



FEBRUARY 2008

NEW DRUGS UNDER INTENSIVE SURVEILLANCE

(Marketed drugs only)

REPORT ANY ADVERSE REACTION WHICH COULD CONCEIVABLY BE ASSOCIATED WITH:



New additions this month: Fostair (Formoterol and Beclometasone), Isentress (Raltegravir), Yondelis (Trabectedin)

Removals this month: Pletal (Cilostazol), Prozac (Fluoxetine)

Trade Name/s (Generic Name)
Aclasta (Zoledronic acid)
Acomplia (Rimonabant)
Actos (Pioglitazone)
Adartrel (Ropinirole)
Aldara (Imiquimod)
Aldurazyme (Laronidase)
Aldurazyme (Laronidase)
Alimta (Pemetrexed)
Aloxi (Palonosetron)
Alvesco (Ciclesonide)
Amavio (Ciclesonide)
Ambirix (Inactivated Hepatitis A Virus Recombinant DNA)
Abtigen/Hepatitis B Surface Antigen Recombinant DNA
Angiox (Bivalirudin)
Anzemet (Dolasetron)
Apidra (Insulin glulisine)
Aptivus (Tipranavir)
Arcoxia (Etoricoxib)
Arixtra (Fondaparinux)
Asmanex Twisthaler (Mometasone Furoate)
Atimos modulite (Formoterol fumarate cfc free)
Atriance (Nelarabine)
Atrovent CFC-free (Ipratropium bromide)
Atryn (Antithrombin Alfa)
Avandamet (Rosiglitazone/Metformin)
Avastin (Bevacizumab)
Avelox (Moxifloxacin)
Baraclude (Entecavir)
BCG Vaccine SSI (BCG)
Bondronat (Ibandronic acid)
Bonviva (Ibandronic acid)
Busilvex (Busulfan)
Byetta (Exenatide)
Carbaglu (Carglumic acid)
Cardioxane (Dexrazoxane)
Celsentri (Maraviroc)
Ceprotin (Human Protein C)
Cervarix (Papillomavirus (Human Types 16, 18))
Champix (Varenicline)
Cholestagel (Colesevelam)
Ciloxan (Ciprofloxacin ophthalmic ointment)
Clenil Modulite (Beclometasone dipropionate)
Co-diovan (Valsartan & Hydrochlorothiazide)
Combigan (Brimonidine tartrate & Timolol maleate)
Comptact (Pioglitazone/Metformin)
Cubicin (Daptomycin)
Cymbalta (Duloxetine)
Dukoral (Cholera vaccine)
Duodopa (Levodopa and Carbidopa)
Duotrav (Timolol/Travoprost)
Dynastat (Parecoxib)
Dynepo (Epoetin Delta)
Ecalta (Anidulafungin)
Elaprase (Idursulfase)
Elidel (Pimecrolimus)
Emend (Aprepitant)
Emselex (Darifenacin)

Trade Name/s (Generic Name)
Enbrel (Etanercept)
Erbix (Cetuximab)
Erdotin (erdosteine)
Evoltra (Clofarabine)
Evra (Norelgestromin-ethinylestradiol)
Exelon (Rivastigmine)
Exforge (Amlodipine & Valsartan)
Exjade (deferasirox)
Exubera (Insulin human powder for inhalation)
Ezetrol (Ezetimibe)
Fendrix (Hepatitis B (rDNA))
Flofan 1.5mg (Epoprostenol)
Forsteo (Teriparatide)
Fosavance (Alendronic acid & Calcitriol)
Foscan (Temoporfin)
Fosrenol (Lanthanum Carbonate)
Fostair (Formoterol and Beclometasone)
Freathe (Ciclesonide)
Fuzeon (Enfuvirtide)
Gadovist (Gadobutrol)
Ganfort (Bimatoprost & Timolol)
Gardasil (Human papilloma virus)
Glivec (Imatinib)
Grazax (Phleum pratense)
Herceptin (Trastuzumab)
Hipfix (Human blood coagulation factor IX)
Humira (Adalimumab)
Increlex (Mecasermin)
Inegy (Ezetimibe & Simvastatin)
Infanrix-IPV (Diphtheria, Tetanus, Pertussis, and inactivated polio virus)
Infanrix-IPV+HIB (Diphtheria toxoid, haemophilus influenzae type b, inactivated polio, pertactin, pertussis toxoid, tetanus toxoid)
Inovelon (Rufinamide)
Inspra (Eplerenone)
Insuman Basal (Human insulin)
Insuman Comb (Human insulin)
Insuman Rapid (Human insulin)
Intrinsa (Testosterone)
Invanz (Ertapenem)
Invega (Paliperidone)
Isentress (Raltegravir)
Januvia (Sitagliptin)
Kentera (Oxybutynin transdermal patch)
Kepivance (Palifermin powder for solution for injection)
Ketek (Telithromycin)
Konakion MM Paediatric (Phytomenadione)
Lantus (Insulin glargine)
Litak (Cladribine)
Lucentis (Ranibizumab)
Lyrica (Pregabalin)
Lysodren (Mitotane)
Mabcampath (Alemtuzumab)
Macugen (Pegaptanib)
Malarone Paediatric (Atovaquone & Proguanil)
Menitorix (Haemophilus type B and Neisseria meningitidis group C polysaccharide)

