

## \*NEW DRUGS APPROVED BY THE HSA IN 2002

The Pharmacovigilance Unit, Centre For Pharmaceutical Administration, encourages the reporting of ALL suspected adverse drug 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 / biological entities and formulations

New entity	Pharmacotherapeutic group
Apomorphine 2 mg, 3 mg <b>Uprima</b> <sup>®</sup> sublingual tablet	Drugs used in erectile dysfunction
Bimatoprost 0.03% <b>Lumigan</b> <sup>®</sup> ophthalmic solution	Antiglaucoma agents
Caspofungin 50 mg, 70 mg <b>Cancidas</b> <sup>®</sup> injection	Antimycotic agents
Choriogonadotropin alfa 250 mcg <b>Ovidrel</b> <sup>®</sup> injection	Gonadotrophins
Deferiprone 500 mg <b>Ferriprox</b> <sup>®</sup> tablet	Iron chelating agents
Drotrecogin alfa (activated) 2 mg/ml <b>Xigris</b> <sup>®</sup> infusion	Antithrombotic agents - Enzymes
Eletriptan 20 mg, 40 mg, 80 mg <b>Relpax</b> <sup>®</sup> tablet	Antimigraine agents - Selective serotonin (5HT <sub>1</sub> ) agonists
Ertapenem 1 g <b>Invanz</b> <sup>®</sup> injection	Antibacterial agents - Carbapenems
Etanercept 25 mg <b>Enbrel</b> <sup>®</sup> injection	Selective immunosuppressive agents
Etonogestrel 68 mg <b>Implanon</b> <sup>®</sup> implant	Hormonal contraceptives - Progestogens
Etoricoxib 60 mg, 120 mg <b>Arcoxia</b> <sup>®</sup> tablet	Nonsteroidal anti-inflammatory agents - Coxibs
Fondaparinux 2.5 mg/0.5 ml <b>Arixtra</b> <sup>®</sup> injection	Antithrombotic agents
Human autologous chondrocytes min 1,000,000 cells (tissue implantation) <b>Cartogen</b> <sup>®</sup>	Human cell products
Human autologous chondrocytes min 800,000 cells (tissue implantation) <b>Co.Don Chondrotransplant</b> <sup>®</sup>	Human cell products
Infliximab 100 mg <b>Remicade</b> <sup>®</sup> infusion	Selective immunosuppressive agents
Insulin glargine (rDNA) 100 iu/ml <b>Lantus</b> <sup>®</sup> injection Insulin glargine 100 iu/ml <b>Lantus</b> <sup>®</sup> Optiset Solution for injection	Antidiabetics - Insulin analogues (long-acting)
Ivermectin 3 mg <b>Stromectol</b> <sup>®</sup> tablet	Anthelmintics

New entity	Pharmacotherapeutic group
Latanoprost 0.005% Timolol maleate 0.5% <b>Xalacom</b> <sup>®</sup> eyedrops	Antiglaucoma agents
Lercanidipine 10 mg <b>Zanidip</b> <sup>®</sup> tablet	Selective calcium channel blockers with mainly vascular effects - Dihydropyridine derivatives
Levocetirizine 5 mg <b>Xyzal</b> <sup>®</sup> tablet	Antihistamines - Piperazine derivatives
Lutropin alfa 75 iu <b>Luveris</b> <sup>®</sup> injection	Gonadotrophins
Peginterferon alfa-2a 135 mcg/ml, 180 mcg/ml <b>Pegasys</b> <sup>®</sup> injection	Immunostimulants - Interferons
Peginterferon alfa-2b 50 mcg/0.5 ml, 80 mcg/0.5 ml, 100 mcg/0.5 ml, 120 mcg/0.5 ml, 150 mcg/0.5 ml <b>Peg-intron</b> <sup>®</sup> injection	Immunostimulants - Interferons
Rasburicase 1.5 mg <b>Fasturtec</b> <sup>®</sup> infusion	Detoxifying agents for antineoplastic treatment
Rosuvastatin 10 mg, 20 mg, 40 mg <b>Crestor</b> <sup>®</sup> tablet	Serum lipid reducing agents - HMG CoA reductase inhibitors
Sirolimus 1 mg tab, 1 mg/ml oral solution <b>Rapamune</b> <sup>®</sup>	Selective immunosuppressive agents
Streptococcus Pneumoniae Polysaccharide (serotypes 4, 6B, 9V, 14, 18C, 19F, 23F) <b>Prevenar</b> <sup>®</sup> vaccine	Pneumococcal vaccines
Tegaserod 6 mg <b>Zelmac</b> <sup>®</sup> tablet	Drugs for functional gastrointestinal disorders - Drugs acting on serotonin receptors
Tenecteplase 6,000 iu, 8,000 iu, 10,000 iu <b>Metalyse</b> <sup>®</sup> injection	Antithrombotic agents - Enzymes
Travoprost 0.004% <b>Travatan</b> <sup>®</sup> ophthalmic solution	Antiglaucoma agents
Valdecoxib 10 mg, 20 mg <b>Bextra</b> <sup>®</sup> tablet	Nonsteroidal anti-inflammatory agents - Coxibs
Ziprasidone 20 mg, 40 mg, 60 mg, 80 mg <b>Zeldox</b> <sup>®</sup> capsule	Antipsychotics - Indole derivatives

