

DRUGS APPROVED in 2019



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 ADR monitoring programme will provide valuable support to the post-marketing surveillance on drug safety.

HOW TO REPORT

Please report to us as soon as you are made aware of the adverse events. You may do so by reporting online at <https://www.hsa.gov.sg/adverse-events> or download the ADR reporting form and send the completed form 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
Abemaciclib 50 mg, 100 mg, 150 mg Verzenio® film-coated tablets	Antineoplastic agent (POM)
Acalabrutinib 100 mg CALQUENCE® hard capsules	Antineoplastic agent (POM)
Aceclofenac 100 mg Airtal® film-coated tablet	Antiinflammatory & antirheumatic agent (POM)
Albutrepenonacog alfa 250 IU/vial, 500 IU/vial, 1000 IU/vial, 2000 IU/vial IDELVION® powder & solvent for solution for injection	Antihæmorrhagic agent (POM)
Apalutamide 60 mg ERLEADA™ film-coated tablet	Antineoplastic & immunomodulating agent (POM)
Avelumab 200 mg/10 ml Bavencio® concentrate for solution for infusion	Antineoplastic agent (POM)
Avibactam 500 mg, Cefazidime 2 g Zavicefta® powder for concentrate for solution for infusion 2 g/0.5 g	Antibacterial agents for systemic use (POM)
Baloxavir marboxil 20 mg, 40 mg Xofluza® film-coated tablets	Antiviral agent for systemic use (POM)
Benralizumab 30 mg/ml FASENRA® solution for injection 30 mg/ml (pre-filled syringe)	Agent for obstructive airway diseases (POM)
Bictegravir 50 mg, Emtricitabine 200 mg, Tenofovir alafenamide 25 mg BIKTARVY® film-coated tablet 50 mg/200 mg/25 mg	Antiviral agents for systemic use (POM)
Botulism antitoxin (Equine) Serotype A > 4500 U/vial, Serotype B > 3300 U/vial, Serotype C > 3000 U/vial, Serotype D > 600 U/vial, Serotype E > 5100 U/vial, Serotype F > 3000 U/vial, Serotype G > 600 U/vial BAT® sterile solution for injection	Immune serum & immunoglobulin (POM)
Brexpiprazole 0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg, 4 mg Rexulti® film-coated tablets	Antipsychotic agent (POM)
Brigatinib 30 mg, 90 mg, 180 mg; Brigatinib 90 mg + 180 mg ALUNBRIG® film-coated tablets; ALUNBRIG® initiation pack film-coated tablet	Antineoplastic agent (POM)
Cabozantinib 20 mg, 40 mg, 60 mg CABOMETYX® film-coated tablets	Antineoplastic agent (POM)
Cariprazine 1.5 mg, 3 mg, 4.5 mg, 6 mg Symvenu® hard capsules	Antipsychotic agent (POM)
Cladribine 10 mg MAVENCLAD® tablet	Immunosuppressant (POM)
Doravirine 100 mg PIFELTRO™ film-coated tablet	Antiviral agent for systemic use (POM)
Dupilumab 300 mg/2 ml DUPIXENT® solution for injection in a pre-filled syringe	Antiinflammatory agent for dermatological use (POM)
Erdosteine 300 mg ERDOMED® hard capsules; ERDOMED® dispersible tablets	Mucolytic agent (POM)
Ferric derisomaltose 417 mg/ml (elementary iron 100 mg/ml) Monofer® solution for injection or infusion 100 mg/ml	Antianaemic preparation (POM)
Inotuzumab ozogamicin 1 mg/vial BESPOUSA® powder for concentrate for solution for infusion	Antineoplastic agent (POM)
Insulin degludec 100 U/ml, 200 U/ml Tresiba® FlexTouch® solution for injection in pre-filled pen	Antidiabetic agent (POM)
Isavuconazole 100 mg, 200 mg CRESEMBA® capsules 100 mg CRESEMBA® powder for concentrate for solution for infusion 200 mg	Antimycotic agent for systemic use (POM)
Letermovir 240 mg, 480 mg, 20 mg/ml PREVYMIS™ film-coated tablets 240 mg, 480 mg PREVYMIS™ concentrate for solution for infusion 20 mg/ml	Antiviral agent for systemic use (POM)
Lisdexamfetamine dimesylate 20 mg, 30 mg, 40 mg, 50 mg, 60 mg, 70 mg VYVANSE® capsules	Psychostimulant agent (POM)
Lonococog alfa 250 IU/vial, 500 IU/vial, 1000 IU/vial, 2000 IU/vial, 3000 IU/vial AFSTYLA® powder & solvent for solution for injection	Antihæmorrhagic agent (POM)
Lorlatinib 25 mg, 100 mg LORVQUA® film-coated tablets	Antineoplastic agent (POM)
MnB rLP2086 subfamily A 0.06 mg/0.5 ml, MnB rLP2086 subfamily B 0.06 mg/0.5 ml Trumenba® suspension for injection in single-dose pre-filled syringe 0.5 ml	Meningococcal vaccine (POM)
Neratinib 40 mg NERLYNX® film-coated tablet	Antineoplastic agent (POM)
Pandemic influenza virus type A (A/HxNy Official strain), inactivated and adjuvanted 30 mcg HA/0.5 ml Panvax® pandemic influenza vaccine (adjuvanted) 10 ml suspension for injection vial	Influenza vaccine (POM)