Trade Name/s (Generic Name)
Metvix (Methylaminolevulinate Hcl)
Miacalcin Nasal Spray (Calcitonin (salmon))
Mirapexin (Pramipexole)
Mircera (Methoxy Polyethylene Glycol-Epoetin Beta)
Mucagen (pegaptanib)
Myocet (Doxorubicin)
Myozyme (alglucosidase alfa)
Naglazyme (Galsulfase)
Navelbine capsules (Vinorelbine)
Nebido (Testosterone undecanoate)
Neupro (Rotigotine)
Nexavar (Sorafenib)
Noxafil (Posaconazole)
Octegra (Moxifloxacin)
Oftraquix (Levofloxacin eye drops)
Olmotec Plus (Olmesartan and Hydrochlorothiazide)
Omnitrope (Somatropin)
Orencia (Abatacept)
Ovitrelle (Choriogonadotropin alfa)
Pabal (Carbetocin)
Pediaceal (Tetanus, diphtheria, acellular pertussis, inactivated poliomyelitis, haemophilus influenza type B)
Perfalgan (Paracetamol)
Photofrin (Porfimer Sodium)
Physeptone (Methadone injection)
Pravagettes (Acetylsalicylic acid and Pravastatin Sodium)
Preotact (Parathyroid Hormone (RDNA))
Prevenar (Pneumococcal conjugate)
Prezista (Darunavir)
Prialt (Ziconotide)
Primovist (Gadoxetic Acid)
Procoralan (Ivabradine)
Protelos (Strontium ranelate)
Protopic (Tacrolimus)
Provigil (Modafinil)
Rapamune (Sirolimus)
Raptiva (Efalizumab)
Rasilez (Aliskiren)
Rectogesic (Glyceryl trinitrate)
Relenza (Zanamivir)
Remicade (Infliximab)
Repevax (Low dose diphtheria, tetanus, acellular pertussis, inactivated poliomyelitis virus)
Revatio (Sildenafil citrate)
Revlimid (Lenalidomide)
Riamet (Artemether & Lumefantrine)
Risperdal Consta (Risperidone)
Rotarix (Rotavirus vaccine)
Savene (Dexrazoxane)
Sebivo (Telbivudine)
Seractil (Dexibuprofen)
Serevent evohaler (salmeterol xinafoate CFC free inhaler)
Somavert (Pegvisomant)
Spiriva Respimat (Tiotropium)
Sprycel (Dasatinib)
Stalevo (Levodopa/Carbidopa/Entacapone)
Strattera (Atomoxetine hydrochloride)

How to report:

Yellow cards can be found in:

- * The BNF
- * FP10 prescription pads
- * Online at www.yellowcard.gov.uk
- * by calling the National Yellow Card Information Service on: 0800 731 6789
- * ABPI Data Sheet Compendium
- * The OTC Directory

Where to send your report:

The Medicines and Healthcare products Regulatory Agency
Commission of Human Medicines
Freeport
London SW8 5BR



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COMMISSION ON
HUMAN MEDICINES

Suboxone (Buprenorphine & Naloxone)	▼
Sutent (Sunitinib)	▼
Synagis (Palivizumab)	▼
TachoSil (Fibrinogen/thrombin)	▼
Tamiflu (Oseltamivir)	▼
Tarvceva (Erlotinib)	▼
Tasmar (Tolcapone)	▼
Telzir (Fosamprenavir)	▼
Testim (Testosterone gel)	▼
Thelin (Sitaxentan)	▼
Tilade (Nedocromil sodium)	▼
Tisseel Kit (Fibrinogen)	▼
Topamax (Topiramate)	▼
Tracleer (Bosentan)	▼
Triapin (Felodipine & Ramipril)	▼

Trisenox (Arsenic trioxide)	▼
Tygacil (Tigecycline)	▼
Tysabri (natalizumab)	▼
Uftoral (Tegafur/Uracil)	▼
Valtropin (Somatropin)	▼
Vaniqa (Eflornithine)	▼
Varilrix (Varicella virus OKA strain)	▼
Varivax (Varicella virus OKA strain)	▼
Vasovist (Gadofosveset trisodium)	▼
Velcade (Bortezomib)	▼
Ventavis (Iloprost)	▼
Viadur (Leuprorelin)	▼
Wilzin (Zinc acetate dihydrate)	▼
Xagrid (Anagrelide)	▼
Xeloda (Capecitabine)	▼

Xigris (Drotrecogin alfa [activated])	▼
Xolair (Omalizumab)	▼
Xyrem (Sodium oxybate)	▼
Yentreve (Duloxetine)	▼
Yondelis (Trabectedin)	▼
Ytracis (Yttrium chloride)	▼
Zavesca (Miglustat)	▼
Zemplar (Paricalcitol)	▼
Zenapax (Daclizumab)	▼
Zevalin (Ibritumomab tiuxetan)	▼
Zibor (Bemiparin sodium)	▼
Zonegran (Zonisamide)	▼
Zyprexa IM (Olanzapine)	▼
Zyvox (Linezolid)	▼

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