

## \*NEW DRUGS APPROVED BY THE HSA IN 2001

The Pharmacovigilance Unit, Centre For Pharmaceutical Administration encourages the reporting of ALL suspected reactions to the new drugs listed below. Your active reporting in the postmarketing surveillance will ensure the ongoing safety monitoring of these new drugs.



\* New approved chemical entities, formulations, indications.

Product	Approved indication	Product	Approved indication	Product	Approved indication
Abacavir 300 mg, lamivudine 150 mg, zidovudine 300 mg, <b>Trizivir</b> <sup>®</sup> tablet	Antiretroviral therapy for treatment of HIV infected adults	Galantamine 4 mg, 8 mg, 12 mg tab, 4 mg/ml oral solution. <b>Reminyl</b> <sup>®</sup> tablet and oral solution	Treatment of mild to moderately severe dementia of the Alzheimer type	Nicotine 1 mg <b>Nicotinell Mint</b> <sup>®</sup> lozenge	For relief of nicotine withdrawal symptoms, in nicotine dependency as an aid to smoking cessation
Acrivastin 8 mg, pseudoephedrine 60 mg <b>Duact IR</b> <sup>®</sup> capsule	Symptomatic relief of allergic rhinitis	Gemtuzumab ozogamicin 5 mg <b>Mylotarg</b> <sup>®</sup> injection	Treatment of patients with CD33 positive acute myeloid leukemia in first relapse who are ≥ 60 years old and who are not considered candidates for cytotoxic chemotherapy	Octreotide 10 mg, 20 mg, 30 mg <b>Sandostatin Lar</b> <sup>®</sup> for injection	Treatment of patients with agromegaly and patients with symptoms associated with functional gastro-entero-pancreatic endocrine tumours
Alendronate 70 mg <b>Fosamax</b> <sup>®</sup> tablet	Treatment and prevention of osteoporosis in postmenopausal women	Gestodene 60 mcg, ethinyl estradiol 15 mcg <b>Minesse</b> <sup>®</sup> tablet	Prevention of pregnancy	Ofloxacin 3% <b>Tarivid</b> <sup>®</sup> ointment (ophthalmic)	Fluoroquinone antibacterial for ophthalmological infections
Bisoprolol fumarate 2.5 mg, hydrochlorothiazide 6.25 mg <b>Lodoz</b> <sup>®</sup> tablet	Treatment of hypertension	Imatinib 100 mg, 500 mg <b>Glivec</b> <sup>®</sup> capsule	Treatment of chronic myeloid leukaemia (CML) in blast crisis, accelerated phase, or in chronic phase after failure of interferon-alpha therapy	Pilocarpine 5 mg <b>Salagen</b> <sup>®</sup> tablet	(1) Treatment of symptoms of dry mouth from salivary gland hypofunction caused by radiotherapy for cancer of the head and neck (2) Treatment of symptoms of dry mouth in patients with Sjogren's syndrome
Desloratadine 5 mg <b>Aerius</b> <sup>®</sup> tablet	For relief of symptoms associated with seasonal allergic rhinitis	Irbesartan 150 mg, hydrochlorothiazide 12.5 mg <b>CoAprovel</b> <sup>®</sup> tablet	Treatment of essential hypertension	Risedronate sodium 5 mg, 30mg <b>Actonel</b> <sup>®</sup> tablet	Treatment of Paget's disease of the bone (osteitis deformans)
Dexmedetomidine 100 mcg/ml <b>Precedex Concentrate</b> <sup>®</sup> injection	Sedation of initially intubated and mechanically ventilated patients during treatment in an intensive care setting	Levetiracetam 250 mg, 500 mg, 1 g <b>Keppra</b> <sup>®</sup> tablet	Adjunctive therapy in the treatment of partial onset seizures with or without secondary generalisation in patients with epilepsy	Ritonavir 33.3 mg/ iopinavir 133.3 mg/cap, Ritonavir 20 mg/iopinavir 80 mg/oral solution <b>Kaletra</b> <sup>®</sup> capsule, oral solution	Treatment of HIV-infection, when used in combination with other anti-retroviral agents
