June 2022

Consumer Update

Isavuconazole and risk of Anaphylactic reaction

EDA performs label update to include the following:

WARNINGS AND PRECAUTIONS

Sensitivity/Resistance

Hypersensitivity Reactions

Hypersensitivity to Isavuconazole may result in adverse reactions that include: anaphylactic reactions (including fatal outcome), hypotension, respiratory failure, dyspnea, drug eruption, pruritus, and rash.

Discontinue Isavuconazole if a patient experiences an anaphylactic reaction.

Serious hypersensitivity and severe skin reactions, such as anaphylaxis or Stevens-Johnson syndrome, have been reported during treatment with other azole antifungal agents. Discontinue Isavuconazole if a patient develops a severe cutaneous adverse reaction. There is no information regarding cross-sensitivity between Isavuconazole and other azole antifungal agents. However, caution should be used in prescribing Isavuconazole to patients with hypersensitivity to other azole antifungal agents.

Post-Market Adverse Reactions

Immune system disorders: anaphylactic reaction

Background:

Clinical particulars

Therapeutic indications

Isavuconazole is indicated in adults for the treatment of

- invasive aspergillosis
- mucormycosis in patients for whom amphotericin B is inappropriate .

Consideration should be given to official guidance on the appropriate use of antifungal agents.

<u>References:</u> AEMPS (<u>Click here</u>)