

NEW DRUGS APPROVED in 2022



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
Abrocitinib 50 mg, 100 mg, 200 mg CIBINQO™ film-coated tablets	Dermatological preparation for systemic use (POM)
Amivantamab 350 mg/7 ml RYBREVA™ concentrate for solution for infusion	Antineoplastic agent (POM)
Arsenic trioxide 1 mg/ml Asadin® injection	Antineoplastic agent (POM)
Asciminib 20 mg, 40 mg Scemblix® film-coated tablets	Antineoplastic agent (POM)
Belantamab mafodotin 100 mg/vial BLENREP® powder for concentrate for solution for infusion 100 mg	Antineoplastic agent (POM)
Bemiparin sodium 2500 IU Anti-Xa/0.2 ml, 3500 IU Anti-Xa/0.2 ml HIBOR® solution for injection in pre-filled syringes	Antithrombotic agent (POM)
Cabotegravir 30 mg, 200 mg/ml VOCABRIA® film-coated tablet 30 mg; VOCABRIA® prolonged-release suspension for injection 400 mg/2 ml, 600 mg/3 ml	Antiviral agent for systemic use (POM)
Crisaborole 2% w/w STAKUIS® ointment	Dermatological preparation for topical use (POM)
CRM ₁₉₇ carrier protein approximately 51 µg/0.5 ml, Pneumococcal polysaccharide: serotype 1 (conjugate) 2.2 µg/0.5 ml, serotype 3 (conjugate) 2.2 µg/0.5 ml, serotype 4 (conjugate) 2.2 µg/0.5 ml, serotype 5 (conjugate) 2.2 µg/0.5 ml, serotype 6A (conjugate) 2.2 µg/0.5 ml, serotype 6B (conjugate) 4.4 µg/0.5 ml, serotype 7F (conjugate) 2.2 µg/0.5 ml, serotype 8 (conjugate) 2.2 µg/0.5 ml, serotype 9V (conjugate) 2.2 µg/0.5 ml, serotype 10A (conjugate) 2.2 µg/0.5 ml, serotype 11A (conjugate) 2.2 µg/0.5 ml, serotype 12F (conjugate) 2.2 µg/0.5 ml, serotype 14 (conjugate) 2.2 µg/0.5 ml, serotype 15B (conjugate) 2.2 µg/0.5 ml, serotype 18C (conjugate) 2.2 µg/0.5 ml, serotype 19A (conjugate) 2.2 µg/0.5 ml, serotype 19F (conjugate) 2.2 µg/0.5 ml, serotype 22F (conjugate) 2.2 µg/0.5 ml, serotype 23F (conjugate) 2.2 µg/0.5 ml, serotype 33F (conjugate) 2.2 µg/0.5 ml Apexxna® suspension for injection in single-dose pre-filled syringe 0.5 ml	Bacterial vaccine (POM)
Difelikefalin 50 mcg/ml KORSUVA® solution for injection	Analgesic opioid peptide (POM)
Diphtheria toxoid 2.0 Lf/0.5 ml, Filamentous haemagglutinin 5 ug/0.5 ml, Recombinant pertussis toxin 5 ug/0.5 ml, Tetanus toxoid 7.5 Lf/0.5 ml Boostagen® suspension for injection	Bacterial vaccine (POM)
Dostarlimab 500 mg/10 ml JEMPERLI® concentrate for solution for infusion	Antineoplastic agent (POM)
Enfortumab vedotin 20 mg/vial, 30 mg/vial PADCEV® powder for concentrate for solution for infusion	Antineoplastic agent (POM)
Faricimab 6 mg/0.05 ml Vabysmo® solution for injection	Ophthalmological agent (POM)
Fedratinib 100 mg Inrebic® capsule	Antineoplastic agent (POM)
Isatuximab 20 mg/ml SARCLISA® concentrate for solution for infusion	Antineoplastic agent (POM)
Luliconazole 5% w/w LUCONAC® external solution for nails	Antifungal agent for topical use (POM)
Luspatercept 25 mg/vial, 75 mg/vial Reblozyl® powder for solution for injection	Antianemic preparation (POM)
Niraparib 100 mg, 200 mg, 300 mg ZEJULA® film-coated tablets	Antineoplastic agent (POM)
Orelabrutinib 50 mg HIBRUKA® tablet	Antineoplastic agent (POM)
Pemafibrate 0.1 mg PARMODIA® film-coated tablet	Lipid modifying agent (POM)
Sacituzumab govitecan 180 mg/vial TRODELVY™ powder for solution for infusion	Antineoplastic agent (POM)
Safinamide 50 mg Equifina® film-coated tablet	Antiparkinson agent (POM)
Selinexor 20 mg XPOVIO® film-coated tablet	Antineoplastic agent (POM)
Sotorasib 120 mg LUMAKRAS® film-coated tablet	Antineoplastic agent (POM)
Thiotepa 15 mg/vial, 100 mg/vial TEPADINA® powder for concentrate for solution for infusion	Antineoplastic agent (POM)
Trifarotene 50 mcg/g Aklief® cream	Anti-acne preparation for topical use (POM)

