-angiotensin system (POM)
Simeprevir 150 mg OLYSIO® oral capsules	Antiviral agent for systemic use (POM)
Vedolizumab 300 mg/vial Entyvio® powder for concentrate for solution for infusion	Immunosuppressant (POM)
NEW COMBINATION	PHARMACOTHERAPEUTIC GROUP
Alogliptin benzoate, Pioglitazone hydrochloride OSENi® film-coated tablet 12.5 mg/15 mg, 12.5 mg/30 mg, 25 mg/15 mg, 25 mg/30 mg	Antidiabetic agents (POM)
Bisoprolol fumarate, Amlodipine Concor® AMLO tablet 5 mg/5 mg, 5 mg/10 mg	Antihypertensive agents (POM)
Brimonidine tartrate 2 mg/ml, Brinzolamide 10 mg/ml SIMBRINZA® eye drops, suspension 2 mg/ml + 10 mg/ml	Ophthalmological agents (POM)

Dapagliflozin, Metformin hydrochloride XIGDUO® XR tablets 5 mg/500 mg, 5 mg/1000 mg, 10 mg/500 mg, 10 mg/1000 mg	Antidiabetic agents (POM)
Dolutegravir 50 mg, Abacavir 600 mg, Lamivudine 300 mg TRIUMEQ® film-coated tablet 50 mg/600 mg/300 mg	Antiviral agents for systemic use (POM)
Empagliflozin, Metformin hydrochloride Jardiance Duo® film-coated tablet 5 mg/500 mg, 12.5 mg/500 mg, 12.5 mg/850 mg, 12.5 mg/1000 mg	Antidiabetic agents (POM)
Emtricitabine 200 mg, Rilpivirine 25 mg, Tenofovir disoproxil fumarate 300 mg COMPLERA™ film-coated tablet 200 mg/25 mg/300 mg	Antiviral agents for systemic use (POM)
Ezetimibe, Atorvastatin ATOZET® tablet 10 mg/10 mg, 10 mg/20 mg, 10 mg/40 mg, 10 mg/80 mg	Lipid modifying agents (POM)
Influenza virus: A/California/07/2009 X-179A (H1N1) 7.5 mcg/0.25 ml, A/Texas/50/2012 X-223A (H3N2) 7.5 mcg/0.25 ml, B/Brisbane/60/2008 (B Victoria lineage) 7.5 mcg/0.25 ml, B/Massachusetts/02/2012 (B Yamagata lineage) 7.5 mcg/0.25 ml; Influenza virus: A/California/07/2009 X-179A (H1N1) 15 mcg/0.5 ml, A/ Texas/50/2012 X-223A (H3N2) 15 mcg/0.5 ml, B/Brisbane/60/2008 (B Victoria lineage) 15 mcg/0.5 ml, B/Massachusetts/02/2012 (B Yamagata lineage) 15 mcg/0.5 ml FluQuadri™ vaccine 0.25 ml/pre-filled syringe; FluQuadri™ vaccine 0.5 ml/pre-filled syringe	Influenza vaccine (POM)
Olodaterol 2.5 mcg/actuation, Tiotropium 2.5 mcg/actuation Spiolto® Respimat® inhalation solution 2.5 mcg/2.5 mcg per actuation	Agents for obstructive airway diseases (POM)
Perindopril arginine, Indapamide, Amlodipine Triplixam® film-coated tablets 2.5 mg/0.625 mg/5 mg, 5 mg/1.25 mg/5 mg, 5 mg/1.25 mg/10 mg, 10 mg/2.5 mg/5 mg, 10 mg/2.5 mg/10 mg	Agents acting on the renin-angiotensin system (POM)
Tafloprost 0.015 mg/ml, Timolol 5 mg/ml TAPCOM®-S ophthalmic solution	Ophthalmological agent (POM)
Virus Polio Type 1, strain LSc, 2ab ≥ 106.0 CCID ₅₀ , Virus Polio Type 3, strain Leon 12a, 1b ≥ 105.8 CCID ₅₀ Polio Sabin™ One and Three (Oral) vaccine	Viral vaccine (POM)
NEW FORMULATION	PHARMACOTHERAPEUTIC GROUP
Alemtuzumab 12 mg/1.2 ml LEMTRADA® concentrate for solution for infusion	Immunosuppressant (POM)
