

DRUGS APPROVED in 2018



Healthcare professionals are encouraged to report all serious and non-serious suspected adverse drug reactions (ADRs) with the use of 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
Atezolizumab 1200 mg Tecentriq® concentrate for solution for infusion 1200 mg/20 ml	Antineoplastic agent (POM)
Baricitinib 2 mg, 4 mg Olumiant® film-coated tablet	Immunosuppressant (POM)
Bifonazole micronised 1% Canespro® once daily cream	Antifungal agent for topical use (GSL)
Deoxycholic acid 10 mg/ml BELKYRA™ injection	Cytolytic agent for dermatological use (POM)
Durvalumab 50 mg/ml IMFINZI® concentrate for solution for infusion	Antineoplastic agent (POM)
Elbasvir 50 mg, Grazoprevir 100 mg ZEPATIER® film-coated tablet 50 mg/100 mg	Antiviral agents for systemic use (POM)
Emicizumab 30 mg/ml, 150 mg/ml Hemlibra® solution for injection	Antithrombotic agent (POM)
Erenumab 70 mg/ml AIMOVIG™ solution for injection in pre-filled pen; AIMOVIG™ solution for injection in pre-filled syringe	Antimigraine preparation (POM)
Etelcalcetide 2.5 mg/0.5 ml, 5 mg/ml, 10 mg/2 ml Parsabiv® solution for injection	Anti-parathyroid agent (POM)
Flutemetamol [¹⁸ F] 150 MBq/ml at reference time Vizamyl™ solution for injection	Diagnostic radiopharmaceutical agent (POM)
Follitropin delta 12 mcg, 36 mcg, 72 mcg REKOVELLE® solution for injection 12 mcg/0.36 ml, 36 mcg/1.08 ml, 72 mcg/2.16 ml	Sex hormone & modulator of the genital system (POM)
Glecaprevir 100 mg, Pibrentasvir 40 mg Maviret® film-coated tablet 100 mg/40 mg	Antiviral agents for systemic use (POM)
Guselkumab 100 mg/ml TREMIFYA™ solution for injection in pre-filled syringe	Immunosuppressant (POM)
Ixekizumab 80 mg/ml Taltz® solution for injection in pre-filled pen	Immunosuppressant (POM)
L-ornithine L-aspartate 5 g Hepa-Merz® infusion concentrate 5 g/10 ml	Agent for hepatic diseases (POM)
Midostaurin 25 mg Rydapt® soft capsule	Antineoplastic agent (POM)
Mifepristone 200 mg Mifegyne® tablet	Sex hormone & modulator of the genital system (POM)
Ospemifene 60 mg Senshio® film-coated tablet	Sex hormone & modulator of the genital system (POM)
Ponatinib hydrochloride 15 mg, 45 mg ICLUSIG® tablet	Antineoplastic agent (POM)
Ribociclib 200 mg KISQALI™ film-coated tablet	Antineoplastic agent (POM)
Trifluridine, Tipiracil hydrochloride Lonsurf® film-coated tablet 15 mg/6.14 mg, 20 mg/8.19 mg	Antineoplastic agent (POM)
Vonoprazan 10 mg, 20 mg VOCINTI® film-coated tablet	Agent for peptic ulcer & gastro-oesophageal reflux disease (POM)
NEW COMBINATION	PHARMACOTHERAPEUTIC GROUP
(Acellular pertussis) Filamentous hemagglutinin adsorbed (FHA) 5 mcg/0.5 ml, (Acellular pertussis) Fimbriae type 2 & 3 adsorbed (FIM) 5 mcg/0.5 ml, (Acellular pertussis) Pertactin adsorbed (PRN) 3 mcg/0.5 ml, (Acellular pertussis) Pertussis toxin adsorbed (PT) 2.5 mcg/0.5 ml, Diphtheria toxin adsorbed 2 Lf, Inactivated poliomyelitis vaccine (IPV) Type 1 (Mahoney) 40 D-antigen units, Inactivated poliomyelitis vaccine (IPV) Type 2 (MEF-1) 8 D-antigen units, Inactivated poliomyelitis vaccine (IPV) Type 3 (Saukett) 32 D-antigen units, Tetanus toxin adsorbed 5 Lf ADACEL®-POLIO suspension for injection in pre-filled syringe	Influenza & polio vaccine (POM)
Alanine 4.656 g/1000 ml, Arginine 2.592 g/1000 ml, Aspartic acid 1.44g/1000 ml, Calcium chloride dihydrate 0.47 g/1000 ml, Glucose monohydrate 132.0g/1000 ml, Glutamic acid 3.368 g/1000 ml, Glycine 1.584 g/1000 ml, Histidine hydrochloride monohydrate 1.624 g/1000 ml, Isoleucine 2.256g/1000 ml, Leucine 3.008 g/1000 ml, Lysine hydrochloride 2.728 g/1000 ml, Magnesium acetate tetrahydrate 0.686 g/1000 ml, Methionine 1.88 g/1000 ml, Omega-3-acid triglycerides 4.00 g/1000 ml, Phenylalanine 3.368 g/1000 ml, Potassium acetate 2.747 g/1000 ml, Proline 3.264 g/1000 ml, Serine 2.88 g/1000 ml, Sodium acetate trihydrate 0.222 g/1000 ml, Sodium chloride 0.402 g/1000 ml, Sodium dihydrogen phosphate dehydrate 1.872 g/1000 ml, Sodium hydroxide 0.781 g/1000 ml, Soya bean oil, refined 16.00 g/1000 ml, Threonine 1.744 g/1000 ml, Triglycerides, medium chain 20.00 g/1000 ml, Tryptophan 0.544 g/1000 ml, Valine 2.496 g/1000 ml, Zinc acetate dihydrate 5.264mg/1000 ml,	Solution for parenteral nutrition (POM)