New formulation	Pharmacotherapeutic group
Amphotericin B 50 mg <b>Ambisome</b> <sup>®</sup> injection	Antimycotic agents
Azithromycin 500 mg <b>Zithromax</b> <sup>®</sup> infusion	Antibiotics - Macrolides
Calcitriol 3 mcg/g <b>Silkis</b> <sup>®</sup> Ointment	Antipsoriatics for topical use
Flurbiprofen 40 mg/sheet <b>Acustop cataplasma</b> <sup>®</sup> plaster	Nonsteroidal anti-inflammatory agents for topical use
Ganciclovir 0.15% <b>Virgan</b> <sup>®</sup> ophthalmic gel	Antivirals for ophthalmic use
Itraconazole 10 mg/ml <b>Sporanox</b> <sup>®</sup> injection	Antimycotics - Triazole derivatives
Levofloxacin infusion 500 mg/100 mL, ophthalmic solution 5% <b>Cravit</b> <sup>®</sup>	Antibiotics - Fluoroquinolones
Meloxicam 15 mg/1.5 ml <b>Mobic</b> <sup>®</sup> injection	Nonsteroidal anti-inflammatory and antirheumatic agents - Oxycams
Melphalan 50 mg <b>Alkeran</b> <sup>®</sup> injection	Antineoplastic agents - Nitrogen mustard analogues
Methylphenidate 18 mg, 36 mg, 54 mg <b>Concerta</b> <sup>®</sup> extended-release tablet	Psychostimulants - Centrally acting sympathomimetics
Moxifloxacin 400 mg/250 ml <b>Avelox</b> <sup>®</sup> solution for infusion	Antibiotics - Fluoroquinolones
Oestradiol 150 mcg/dose <b>Aerodiol</b> <sup>®</sup> nasal spray solution	Oestrogens
White tab: Oestradiol 1 mg Grey tab: Oestradiol 1 mg Dydrogesterone 10 mg <b>Femoston</b> <sup>®</sup> 1/10 <sup>®</sup> tablet	Progestogens and oestrogens for sequential administration
Oestradiol 1 mg, Dydrogesterone 5 mg (salmon-coloured) <b>Femoston</b> <sup>®</sup> Conti 1/5 tablet	Progestogens and oestrogens for sequential administration
Phase 1 patch: Oestradiol 1.5 mg Phase 2 patch: Oestradiol 1.5 mg, levonorgestrel 1.5 mg <b>FEM 7</b> <sup>®</sup> Combi transdermal patch	Progestogens and oestrogens for sequential administration
Sertaconazole 300 mg <b>Zalain</b> <sup>®</sup> vaginal suppository	Antifungals for dermatological use - Imidazole and triazole derivatives

### How to report:

The ADR reporting form can be downloaded at <http://www.hsa.gov.sg> or obtained from pharmacies at public hospitals/institutions and Pharmacovigilance Unit at the Centre for Pharmaceutical Administration. Please send the completed ADR reporting form by mail, email or fax to the Pharmacovigilance Unit. Online ADR reporting is available at [http://www.hsa.gov.sg/ADR\\_online](http://www.hsa.gov.sg/ADR_online).

### Where to send your report:

**Pharmacovigilance Unit  
Centre for Pharmaceutical Administration  
Health Sciences Authority**  
2 Jalan Bukit Merah Singapore 169547  
Tel : 6 325 5604  
Fax : 6 325 5448  
Email: HSA\_DRUGSAFETY@hsa.gov.sg

The pharmacotherapeutic groups are based on the Anatomical Therapeutic Chemical (ATC) classification produced by the WHO Collaborating Centre for Drug Statistics Methodology.