

FACING SCRUTINY

The list of drugs and their potential risks identified by FDA's Adverse Event Reporting System from January to March 2008.

Product name: active ingredient (trade) or product class	Potential signal of serious risk/new safety information
<ul style="list-style-type: none"> Indian manufacturers (brand names) 	
Arginine hydrochloride injection (R-Genex 10)	Paediatric overdose due to labelling/packaging confusion
Desflurane (Suprane)	Cardiac arrest
Duloxetine (Cymbalta)	Urinary retention
<ul style="list-style-type: none"> Orchid (2-Dep), Sun (Duotop), Torrent (Dulojoy), Lupin (Dumore), Wockhardt (Dupact), Ranbaxy (Dutin) 	
Etravirine (Intelece)	Haemarthrosis
Fluorouracil cream (Carac) and Ketoconazole cream (Kuric)	Adverse events due to name confusion
Heparin	Anaphylactic-type reactions
<ul style="list-style-type: none"> Bio Evans (Beparine), Troikaa (Cathflush) 	
Icodextrin (Extraneal)	Hypoglycaemia
Insulin U-500 (Humulin R)	Dosing confusion
Ivermectin (Stromectol) and warfarin	Drug interaction
<ul style="list-style-type: none"> Ochoa Laboratories Ltd (Ivermectol), Sanify (Iversan), Meridian (Mectin), Cipla (Warf tab) 	
Lapatinib (Tykerb)	Hepatotoxicity
Lenalidomide (Revlimid)	Stevens Johnson Syndrome
Natalizumab (Tysabri)	Skin melanomas
Nitroglycerine (Nitrostat)	Overdose due to labelling confusion
<ul style="list-style-type: none"> GSK (Angised), Cadila (Myovin), Novartis (Nglong) 	
Octreotide acetate depot (Sandostatin LAR)	Ileus
<ul style="list-style-type: none"> Sun (Octrade), Novartis (Sandostatin) 	
Oxycodone hydrochloride controlled-release (Oxycontin)	Drug misuse, abuse and overdose
Perflutren lipid microsphere (Definity)	Cardiopulmonary reactions
Phenytoin injection (Dilantin)	Purple Glove Syndrome
Quetiapine (Seroquel)	Overdose due to sample pack labelling confusion
<ul style="list-style-type: none"> Orchid (Pincalm), Lupin (Placidin), Torrent (Q-Mind) 	
Telbivudine (Tyzeka)	Peripheral neuropathy
Tumour necrosis factor (TNF) blockers	Cancers in children and young adults

Mint could not immediately ascertain whether Indian equivalents of the other drugs were available.

Source: FDA; Mint research