

NEW DRUGS APPROVED in 2023



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 or email.

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 • Email: HSA_productsafety@hsa.gov.sg

NEW CHEMICAL/ BIOLOGICAL ENTITY	PHARMACOTHERAPEUTIC GROUP
Binimetinib 15 mg MEKTOVI® film-coated tablet	Antineoplastic agent (POM)
<i>Centella asiatica</i> extract 10 mg/g, <i>Plectranthus amboinicus</i> extract 2.5 mg/g FESPION® cream	Preparation for treatment of wounds & ulcers (POM)
Davesomeran 50 mcg/ml, Elasoneran 50 mcg/ml Spikevax® bivalent Original/Omicron BA.4-5 (50 micrograms/50 micrograms)/ml dispersion for injection	Viral vaccine (POM)
Andusomeran (previously Elasoneran) 0.1 mg/ml, 0.2 mg/ml Spikevax® 0.1 mg/ml dispersion for injection, Spikevax® 0.2 mg/ml dispersion for injection	Viral vaccine (POM)
Elobixibat 5 mg GOOFICE® film-coated tablet	Agent for constipation (POM)
Encorafenib 50 mg, 75 mg BRAFTOVI® hard capsules	Antineoplastic agent (POM)
Famtozinameran 15 mcg/dose, Tozinameran 15 mcg/dose COMIRNATY® Original/Omicron BA.4-5 dispersion for injection 15/15 micrograms/dose (multi-dose vial), COMIRNATY® Original/Omicron BA.4-5 dispersion for injection 15/15 micrograms/dose (single-dose vial)	Viral vaccine (POM)
Fosnetupitant 235 mg/vial, Palonosetron 0.25 mg/vial Akynzeo® IV concentrate for solution for infusion 235 mg/0.25 mg/vial	Antiemetic & antinausea agent (POM)
Galsulfase 5 mg/5 ml NAGLAZYME® concentrate for solution for infusion	Enzyme replacement therapy (POM)
Germanium (⁶⁸ Ge) chloride 0.74 – 1.85 GBq, Gallium (⁶⁸ Ga) chloride > 60 % of the loaded activity GalliaPharm® radionuclide generator	Diagnostic radiopharmaceutical agent (POM)
Gozetotide 25 µg/vial Locametz® 25 micrograms, kit for radiopharmaceutical preparation of gallium (⁶⁸ Ga) gozetotide solution for injection	Diagnostic radiopharmaceutical agent (POM)
Lutetium (¹⁷⁷ Lu) vipivotide tetraxetan 1000 Bq/mL Pluvicto® solution for injection/infusion	Therapeutic radiopharmaceutical agent (POM)
Mavacamten 2.5 mg, 5 mg, 10 mg, 15 mg CAMZYOS™ capsules	Cardiac therapy (POM)
Netarsudil 0.02 % w/v RHOPRESSA® ophthalmic solution	Antiglaucoma preparation & miotic agent (POM)
Nirmatrelvir 150 mg, Ritonavir 100 mg PAXLOVID® film-coated tablet	Antiviral agent for systemic use (POM)
Nivolumab 240 mg per vial, Relatlimab 80 mg per vial OPDUALAG® concentrate for solution for infusion 240 mg/80 mg	Antineoplastic agent (POM)
Nusinersen 12 mg/5 ml SPINRAZA® solution for injection	Agent for disorders of the musculoskeletal system (POM)
Ocrelizumab 300 mg/10 ml Ocrevus® concentrate for solution for infusion	Immunosuppressant (POM)
Ozanimod 0.46 mg & 0.23 mg, 0.92 mg Zeposia® capsules treatment initiation pack, Zeposia® capsule 0.92 mg	Immunosuppressant (POM)
Pralsetinib 100 mg Gavreto™ hard capsule	Antineoplastic agent (POM)
Rimegepant 75 mg NURTEC® orally disintegrating tablet	Antimigraine preparation (POM)
Ripretinib 50 mg QINLOCK® tablet	Antineoplastic agent (POM)