Diatrizoate meglumine 660 mg/ml, diatrizoate sodium 100 mg/ml <b>MD-Gastroview</b> <sup>®</sup> solution (oral)	Radiographic examination of the gastrointestinal tract	Levobupivacaine 2.5 mg/ml, 5 mg/ml, 7.5 mg/ml <b>Chirocaine</b> <sup>®</sup> injection	Adults: Surgical anaesthesia and pain management Children: Infiltration analgesia	Sibutramine HCl 10 mg, 15 mg <b>Reductil</b> <sup>®</sup> capsule	Adjunctive therapy within a weight management programme for obesity
Dorzolamide HCl 2%, timolol maleate 0.5% <b>Cosopt</b> <sup>®</sup> solution (ophthalmic)	Treatment of elevated intraocular pressure in patients with ocular hypertension, open-angle glaucoma, pseudoexfoliative glaucoma or other secondary open-angle glaucomas where use of combination therapy is appropriate	Meningococcal polysaccharide serogroup W135 50 mcg, serogroup A 50 mcg, serogroup Y 50 mcg, serogroup C 50 mcg (one dose) <b>Mencevax ACWY Vaccine</b> <sup>®</sup> powder for injection	Active immunisation against meningococcal meningitis caused by meningococci of serogroups A, C, W135 and Y for adults and children > 2 years of age	Temozolomide 5 mg, 20 mg, 100 mg, 250 mg <b>Temodal</b> <sup>®</sup> capsule	Treatment of patients with malignant glioma, such as glioblastoma multiforme or anaplastic astrocytoma, showing recurrence or progression after standard therapy
Esomeprazole 20 mg, 40 mg <b>Nexium</b> <sup>®</sup> tablet	(1) Gastroesophageal reflux disease (2) Eradication of Helicobacter pylori, when used in combination with appropriate antibacterial therapeutic regimens	Midodrine HCl 5 mg <b>Gutron</b> <sup>®</sup> tablet	Treatment of idiopathic / neurogenic orthostatic hypotension	Tiagabine 5 mg, 10 mg, 15 mg <b>Gabitril</b> <sup>®</sup> tablet	Add-on therapy for partial seizures with or without secondary generalisations
Fexofenadine 120 mg, 180 mg <b>Telfast</b> <sup>®</sup> tablet	120 mg tab – Relief of symptoms associated with allergic rhinitis 180 mg tab – Relief of symptoms associated with chronic idiopathic urticaria	Montelukast 4 mg <b>Singulair</b> <sup>®</sup> tablet	Prophylaxis and chronic treatment of asthma in adults and pediatric patients ≥ 2 years of age	Tretinoin 0.05% <b>Retinova</b> <sup>®</sup> cream	Topical treatment of mottled hyperpigmentation, roughness and fine wrinkling of photodamaged skin due to chronic sun exposure
Formoterol fumarate dihydrate 4.5 mcg, budesonide 80 mcg per dose <b>Symbicort Turbuhaler</b> <sup>®</sup>	Treatment of asthma where use of a combination inhaled corticosteroid and long acting beta-agonist is appropriate	Nateglinide 60 mg, 120 mg <b>Starlix</b> <sup>®</sup> tablet	Treatment of patients with type II diabetes (NIDDM)	Verteporfin 15 mg/vial <b>Visudyne</b> <sup>®</sup> injection	Treatment of age-related macular degeneration in patients with predominantly classic subfoveal choroidal neovascularisation
		Nebivolol 5 mg <b>Nebilet</b> <sup>®</sup> tablet	Treatment of essential hypertension	Zoledronic acid 4 mg/vial <b>Zometa</b> <sup>®</sup> powder for solution for infusion	Treatment of tumour-induced hypercalcaemia

### How to report:

The ADR Report Forms can be downloaded at <http://www.hsa.gov.sg/cpa> or obtained from pharmacies at public hospitals/institutions and Pharmacovigilance Unit, Centre for Pharmaceutical Administration.

Please send the completed forms (through your respective hospital pharmacies, if applicable) by mail, email or fax to Pharmacovigilance Unit.

### Where to send your report:

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