Continue in the next column

NEW COMBINATION	PHARMACOTHERAPEUTIC GROUP
Nutriflex® Omega plus emulsion for infusion, Alanine 6.792 g/1000 ml, Arginine 3.78 g/1000 ml, Aspartic acid 2.10 g/1000 ml, Calcium chloride dihydrate 0.623 g/1000 ml, Glucose monohydrate 158.4 g/1000 ml, Glutamic acid 4.908 g/1000 ml, Glycine 2.312 g/1000 ml, Histidine hydrochloride monohydrate 2.368 g/1000 ml, Isoleucine 3.284 g/1000 ml, Leucine 4.384g/1000 ml, Lysine hydrochloride 3.98 g/1000 ml, Magnesium acetate tetrahydrate 0.91 g/1000ml, Methionine 2.736 g/1000 ml, Omega-3-acid triglycerides 4.00 g/1000 ml, Phenylalanine 4.916 g/1000 ml, Potassium acetate 3.689 g/1000 ml, Proline 4.76 g/1000 ml, Serine 4.20 g/1000 ml, Sodium acetate trihydrate 0.25g/1000ml, Sodium chloride 0.378 g/1000 ml, Sodium dihydrogen phosphate dihydrate 2.496 g/1000 ml, Sodium hydroxide 1.171 g/1000 ml, Soya bean oil, refined 16.00 g/1000 ml, Threonine 2.54 g/1000 ml, Triglycerides, medium chain 20.00 g/1000 ml, Tryptophan 0.80 g/1000 ml, Valine 3.604 g/1000 ml, Zinc acetate dihydrate 7.024 mg/1000 ml Nutriflex® Omega special emulsion for infusion	
Atorvastatin, Perindopril arginine, Amlodipine Triveram® film-coated tablet 10 mg/5 mg/5 mg, 20 mg/5 mg/5 mg, 20 mg/10 mg/5 mg, 20 mg/10 mg/10 mg, 40 mg/10 mg/10 mg	Agents for cardiovascular diseases (POM)
Influenza virus (NH): A/California/07/2009 (H1N1) X-181 15 mcg/0.5 ml, A/Texas/50/2012 (H3N2) X-223A 15 mcg/0.5 ml, B/Brisbane/60/2008, wild type 15 mcg/0.5 ml, B/Massachusetts/2/2012 BX-51B 15 mcg/0.5 ml Influvac® Tetra, suspension for injection in pre-filled syringe 0.5 ml	Influenza vaccine (POM)
Influenza virus (NH): A/California/7/2009 (H1N1) X-179A 15 mcg/0.5 ml, A/Texas/50/2012 (H3N2) X-223A 15 mcg/0.5 ml, B/Massachusetts/2/2012 15 mcg/0.5 ml, B/Brisbane/60/2008 15 mcg/0.5 ml VaxigripTetra® suspension for injection in pre-filled syringe	Influenza vaccine (POM)
Insulin glargine, Lixisenatide Soliqua® solution for injection in a pre-filled pen 100 units/ml + 33 mcg/ml, 100 units/ml + 50 mcg/ml	Antidiabetic agent (POM)
Large compartment: Disodium phosphate dihydrate 0.187 g/L, Potassium chloride 0.314 g/L, Sodium chloride 7.013 g/L, Sodium hydrogen carbonate 2.122 g/L, Small compartment: Magnesium chloride hexahydrate 3.05 g/L Biphozyl® solution for haemodialysis/ haemofiltration	Blood substitute & perfusion solution (POM)
Sodium chloride 5.03 g/L, Sodium citrate 5.29 g/L Regiocit® solution for haemofiltration	Blood substitute & perfusion solution (POM)
NEW FORMULATION	PHARMACOTHERAPEUTIC GROUP
