Guidance, Compliance & Regulatory Information

Surveillance

Adverse Events Reporting System (AERS)

Adverse Event Reporting System (AERS) Statistics

Potential Signals of Serious Risks/New Safety Information Identified from the Adverse Event Reporting System (AERS)

Adverse Events Reporting System (AERS) Electronic Submissions

Potential Signals of Serious Risks/New Safety Information Identified by the Adverse Event Reporting System (AERS) between January – March 2010

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 2010 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 2010

Product Name: Active Ingredient (Trade) *or* Product Class	Potential Signal of a Serious Risk / New Safety Information	Additional Information (as of August 15, 2011)
Azacitidine (Vidaza)	Acute febrile neutrophilic dermatosis (Sweet's syndrome)	FDA is continuing to evaluate this issue to determine the need for any regulatory action.
Azithromycin (Zithromax)	Liver failure	The Warnings and Precautions, Contraindications, and Adverse Reactions sections of the labeling for Zithromax were updated January 2011, to include liver failure. Azithromycin (Zithromax) Labeling approved January 28, 2011 (PDF - 459KB)
Azithromycin extended release 2 g (Zmax)	Pyloric stenosis	UPDATED The Adverse Reactions section of the labeling for Zmax was updated June 2011, to include pyloric stenosis. Azithromycin extended release 2 g (Zmax) Labeling approved June 7, 2011 (134KB)
C1 esterase inhibitors (Cinryze, Berinert)	Thromboembolic events in patients with certain thrombogenic risk factors	The Warnings and Precautions and Adverse Reactions sections of the labeling for Cinryze were updated November 2010, to include thrombotic events. C1 Esterase Inhibitor [human] (Cinryze) Labeling approved November 2010 (PDF - 436KB) FDA is continuing to evaluate this issue to determine the need for further regulatory action.
Clarithromycin (Biaxin)	Liver failure	UPDATED The Warnings and Precautions

		section of the labeling for Biaxin was updated May 2011, to include liver failure. Clarithromycin (Biaxin) Labeling approved May 27, 2011 (776KB)
Daptomycin (Cubicin)	Pulmonary eosinophilia, Eosinophilic pneumonia	FDA Drug Safety Communication The Warnings and Precautions section of the labeling for Cubicin was updated September 2010, to include pulmonary eosinophilia and eosinophilic pneumonia. Daptomycin (Cubicin) Labeling approved August 13, 2010 (PDF - 236KB)
Dronedarone hydrochloride (Multaq)	Congestive heart failure	UPDATED FDA Drug Safety Communication The Warnings and Precautions and Adverse Reactions sections of the labeling for Multaq were updated February 2011, to include congestive heart failure. Dronedarone hydrochloride (Multaq) Labeling approved February 11, 2011 (PDF - 198KB)
Estrogens, conjugated (Premarin)	Angioedema	FDA is continuing to evaluate this issue to determine the need for any regulatory action.
Modafinil (Provigil)	Convulsion	FDA is continuing to evaluate this issue to determine the need for any regulatory action.
Prasugrel hydrochloride (Effient)	Thrombotic thrombocytopenic purpura	The Warnings and Precautions section of the labeling for Effient was updated November 2010, to include thrombotic thrombocytopenic purpura. Prasugrel hydrochloride (Effient) Labeling approved December 6, 2010 (PDF - 983KB)
Ranolazine (Ranexa)	Torsades de Pointes	FDA decided that no action is necessary at this time based on available information. FDA is continuing to monitor the issue.
Sodium oxybate (Xyrem)	Convulsion	FDA decided that the current labeling, which addresses the risk of convulsions in the Boxed Warning and Overdosage sections of the labeling, is adequate. No action is necessary at this time based on available information.
Temsirolimus (Torisel)	Infusion site extravasation	UPDATED The Warnings and Precautions and Adverse Reactions sections of the labeling for Torisel were updated June 2011, to include information about infusion site extravasation. Temsirolimus (Torisel) Labeling approved June 16, 2011 (PDF - 220KB

Page Last Updated: 09/21/2011
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.