

## Safety Alert

Jan 2024

**Fluconazole—Risk of miscarriage and congenital malformations when using fluconazole during pregnancy also includes the use of lower doses.**

**EDA performs label update to include the following:**

### Use in Pregnancy

#### **Pregnancy Category: D**

Use in pregnancy should be avoided except in patients with severe or potentially life-threatening fungal infections in whom fluconazole may be used if the anticipated benefit outweighs the possible risk to the foetus.

Effective contraceptive measures should be considered in women of child-bearing potential and should continue throughout the treatment period and for approximately 1 week (5 to 6 half-lives) after the final dose.

**There have been reports of spontaneous abortion and congenital abnormalities in infants whose mothers were treated with 150 mg of fluconazole as a single or repeated dose in the first trimester.**

### Background:

#### Therapeutic indications

1. Treatment of cryptococcal meningitis in patients who are unable to tolerate amphotericin
2. Maintenance therapy to prevent relapse of cryptococcal meningitis in patients with AIDS.
3. Treatment of oropharyngeal and oesophageal candidiasis in AIDS and other immunosuppressed patients.
4. Secondary prophylaxis of oropharyngeal candidiasis in patients with HIV infection.
5. Serious and life-threatening *Candida* infections in patients who are unable to tolerate amphotericin B.
6. Vaginal candidiasis, when topical therapy has failed.

#### **References:**

Norway ([Click here](#))