Continue in the next column

Pitavastatin calcium 2 mg, 4 mg LIVALO® film-coated tablets	Lipid modifying agent (POM)
Rifapentine 150 mg PRIFTIN® film-coated tablet	Antimycobacterial agent (POM)
Sarilumab 150 mg, 200 mg KEVZARA® solution for injection in pre-filled syringe KEVZARA® solution for injection in pre-filled pen	Immunosuppressant (POM)
Sofosbuvir 400 mg, Velpatasvir 100 mg, Voxilaprevir 100 mg VOSEVI® film-coated tablet 400 mg/100 mg/100 mg	Antiviral agents for systemic use (POM)
NEW COMBINATION	PHARMACOTHERAPEUTIC GROUP
Acetylsalicylic acid, Atorvastatin, Ramipril Trinomia® hard capsules 100 mg/20 mg/2.5 mg, 100 mg/20 mg/5 mg, 100 mg/20 mg/10 mg	Agents for cardiovascular diseases (POM)
Canagliflozin, Metformin hydrochloride VOKANAMET™ film-coated tablets 50 mg/500 mg, 50 mg/1000 mg, 150mg/500 mg, 150 mg/1000 mg	Antidiabetic agents (POM)
Carvedilol, Ivabradine Carivalan® film-coated tablets 6.25 mg/5 mg, 6.25 mg/7.5 mg, 12.5 mg/5 mg, 12.5 mg/7.5 mg, 25 mg/5 mg, 25 mg/7.5 mg	Agents for cardiovascular diseases (POM)
Dolutegravir 50 mg, Rilpivirine 25 mg JULUCA® film-coated tablet 50 mg/25 mg	Antiviral agents for systemic use (POM)
Fenofibrate 145 mg, Simvastatin 20 mg Cholib® film-coated tablet 145 mg/20 mg	Agents for cardiovascular diseases (POM)
Fimasartan potassium, Hydrochlorothiazide Kanarb® Plus film-coated tablets 60 mg/12.5 mg, 120 mg/12.5 mg	Antihypertensive agents (POM)
Fluticasone furoate 100 mcg, Umeclidinium 62.5 mcg, Vilanterol 25 mcg Trelegy Ellipta® inhalation powder 100mcg/62.5mcg/25mcg	Agents for obstructive airway diseases (POM)
Insulin aspart 180 nmol/ml, Insulin degludec 420 nmol/ml Ryzodeg® FlexTouch® solution for injection in pre-filled pen 100 U/ml	Antidiabetic agents (POM)
Large compartment: Disodium phosphate dihydrate 0.225 g/L, Potassium chloride 0.314 g/L, Sodium chloride 6.435 g/L, Sodium hydrogen carbonate 2.918 g/L, Small compartment: Calcium chloride dihydrate 3.675 g/L, Magnesium chloride hexahydrate 2.440 g/L PHOXILIUM® 1.2 mmol/l phosphate solution for haemodialysis/haemofiltration	Blood substitute & perfusion solution (POM)
Purified inactivated influenza virus surface antigen: A/Christchurch/16/2010, NIB-74xp(H1N1) 15 mcg/0.5 ml, A/Hong Kong/4801/2014, NYMC X-263(H3N2) 15mcg/0.5ml, B/Brisbane/60/2008, NYMC BX-35 15 mcg/0.5 ml, B/Phuket/3073/2013 15 mcg/0.5 ml SKYCellflu Quadrivalent® pre-filled syringe 0.5 ml	Influenza vaccine (POM)
NEW FORMULATION	PHARMACOTHERAPEUTIC GROUP
