Generic Name:
Asenapine
Trade Name:
Saphris
Company:
Merck
Notes:

Serious allergic reactions have been reported with use of asenapine, according to a FDA safety communication released today. Since the drug's approval in August 2009 through September 2010, 52 cases of Type I hypersensitivity reactions have been reported to the agency?s Adverse Event Reporting System.

Type I hypersensitivity reactions are severe and can include anaphylaxis, angioedema, hypotension, tachycardia, swollen tongue, difficulty breathing, wheezing, or rash. These signs and symptoms are consistent with the reactions reported in the 52 cases and several cases reported multiple hypersensitivity reactions occurring at the same time. In addition, some reactions occurred after the first dose of the drug.

Of the 52 cases, symptoms resolved following discontinuation of asenapine in 15 patients, 2 had reappearance of symptoms upon reintroduction of the drug, 19 resulted in hospitalization or emergency department visits, and therapeutic interventions were needed in 7 cases.

FDA advises that health providers be aware of the risk of hypersensitivity reactions with asenapine and counsel patients who are receiving the drug about how to recognize the signs and symptoms of a serious allergic reaction. The Contraindications, Warnings and Precautions, Adverse Reactions, and Patient Counseling Information sections of the drug label have been revised to include information about this risk.

Medication Monitor Categories:
Alerts and Recalls