Adapalene 0.3% w/w, Benzoyl peroxide 2.5% w/w EPIDUO® FORTE® gel 0.3%/2.5%	Anti-acne preparation for topical use (POM)
Antithrombotic factor (recombinant) 250 IU, 500 IU Kovaltry® powder & solvent for solution for injection 250 IU/vial, 500 IU/vial	Antithrombotic agent (POM)
Benzylamine hydrochloride 3 mg, 2,4-dichlorobenzyl alcohol 1.2 mg, Lignocaine hydrochloride 4 mg Diffiam® plus ANAESTHETIC sore throat lozenges (sugar free) menthol & eucalyptus flavour; Diffiam® plus ANAESTHETIC sore throat lozenges (sugar free) honey lemon flavour	Anti-inflammatory & analgesic throat preparation (P)
Diclofenac sodium 2% Voltaren® 12 hours emulgel	Anti-inflammatory preparation for topical use (GSL)
Dorzolamide 20 mg/ml, Timolol 5 mg/ml COSOPT-S® ophthalmic solution	Antiglaucoma agents (POM)
Human immunoglobulin 100 g/L Privigen® solution for infusion	Immunoglobulin (POM)
NEW DOSAGE FORM	PHARMACOTHERAPEUTIC GROUP
Dolutegravir 10 mg, 25 mg TIVICAY® film-coated tablet	Antiviral agent for systemic use (POM)
Insulin aspart (600 nmol) (approx. 3.5 mg) 100 U/ml NovoMix® 30 Penfill®	Antidiabetic agent (POM)
Insulin detemir (2400 nmol) (approx. 14.2 mg) 100 U/ml Levemir® Penfill®	Antidiabetic agent (POM)
Pirfenidone 267 mg, 801 mg ESBRIET® film-coated tablet	Immunosuppressant (POM)
Polidocanol 10 mg/ml VARITHENA® polidocanol injectable foam	Antivascular therapy (POM)
NEW INDICATION	PHARMACOTHERAPEUTIC GROUP
Carmustine 100 mg/vial BicNu®-100 mg (carmustine for injection USP 100 mg) & dehydrated alcohol injection USP as a combipack	Antineoplastic agent (POM)
Desmopressin 25 mcg, 50 mcg NOCDURNA® oral lyophilisate	Agent for treatment of nocturia in adults (POM)
Epoprostenol 0.5 mg, 1.5 mg Veletri® powder for solution for infusion 0.5 mg/vial, 1.5 mg/vial	Platelet aggregation inhibitor (POM)
Human immunoglobulin 200 g/L Hizentra® solution for subcutaneous injection	Immunoglobulin (POM)
Perindopril arginine, Amlodipine VIACORAM® START tablet 3.5 mg/2.5 mg, VIACORAM® tablet 7 mg/5 mg, 14 mg/10 mg	Agents acting on the renin-angiotensin system (POM)
Rabeprazole sodium 5 mg Pariet® tablet	Agent for peptic ulcer & gastro-oesophageal reflux disease (POM)
Sodium iodide Na ¹³¹ I, solution 37-5500 MBq Sodium iodide Na ¹³¹ I POLATOM capsule	Therapeutic radiopharmaceutical agent (POM)
Ustekinumab 130 mg/vial STELARA® concentrate for solution for infusion 130 mg/26 ml	Immunosuppressant (POM)
NEW PRESENTATION	PHARMACOTHERAPEUTIC GROUP
Cetirizine dihydrochloride 5 mg/5 ml Zyrtec®-R oral solution 1 mg/ml	Antihistamine for systemic use (GSL)

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