Adalimumab 20 mg/0.2 ml, 20 mg/0.4 ml, 40 mg/0.4 ml, 40 mg/0.8 ml HUMIRA® solution for injection in pre-filled syringe 20 mg/0.2 ml, 40 mg/0.4 ml, 40 mg/0.8 ml AMGEVITA® solution for injection in pre-filled syringe 20 mg/0.4 ml, 40 mg/0.8 ml, AMGEVITA® solution for injection in pre-filled autoinjector 40mg/0.8 ml	Immunosuppressant (POM)
Alirocumab 75 mg, 150 mg Praluent® solution for injection in pre-filled syringe 75 mg/ml, 150 mg/ml	Lipid modifying agent (POM)
Clostridium botulinum type A toxin-hæmagglutinin complex 100units/vial Neuronox® lyophilised powder for injection	Peripherally acting muscle relaxant (POM)
Dexmedetomidine 4 mcg/ml Precedex™ in 0.9% sodium chloride injection	Psycholeptic agent (POM)
Hepatitis B surface antigen 10 mcg/0.5 ml, 20 mcg/ml Engerix™ B suspension for injection in pre-filled syringe	Hepatitis vaccine (POM)
Human coagulation factor VIII 250 IU/vial, 500 IU/vial Beriate® powder & solvent for solution for injection or infusion	Antihæmorrhagic agent (POM)
Human fibrinogen 1 g FIBRYGA® powder for solution for injection or infusion 1 g/vial	Antihæmorrhagic agent (POM)
Nilotinib 50 mg Tasigna® capsule	Antineoplastic agent (POM)
Rituximab 500 mg/50 ml Truxima® concentrate for solution for infusion	Antineoplastic agent (POM)
Sodium molybdate (⁹⁹ Mo) 2–50 GBq, Sodium pertechnetate (^{99m} Tc) 2 / 4 / 6 / 8 / 10 / 12 / 16 / 20 / 25 / 50 GBq Tekcis® radionuclide generator 2–50 GBq	Diagnostic radiopharmaceutical agent (POM)
Trastuzumab 150 mg/vial, 440 mg/vial Herzuma™ powder for concentrate for solution for infusion 150 mg, 440 mg Ogivri™ lyophilised powder for injection 440 mg per vial	Antineoplastic agent (POM)
NEW DOSAGE FORM	PHARMACOTHERAPEUTIC GROUP
Betamethasone valerate 1 mg/g, Fusidic acid 20 mg/g FUCICORT® lipid cream	Antiinflammatory & antibacterial agents for dermatological use (POM)
Follitropin alfa (r-hFSH), Lutropin alfa (r-LH) Pergoveris® solution for injection in pre-filled pen (300 IU + 150 IU)/0.48 ml, (450 IU + 225 IU)/0.72 ml, (900 IU + 450 IU)/1.44 ml	Sex hormones & modulators of the genital system (POM)
Follitropin delta 12 mcg, 36 mcg, 72 mcg REKOVELLE® solution for injection in a pre-filled pen 12 mcg/0.36 ml, 36 mcg/1.08 ml, 72 mcg/2.16 ml	Sex hormone & modulator of the genital system (POM)
Olaparib 100 mg, 150 mg Lynparza® film-coated tablets	Antineoplastic agent (POM)
Phenylephrine 50 mcg/ml Phenylephrine Aqueuntant® solution for injection in pre-filled syringe	Cardiac stimulant (POM)
Povidone iodine 10 % w/v BETADINE® antiseptic liquid	Antiseptic agent for dermatological use (GSL)
NEW STRENGTH & NEW INDICATION	PHARMACOTHERAPEUTIC GROUP
Fingolimod 0.25 mg GILENYA® capsule	Immunosuppressant (POM)

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