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[Home](#) > FDA names 14 drugs with safety signals

Generic Name:

Multiple drugs

Trade Name:

Various trade names

Company:

Multiple manufacturers

Notes:

Based on a review of data in the Adverse Event Reporting System (AERS) between January and March 2011, FDA has compiled a list of 14 drugs with potential signals of serious risks and/or new safety information.

In its [announcement](#), FDA noted that a potential safety issue has been identified, but that does not mean that a causal relationship between the drug and the listed risk has been identified.

The medications and their associated safety risks are as follows:

- ? Adalimumab (Humira): Hepatic dysfunction, failure
- ? Azathioprine (Imuran): Acute febrile neutrophilic dermatosis (Sweet's syndrome)
- ? Cetuximab (Erbix): corneal infection, ulcerative keratitis, and skin necrosis
- ? Dabigatran etexilate mesylate (Pradaxa): proper storage and handling to preserve potency
- ? Dronedarone HCl (Multaq): renal impairment/renal failure
- ? Fibrin Sealant (Tisseel VH, Evicel): graft failure in ophthalmologic procedures and lack of efficacy in neurosurgical procedures for repair of dural tears
- ? Immune Globulin Subcutaneous (Human) 6% Liquid (Vivaglobin): thromboembolic events with numerous product lots
- ? Iron sucrose injection (Venofer): anaphylactic reactions
- ? Quinolone products: pseudotumor cerebri
- ? Malathion (Ovide): burns and burning sensations
- ? Mercaptopurine (Purinethol): hepatosplenic T-cell lymphoma
- ? Prasugrel HCl (Effient): hypersensitivity reactions
- ? Rituximab (Rituxan): hypogammaglobulinemia
- ? Ropinirole HCl (Requip): medication errors as a result of similarities of product name with risperidone

Medication Monitor Categories:

Alerts and Recalls

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