ASENAPINE (SAPHRIS)-ASSOCIATED SERIOUS ALLERGIC REACTIONS

This special issue is prompted by a FDA safety alert describing the risk serious allergic reactions associated with asenapine (Saphris) therapy. A database search revealed 52 cases of serious allergic reactions (type 1 hypersensitivity reactions) with asenapine. A verbatim copy of the FDA safety alert is pasted below. If you need further information, please contact the Samford University Global Drug Information Service at 205-726-2659.

The U.S. Food and Drug Administration (FDA) is warning the public that serious allergic reactions have been reported with the use of the antipsychotic medication Saphris (asenapine maleate). The Contraindications, Warnings and Precautions, Adverse Reactions, and Patient Counseling Information sections of the Saphris drug label have been revised to include information about this risk and to inform healthcare professionals that Saphris should not be used in patients with a known hypersensitivity to the drug.

A search of the FDA’s Adverse Event Reporting System (AERS) database identified 52 cases of Type I hypersensitivity reactions (allergic reactions) with Saphris use (see Data Summary below). Hypersensitivity reactions can be classified into four categories (Type I to Type IV). Signs and symptoms of Type I hypersensitivity reactions may include anaphylaxis (a life-threatening allergic reaction), angioedema (swelling of the deeper layers of the skin), low blood pressure, rapid heart rate, swollen tongue, difficulty breathing, wheezing, or rash. These signs and symptoms are consistent with the reactions reported in the 52 cases. Several cases reported multiple hypersensitivity reactions occurring at the same time, with some of these reactions occurring after the first dose of Saphris. Healthcare professionals should be aware of the risk of hypersensitivity reactions with Saphris and counsel patients who are receiving the drug about how to recognize the signs and symptoms of a serious allergic reaction. Saphris should not be used in patients with a known hypersensitivity to the drug.

Patients should seek emergency medical attention immediately if they develop any signs and symptoms of a serious allergic reaction while taking Saphris.

Additional Information for Patients
- Serious allergic reactions have been reported in patients treated with Saphris.
- Patients should seek emergency medical attention immediately if they develop any signs and symptoms of a serious allergic reaction such as:
  - Difficulty breathing
  - Swelling of the face, tongue or throat
  - Feeling lightheaded
  - Itching
- Serious side effects from the use of Saphris should be reported to the FDA MedWatch program, using the information in the "Contact Us" box at the bottom of this page.

Additional Information for Healthcare Professionals
- Type I hypersensitivity reactions, including anaphylaxis and angioedema, have been observed in patients treated with Saphris. In several cases, these reactions occurred after the first dose.
- The hypersensitivity reactions included: anaphylaxis, angioedema, hypotension, tachycardia, swollen tongue, dyspnea, wheezing, and rash.
- Saphris is contraindicated in patients with a known hypersensitivity to the product.

Facts about Saphris (asenapine maleate)
- In a class of medications called atypical antipsychotics.
- Used to treat symptoms of schizophrenia and bipolar disorder.
- From approval in August 2009 to June 2011, approximately 235,000 prescriptions were dispensed for Saphris and approximately 87,000 patients received a dispensed prescription for Saphris from U.S. outpatient retail pharmacies.1,2
Additional Information for Healthcare Professionals (continued)

- Patients should be educated to recognize the signs and symptoms of a serious allergic reaction and advised to contact a healthcare professional immediately if they experience any of these symptoms while taking Saphris.
- Adverse events involving Saphris should be reported to the FDA MedWatch program using the information in the "Contact Us" box at the bottom of this page.

Data Summary
Saphris (asenapine maleate) was FDA-approved on August 13, 2009. A search of the AERS database from approval through September 7, 2010 identified 52 cases that reported Type I hypersensitivity reactions associated with Saphris use. Reported signs and symptoms included anaphylaxis, angioedema, hypotension, tachycardia, swollen tongue, dyspnea, wheezing, and rash. Some of the cases reported the occurrence of more than one hypersensitivity reaction following Saphris use. Eight cases reported hypersensitivity reactions after just one dose of Saphris. The reactions reported following one dose included possible angioedema, respiratory distress, and possible anaphylaxis. Type I hypersensitivity reactions typically require a history of previous exposure to the drug. However, the absence of a known prior exposure does not exclude the reaction, because sensitization may have occurred to a cross-reactive compound in the past even if the patient showed no signs of allergy to the sensitizing product. To date, no specific drug has shown cross-reactivity with Saphris.

Of the 52 cases, 15 reported a resolution of symptoms following Saphris discontinuation, while two of these cases reported a reappearance of symptoms upon reintroduction of Saphris. Nineteen of the cases resulted in hospitalization or emergency room visits, and therapeutic interventions were reported in seven cases. Although many of the cases have limited information, the findings from the cases are consistent with hypersensitivity reactions, including anaphylaxis, and support a temporal association between the onset of the reactions and Saphris use.

References

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