Safety Alert Dec 2022

A new warning about Suicidal risk of Metronidazole

EDA performs label update to include the following:

Special warnings and precautions for use

Suicidal ideation

Cases of suicidal ideation with or without depression have been reported during treatment with metronidazole. Patients should be advised to discontinue treatment and contact their healthcare Provider immediately if they experience psychiatric symptoms during treatment.

Background on the safety concerns

DOSE AND METHOD OF ADMINISTRATION

A maximum of 4 g should not be exceeded during a 24 hour period. Dosages should be decreased in patients with severe hepatic disease; plasma metronidazole levels should be monitored.

In elderly patients the pharmacokinetics of metronidazole may be altered and therefore monitoring of serum levels may be necessary to adjust the metronidazole dosage accordingly.

CONTRAINDICATIONS

1. Patients with evidence of or a history of blood dyscrasias should not receive the drug since upon occasion a mild leucopenia has been observed during its administration.
However, no persistent haematological abnormalities have been observed in animals or clinical studies.
2. Active organic disease of the central nervous system.
3. Hypersensitivity to metronidazole and other imidazoles.

References:

TGA (Click here)