



Search  GO powered by 

## Potential Signals of Serious Risks/New Safety Information Identified by the Adverse Event Reporting System (AERS) January - March 2008

The table below lists the names of products and potential signals of serious risks/new safety information that were identified for these products during the period January - March 2008 in the AERS database. The appearance of a drug on this list does not mean that FDA has concluded that the drug has the listed risk. It means that FDA has identified a *potential safety issue*, but does not mean that FDA has identified a causal relationship between the drug and the listed risk. If after further evaluation the FDA determines that the drug is associated with the risk, it may take a variety of actions including requiring changes to the labeling of the drug, requiring development of a Risk Evaluation and Mitigation Strategy (REMS), or gathering additional data to better characterize the risk.

FDA wants to emphasize that the listing of a drug and a potential safety issue on this Web site does not mean that FDA is suggesting prescribers should not prescribe the drug or that patients taking the drug should stop taking the medication. Patients who have questions about their use of the identified drug should contact their health care provider. FDA will complete its evaluation of each potential signal/new safety information and issue additional public communications as appropriate.

### Potential Signals of Serious Risks/New Safety Information Identified by the Adverse Event Reporting System (AERS) January - March 2008

Product Name: Active Ingredient (Trade) or Product Class	Potential Signal of Serious Risk/New Safety Information
Arginine Hydrochloride Injection (R- Gene 10)	Pediatric overdose due to labeling / packaging confusion
Desflurane (Suprane)	Cardiac arrest
Duloxetine (Cymbalta)	Urinary retention
Etravirine (Intelence)	Hemarthrosis
Fluorouracil Cream (Carac) and Ketoconazole Cream (Kuric)	Adverse events due to name confusion

Heparin	Anaphylactic-type reactions
Icodextrin (Extraneal)	Hypoglycemia
Insulin U-500 (Humulin R)	Dosing confusion
Ivermectin (Stromectol) and Warfarin	Drug interaction
Lapatinib (Tykerb)	Hepatotoxicity
Lenalidomide (Revlimid)	Stevens Johnson Syndrome
Natalizumab (Tysabri)	Skin melanomas
Nitroglycerin (Nitrostat)	Overdose due to labeling confusion
Octreotide Acetate Depot (Sandostatin LAR)	Ileus
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 labeling confusion
Telbivudine (Tyzeka)	Peripheral neuropathy
Tumor Necrosis Factor (TNF) Blockers	Cancers in children and young adults

[↑ Back to Top](#)   [↩ Back to Potential Signals Reports](#)

Date created: September 5, 2008

---

[CDER Home Page](#) | [CDER Site Info](#) | [Contact CDER](#) | [What's New @ CDER](#)  
[FDA Home Page](#) | [Search FDA Site](#) | [FDA A-Z Index](#) | [Contact FDA](#) | [Privacy](#) | [Accessibility](#) | [HHS Home Page](#)

FDA/Center for Drug Evaluation and Research

New from CDER

[New from CDER](#)

Recently Added Pages

[Recently Added Pages](#)

Quick Info Links

[Quick Info Links](#)

Who We Are

[Who We Are](#)

What We Do

[What We Do](#)

What We've Accomplished

[What We've Accomplished](#)

Regulatory Authority

[Regulatory Authority](#)

Feedback from Stakeholders

[Feedback from Stakeholders](#)

Online Training

[Online Training](#)

CDER History

[CDER History](#)

Employment Opportunities

[Employment Opportunities](#)

How to Contact Us

[How to Contact Us](#)

New Prescription Drug Approvals

[New Prescription Drug Approvals](#)

Prescription Drug Information

[Prescription Drug Information](#)

Major Drug Information Pages

[Major Drug Information Pages](#)

Consumer Drug Information

[Consumer Drug Information](#)

Over-the-Counter Drug Information

[Over-the-Counter Drug Information](#)

Drug Safety & Side Effects

[Drug Safety & Side Effects](#)

Drug Preparedness and Bioterrorism Response

[Drug Preparedness and Bioterrorism Response](#)

Clinical Trials Information

[Clinical Trials Information](#)

Public Health Alerts & Warning Letters

[Public Health Alerts & Warning Letters](#)

Reports & Publications

[Reports & Publications](#)

Special Projects & Programs

[Special Projects & Programs](#)

Regulatory & Scientific Guidances

[Regulatory & Scientific Guidances](#)

Specific Regulatory Initiatives

[Specific Regulatory Initiatives](#)

Legislation

[Legislation](#)

Prescription Drug User Fee Act

[Prescription Drug User Fee Act](#)

Submitting New Drug Applications

[Submitting New Drug Applications](#)

International Activities

[International Activities](#)

CDER Policies & Procedures

[CDER Policies & Procedures](#)

Compliance Activities

[Compliance Activities](#)

Freedom of Information Act

[Freedom of Information Act](#)

Useful Resources

[Useful Resources](#)

Advisory Committee Meetings

[Advisory Committee Meetings](#)

Meetings, Conferences & Workshops

[Meetings, Conferences & Workshops](#)

CDER Newsletter

[CDER Newsletter](#)

Consumer & Patient Information

[Consumer & Patient Information](#)

Freedom of Information Act

[Freedom of Information Act](#)

International Activities

[International Activities](#)

Pediatrics Initiatives

[Pediatrics Initiatives](#)

Small Business Assistance

[Small Business Assistance](#)

Spanish-Speaking

[Spanish-Speaking](#)

Drug Information Approved Prior to 1998

[Drug Information Approved Prior to 1998](#)

Superseded Guidances

[Superseded Guidances](#)

Archival Reports & Publications

[Archival Reports & Publications](#)

Drug Information Approved Prior to 1998

[Drug Information Approved Prior to 1998](#)

Superseded Guidances

[Superseded Guidances](#)

Archival Reports & Publications

[Archival Reports & Publications](#)