Continue in the next column

SARS-CoV-2 recombinant spike protein 5 mcg/dose Nuvaxovid® dispersion for injection COVID-19 Vaccine (recombinant, adjuvanted)	Viral vaccine (POM)
Somatogon 24 mg/1.2 ml, 60 mg/1.2 ml NGENLA® solution for injection in a pre-filled pen	Systemic hormonal preparation (POM)
Spesolimab 450 mg/7.5 ml Spevigo® concentrate for solution for infusion	Immunosuppressant (POM)
Taliglucerase alfa 200 units/vial Elelyso® powder for concentrate for solution for infusion	Enzyme replacement therapy (POM)
Tegoprazan 50 mg K-CAB® film-coated tablet	Agent for peptic ulcer & gastro-oesophageal reflux disease (POM)
Tezepelumab 210 mg TEZSPIRE™ solution for injection 210 mg in pre-filled syringe, TEZSPIRE™ solution for injection 210 mg in pre-filled pen	Agent for obstructive airway diseases (POM)
Tirzepatide 2.5 mg/0.5 ml, 5 mg/0.5 ml, 7.5 mg/0.5 ml, 10 mg/0.5 ml, 12.5 mg/0.5 ml, 15 mg/0.5 ml Mounjaro® injection	Antidiabetic agent (POM)
Tremelimumab 20 mg/ml IMJUDO® concentrate for solution for infusion	Antineoplastic agent (POM)
Treosulfan 1 g/vial, 5 g/vial Trecondi® powder for solution for infusion	Antineoplastic agent (POM)
BIOSIMILAR	PHARMACOTHERAPEUTIC GROUP
Bevacizumab 25 mg/ml Vegzelma™ concentrate for solution for infusion	Antineoplastic agent (POM)
<i>Clostridium botulinum</i> toxin type A 100 Units/vial NABOTA® powder for solution for injection	Peripherally acting muscle relaxant (POM)
Insulin aspart (rDNA origin) 100 U/ml Kirsty™ solution for injection in vial 100 units/ml, Kirsty™ solution for injection in pre-filled pen 100 units/ml	Antidiabetic agent (POM)
Teriparatide 20 mcg/80 mcL Sondelbay® injection	Agent acting on calcium homeostasis (POM)
NEW COMBINATION	PHARMACOTHERAPEUTIC GROUP
(Compartment 1): Alanine 3.66 g/L, Arginine 2.48 g/L, Aspartic acid 0.73 g/L, Glutamic acid 1.26 g/L, Glycine 1.76 g/L, Histidine 1.51 g/L, Isoleucine 1.26 g/L, Leucine 1.76 g/L, Lysine 1.99 g/L, Magnesium chloride hexahydrate 0.45 g/L, Methionine 1.26 g/L, Phenylalanine 1.76 g/L, Potassium chloride 1.19 g/L, Proline 1.51 g/L, Serine 1.00 g/L, Sodium acetate trihydrate 1.16 g/L, Sodium glycerophosphate, hydrated 1.91 g/L, Threonine 1.26 g/L, Tryptophan 0.42 g/L, Tyrosine 0.06 g/L, Valine 1.62 g/L, (Compartment 2): Calcium chloride dihydrate 0.30 g/L, Glucose anhydrous 75.0 g/L, Refined olive oil + Soya-bean oil (80:20) 30 g/L; PeriOLIMEL® N4E emulsion for infusion	Solution for parenteral nutrition (POM)
Budesonide 160 mcg/actuation, Glycopyrronium 7.2 mcg/actuation, Formoterol fumarate dihydrate 5 mcg/actuation BREZTRI AEROSPHERE® pressurised inhalation suspension 160 mcg/7.2 mcg/5 mcg per actuation	Agents for obstructive airway diseases (POM)
Ibuprofen 150 mg, Paracetamol 500 mg, Phenylephrine hydrochloride 2.5 mg Maxigesic PE® film-coated tablet	Cold & flu preparation (GSL)
Netarsudil 0.02 % w/v, Latanoprost 0.005 % w/v ROCKLATAN® ophthalmic solution, 0.02 %/0.005 %	Antiglaucoma preparation & miotic agent (POM)
Rosuvastatin, Ezetimibe Lipocomb® hard capsules 10 mg/10 mg, 20 mg/10 mg; Suvezen® film-coated tablets 10 mg/10 mg, 20 mg/10 mg	Lipid modifying agents (POM)