BIOSIMILAR	PHARMACOTHERAPEUTIC GROUP
Adalimumab 20 mg/0.4 ml, 40 mg/0.4 ml, 40 mg/0.8 ml ABRILADA® solution for injection in single-dose pre-filled pen 40 mg/0.8 ml, ABRILADA® solution for injection in single-dose pre-filled syringe 20 mg/0.4 ml, 40 mg/0.8 ml; Yuflyma® solution for injection in pre-filled pen 40 mg/0.4 ml	Immunosuppressant (POM)
Bevacizumab 25 mg/ml ABEVMY™ concentrate for solution for infusion	Antineoplastic agent (POM)
Etanercept 25 mg/0.5 ml, 50 mg/ml Nepexto® solution for injection in pre-filled pen 50 mg/ml; Nepexto® solution for injection in pre-filled syringe 25 mg/0.5 ml, 50 mg/ml	Immunosuppressant (POM)
Rituximab 100 mg/10 ml, 500 mg/50 ml RUXIENCE® concentrate for solution for infusion	Antineoplastic agent (POM)
Trastuzumab 150 mg/vial Trazher powder for concentrate for solution for infusion	Antineoplastic agent (POM)
NEW COMBINATION	PHARMACOTHERAPEUTIC GROUP
Dexamethasone 1 mg/ml, Levofloxacin 5 mg/ml Ducressa® eye drops solution 1 mg/ml + 5 mg/ml	Ophthalmological agent (POM)
Meningococcal polysaccharide, serogroup A 10 mcg/0.5 ml, Meningococcal polysaccharide, serogroup C 10 mcg/0.5 ml, Meningococcal polysaccharide, serogroup W 10 mcg/0.5 ml, Meningococcal polysaccharide, serogroup Y 10 mcg/0.5 ml, Tetanus toxoid carrier protein 55 mcg/0.5 ml MenQuadfi® solution for injection	Bacterial vaccine (POM)
Naltrexone hydrochloride 8 mg, Bupropion hydrochloride 90 mg CONTRAVE® prolonged release tablet 8 mg/90 mg	Antiobesity preparation (POM)
Olopatadine 600 mcg/spray, Mometasone furoate 25 mcg/spray RYALTRIS® nasal spray 600 mcg/25 mcg	Antiallergy & antiinflammatory preparation for topical use (POM)
Rosuvastatin, Ezetimibe ROZEVON® film-coated tablets 5 mg/10 mg, 10 mg/10 mg, 20 mg/10 mg, 40 mg/10 mg; LYPSTAPLUS® film-coated tablets 10 mg/10 mg, 20 mg/10 mg	Lipid modifying agents (POM)
NEW FORMULATION	PHARMACOTHERAPEUTIC GROUP
Abemaciclib 50 mg, 100 mg, 150 mg Yulareb® film-coated tablets	Antineoplastic agent (POM)
Bilastine 20 mg ALIGRIN™ tablet	Antihistamine for systemic use (POM)
Dupilumab 100 mg/0.67 ml DUPIXENT® solution for injection in a pre-filled syringe	Antiinflammatory preparation (POM)
Naproxen 25 mg/ml Pronaxen® oral suspension	Antiinflammatory & antirheumatic agent (POM)
