

New Drugs Approved In 2003

The Pharmacovigilance Unit of the Centre for Drug Administration, HSA encourages the reporting of all suspected adverse drug reactions to the new drugs listed below.

Your active participation in the adverse drug reaction monitoring programme will provide valuable support to the ongoing postmarketing surveillance on drug safety.

New drug	Pharmacotherapeutic group
Adalimumab 40 mg/0.8 ml Humira [®] injection (pre-filled syringe)	Selective immunosuppressive agents
Adefovir 10 mg Hepsera [®] tablet	Antivirals - nucleoside reverse transcriptase inhibitors
Aprepitant 80 mg, 125 mg Emend [®] capsule	Antiemetics
Aprepitant 80 mg with 125 mg Emend [®] tri-pack capsule	
Carbetocin 100 mcg/ml Duratocin [®] injection	Drugs acting on uterus - oxytocin analogue
Clostridiopeptidase A 1.2 u/g, proteases 0.24 u/g Iruxol Mono [®] ointment	Dermatologicals - proteolytic enzymes for treatment of wounds and ulcers
Drospirenone 3 mg, ethinyloestradiol 0.03 mg Yasmin [®] tablet	Hormonal contraceptives - progestogen and oestrogens, fixed combinations
Dutasteride 0.5 mg Avodart [®] capsule	Drugs used in benign prostatic hypertrophy - testosterone-5-alpha reductase inhibitors
Escitalopram 5 mg, 10 mg, 15 mg, 20 mg Lexapro [®] tablet	Antidepressants - selective serotonin re-uptake inhibitors
Ezetimibe 10 mg Ezetrol [®] tablet	Antihyperlipidaemic agents
Ferucarbotran eqv iron 0.5 mmol/ml Resovist [®] injection	MRI contrast media
Gadobutrol 604.72 mg/ml (1.0 mmol/ml) Gadovist [®] injection	MRI contrast media
Ganirelix 0.25 mg/0.5 ml Orgalutran [®] injection	Systemic hormones - antigonadotropin releasing hormones

New drug	Pharmacotherapeutic group
Gefitinib 250 mg Iressa [®] tablet	Antineoplastics
Memantine 10 mg/g Ebixa [®] oral drops	Drugs for dementia
Memantine 10 mg Ebixa [®] tablet	
Oxandrolone 2.5 mg Oxandrin [®] tablet	Anabolic steroids
Paricalcitol 5 mcg/ml Zemplar [®] injection	Thyroid therapy
Pimecrolimus 10 mg/g (1%w/w) Elidel [®] cream	Dermatologicals for atopic dermatitis
Pioglitazone 15 mg, 30 mg Actos [®] tablet	Antidiabetics - thiazolidinediones
Tadalafil 20 mg Cialis [®] tablet	Drugs used in erectile dysfunction
Telithromycin 400 mg Ketek [®] tablet	Antibacterials - macrolides
Tiotropium 18 mcg Spiriva [®] inhalation capsule with HandiHaler	Drugs for obstructive airway disease - anticholinergics
Valganciclovir 450 mg Valcyte [®] tablet	Antivirals - nucleosides and nucleotides
Vardenafil 5 mg, 10 mg, 20 mg Levitra [®] tablet	Drugs used in erectile dysfunction
Voriconazole 50 mg, 200 mg Vfend [®] tablet	Antifungals - triazole derivatives
Voriconazole 200 mg/20 ml Vfend [®] for infusion	

How to report:

The ADR reporting form can be obtained at http://www.hsa.gov.sg/adr_form, from pharmacies at hospitals/institutions or Pharmacovigilance Unit at the Centre for Drug Administration. Please send the completed ADR reporting form either by mail, email or fax to the Pharmacovigilance Unit. Online ADR reporting is available at http://www.hsa.gov.sg/adr_online.

Where to send your report:

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