Bimatoprost 0.3 mg/ml, Timolol 5 mg/ml GANFORT® PF eye drops	Ophthalmological agent (POM)
Budesonide, Formoterol fumarate dehydrate Symbicort Rapihaler® suspension for inhalation 40/2.25 mcg/actuation, 80/2.25 mcg/actuation, 80/4.5 mcg/actuation, 160/4.5 mcg/actuation	Agents for obstructive airway diseases (POM)
Diphtheria toxoid ≥ 30 IU/0.5 ml, Filamentous haemagglutinin 25 mcg/0.5 ml, Pertussis toxoid 25 mcg/0.5 ml, Poliovirus (inactivated) Type 1 (Mahoney) 40 DU/0.5 ml, Poliovirus (inactivated) Type 2 (MEF-1) 8 DU/0.5 ml, Poliovirus (inactivated) Type 3 (Saukett) 32 DU/0.5 ml, Tetanus toxoid ≥ 40 IU/0.5 ml TETRIXIM™ vaccine	Bacterial & viral vaccine (POM)
Epinephrine 0.01 mg/ml, Lidocaine hydrochloride 20 mg/ml Octocaine® 100 injection	Local anaesthetic agent (POM)
Fluticasone furoate 100 mcg/12.5 mg blister, 200 mcg/12.5 mg blister ARNUITY™ ELLIPTA™ inhalation powder 100 mcg/dose, 200 mcg/dose	Agents for obstructive airway diseases (POM)
Human normal immunoglobulin 0.1 g/ml GAMUNEX®-C solution for infusion 10%	Immunoglobulin (POM)
Infliximab 100 mg/vial Remsima® powder for concentrate for solution for infusion	Immunosuppressant (POM)
Insulin glargine 100 units/ml Basaglar® injection; Basaglar® KwikPen® injection	Antidiabetic agent (POM)
Insulin glargine 300 units/ml Toujeo® SoloStar® 300 units/ml solution for injection in a pre-filled pen	Antidiabetic agent (POM)
Levofloxacin hydrate 15 mg/ml Cravit® ophthalmic solution 1.5% w/v	Ophthalmological agent (POM)
Levonorgestrel 13.5 mg Jaydess® intrauterine system	Contraceptive for topical use (POM)
Pneumococcal polysaccharides 23 most prevalent types 25 mcg/0.5 ml of each type PNEUMOVAX® 23 (pre-filled syringe)	Pneumococcal vaccine (POM)
NEW DOSAGE FORM	PHARMACOTHERAPEUTIC GROUP
Acetylcysteine 600 mg Fluimucil® granules 600 mg/sachet	Mucolytic agent (P)
Exenatide 2 mg BYDUREON® powder & solvent for prolonged-release suspension for injection in pre-filled pen	Antidiabetic agent (POM)
Iron (III) 100 mg Maltofer® (Iron hydroxide polymaltose complex) film-coated tablets	Antianaemic preparation (GSL)
Mesalazine 1200 mg Mezavant® XL gastro-resistant prolonged release tablet	Intestinal anti-inflammatory agent (POM)
Mesalazine 0.01 g/ml PENTASA® rectal suspension 1 g	Intestinal anti-inflammatory agent (POM)
Misoprostol 200 mcg MISODEL™ vaginal delivery system	Gynaecological agent (POM)
Palivizumab 100 mg/ml SYNAGIS® solution for injection	Immunoglobulin (POM)
Posaconazole 100 mg NOXAFIL® tablet	Antimycotic agent for systemic use (POM)
Progesterone 100 mg ENDOMETRIN® vaginal tablets	Sex hormone & modulator of the genital system (POM)
Rituximab 1400 mg MabThera® solution for subcutaneous injection	Antineoplastic agent (POM)
Saccharomyces boulardii 250 mg BIOFLOR® capsules	Antidiarrhoeal agent (P)

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