Paliperidone 700 mg/3.5 ml, 1000 mg/5 ml INVEGA HAFYERA® prolonged-release suspension for IM injection in pre-filled syringe	Antipsychotic agent (POM)
Tozinameran 3 mcg/dose COMIRNATY®, concentrate for dispersion for injection	Viral vaccine (POM)
NEW DOSAGE FORM	PHARMACOTHERAPEUTIC GROUP
Azacitidine 200 mg, 300 mg ONUREG™ film-coated tablets	Antineoplastic agent (POM)
Diclofenac sodium 1 g/100 g, 15 mg/patch Salonpas® diclofenac gel 1%; Salonpas® diclofenac patch 1%	Antiinflammatory preparation for topical use (GSL)
Dolutegravir 5 mg TIVICAY® dispersible tablet	Antiviral agent for systemic use (POM)
Ibuprofen 4 mg/ml B. Braun® ibuprofen solution for infusion	Antiinflammatory & antirheumatic agent (POM)
Lidocaine 7.5 mg/dose, Prilocaine 2.5 mg/dose Fortacin® cutaneous spray solution 7.5 mg/dose + 2.5 mg/dose	Local anaesthetic agents (POM)
Nicotine 1 mg/spray Nicorette® QuickMist mouthspray	Agent used in addictive disorders (P)
Paracetamol 1000 mg, Ibuprofen 300 mg MAXIGESIC® IV solution for infusion 1000 mg/300 mg per 100 ml vial	Analgesic & antipyretic agent (POM)
Perampanel 0.5 mg/ml Fycompa® oral suspension	Antiepileptic agent (POM)
Rilpivirine 300 mg/ml REKAMBYS® prolonged-release suspension for injection	Antiviral agent for systemic use (POM)
Rivaroxaban 1 mg/ml Xarelto® granules for oral suspension	Antithrombotic agent (POM)
Vancomycin 125 mg, 250 mg Vancover® capsules	Intestinal antiinfective agent (POM)
Vortioxetine 20 mg/ml Brintellix® oral drops, solution	Antidepressant (POM)
NEW INDICATION	PHARMACOTHERAPEUTIC GROUP
Tolvaptan 15 mg, 30 mg, 45 mg + 15 mg, 60 mg + 30 mg, 90 mg + 30 mg JINARC® tablets 15 mg, 30 mg, 45 mg/15 mg, 60 mg/30 mg, 90 mg/30 mg	Aquaretic agent (POM)
NEW STRENGTH	PHARMACOTHERAPEUTIC GROUP
Follitropin alfa 11 mcg/0.25 ml GONAL-F® 150 IU/0.25 ml (11 micrograms/0.25 ml) solution for injection in pre-filled pen	Sex hormone & modulator of the genital system (POM)
Upadacitinib 30 mg RINVOQ® extended-release tablet	Immunosuppressant (POM)
NEW PRESENTATION	PHARMACOTHERAPEUTIC GROUP
Gadoxetate disodium 0.25 mmol/ml Primovist® solution for injection in vial	Contrast media agent (POM)
NEW BRAND	PHARMACOTHERAPEUTIC GROUP
Nebivolol 5 mg NOXBETA™ tablet	Agent acting on the cardiovascular system (POM)

Continue in the next column

POM: Prescription only medicine

P: Pharmacy-only medicine

GSL: General Sales List