Continue to the next page

POM: Prescription only medicine

P: Pharmacy-only medicine

GSL: General Sales List

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NEW FORMULATION	PHARMACOTHERAPEUTIC GROUP
Adrenaline 0.1 mg/ml ADRENALINE AGUETTANT® solution for injection in pre-filled syringe	Cardiac stimulant (POM)
(Compartment 1): Alanine 6.41 g/L, Arginine 4.34 g/L, Aspartic acid 1.28 g/L, Glutamic acid 2.21 g/L, Glycine 3.07 g/L, Histidine 2.64 g/L, Isoleucine 2.21 g/L, Leucine 3.07 g/L, Lysine 3.48 g/L, Magnesium chloride hexahydrate 0.81 g/L, Methionine 2.21 g/L, Phenylalanine 3.07 g/L, Potassium chloride 2.24 g/L, Proline 2.64 g/L, Serine 1.75 g/L, Sodium acetate trihydrate 1.50 g/L, Sodium glycerophosphate, hydrated 3.67 g/L, Threonine 2.21 g/L, Tryptophan 0.74 g/L, Tyrosine 0.11 g/L, Valine 2.83 g/L, (Compartment 2): Calcium chloride dihydrate 0.52 g/L, Glucose anhydrous 140 g/L, Refined olive oil + Soya-bean oil (80:20) 40 g/L OLIMEL® N7E emulsion for infusion;	Solutions for parenteral nutrition (POM)
(Compartment 1): Alanine 8.24 g/L, Arginine 5.58 g/L, Aspartic acid 1.65 g/L, Glutamic acid 2.84 g/L, Glycine 3.95 g/L, Histidine 3.40 g/L, Isoleucine 2.84 g/L, Leucine 3.95 g/L, Lysine 4.48 g/L, Magnesium chloride hexahydrate 0.81 g/L, Methionine 2.84 g/L, Phenylalanine 3.95 g/L, Potassium chloride 2.24 g/L, Proline 3.40 g/L, Serine 2.25 g/L, Sodium acetate trihydrate 1.50 g/L, Sodium glycerophosphate, hydrated 3.67 g/L, Threonine 2.84 g/L, Tryptophan 0.95 g/L, Tyrosine 0.15 g/L, Valine 3.64 g/L, (Compartment 2): Calcium chloride dihydrate 0.52 g/L, Glucose anhydrous 110.0 g/L, Refined olive oil + Soya-bean oil (80:20) 40 g/L OLIMEL® N9E emulsion for infusion	
Doxylamine succinate 20 mg, Pyridoxine hydrochloride 20 mg BONJESTA® extended-release tablets 20 mg/20 mg	Antiemetic agents used in pregnancy (POM)
Larotrectinib 20 mg/ml VITRAKVI® oral solution	Antineoplastic agent (POM)
Menotrophin 600 IU, 1200 IU MENOPUR® solution for injection in pre-filled pen 600 IU/0.96 ml, 1200 IU/1.92 ml	Sex hormone & modulator of the genital system (POM)
Testosterone 1.62 g/100 g AndroGel® gel 16.2 mg/g	Sex hormone & modulator of the genital system (POM)
Zinc 1 mg/ml ZINC AGUETTANT® concentrate for solution for infusion	Mineral supplement (POM)
NEW DOSAGE FORM	PHARMACOTHERAPEUTIC GROUP
Acalabrutinib 100 mg CALQUENCE® film-coated tablet	Antineoplastic agent (POM)
Aripiprazole 400 mg Abilify Maintena® powder & solvent for prolonged release suspension for injection in pre-filled syringe	Antipsychotic agent (POM)
Leuprorelin 3.6 mg, 5 mg Leuprorelin Sandoz® implant in syringe	Antineoplastic & immunomodulating agent (POM)
Nicotine 2 mg SKIIP® nicotine mini lozenge 2 mg (mint)	Agent used in addictive disorders (P)
Topiramate 25 mg, 50 mg, 100mg, 200 mg TROKENDI XR® extended-release capsules	Antiepileptic agent & antimigraine preparation (POM)
Vedolizumab 108 mg/0.68 ml Entyvio® solution for injection in pre-filled pen	Immunosuppressant (POM)
NEW STRENGTH	PHARMACOTHERAPEUTIC GROUP
Selenium 10 mcg/ml SELENIUM AGUETTANT® concentrate for solution for infusion	Mineral supplement (POM)
Turoctocog alfa 2000 IU/vial NovoEight® powder & solvent for solution for injection	Antihæmorrhagic agent (POM)
Upadacitinib 45 mg RINVOQ® extended-release tablet	Immunosuppressant (POM)
NEW PRESENTATION	PHARMACOTHERAPEUTIC GROUP
Famtozinameran 5 mcg/dose, Tozinameran 5 mcg/dose COMIRNATY® Original/Omicron BA.4-5 concentrate for dispersion for injection 5/5 micrograms/dose (multi-dose vial)	Viral vaccine (POM)
Risankizumab 600 mg/10 ml, 360 mg/2.4 ml SKYRIZI® concentrate for solution for infusion 600 mg/10 ml, SKYRIZI® solution for injection in pre-filled cartridge with on-body injector 360 mg/2.4 ml	Immunosuppressant (POM)

NEW BRAND	PHARMACOTHERAPEUTIC GROUP
Aprotinin solution 1000 KIU, Calcium chloride dihydrate 5.9 mg, Factor XIII 60 IU, Fibrinogen 90 mg, Thrombin 500 IU Beriplast® P Combi-Set 1 ml powder & solvent for sealant;	Tissue adhesive & local hæmostatic agent (POM)
Aprotinin solution 3000 KIU, Calcium chloride dihydrate 17.7 mg, Factor XIII 180 IU, Fibrinogen 270 mg, Thrombin 1500 IU Beriplast® P Combi-Set 3 ml powder & solvent for sealant	
Dexmedetomidine 100 mcg/ml Dexdor® concentrate for solution for infusion	Hypnotic & sedative agent (POM)
Human immunoglobulin G 50 mg/ml Immunoglobulins SG® injection 5 %	Agent used in treatment of immunodeficiencies, autoimmune & inflammatory disorders (POM)
Human serum albumin 10 g/50 ml Albumin SG® injection 20 %	Blood substitute & perfusion solution (POM)
NEW INDICATION	PHARMACOTHERAPEUTIC GROUP
Fluticasone furoate 200 mcg, Umeclidinium 62.5 mcg, Vilanterol 25 mcg Trelegy Ellipta® inhalation powder 200 mcg/62.5 mcg/25 mcg	Agents for obstructive airway diseases (POM)
Semaglutide 0.25 mg/0.5 ml, 0.5 mg/0.5 ml, 1 mg/0.5 ml, 1.7 mg/0.75 ml, 2.4 mg/0.75 ml Wegovy® solution for injection in pre-filled pen;	
Semaglutide 0.68 mg/ml, 1.34 mg/ml, 2.27 mg/ml, 3.2 mg/ml Wegovy® 0.25 mg/dose FlexTouch® solution for injection in pre-filled pen 0.68 mg/ml, Wegovy® 0.5 mg/dose FlexTouch® solution for injection in pre-filled pen 1.34 mg/ml, Wegovy® 1 mg/dose FlexTouch® solution for injection in pre-filled pen 1.34 mg/ml, Wegovy® 1.7 mg/dose FlexTouch® solution for injection in pre-filled pen 2.27 mg/ml, Wegovy® 2.4 mg/dose FlexTouch® solution for injection in pre-filled pen 3.2 mg/ml	Agent for weight management (POM)
NEW PATIENT POPULATION	PHARMACOTHERAPEUTIC GROUP
Mepolizumab 40 mg/0.4 ml NUCALA® solution for injection in pre-filled syringe	Agent for obstructive airway diseases (POM)
NEW PACK SIZE	PHARMACOTHERAPEUTIC GROUP
Trastuzumab 420 mg/vial Trazher® (Trastuzumab) powder for concentrate for solution for infusion	Antineoplastic agent (POM)

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