

חברת אמ.בי.איי פארמה מבקשת להודיע על עדכונים בעלון לרופא של התכשיר:

## Fluconazole MBI 2mg/ml

מרכיב פעיל: fluconazole 2mg/ml

צורת המינון: Solution for infusion

### התווית התכשיר:

Fluconazole is indicated in the following fungal infections.

Fluconazole is indicated in adults for the treatment of:

- Cryptococcal meningitis (see section 4.4).
- Coccidioidomycosis (see section 4.4).
- Invasive candidiasis.
- Mucosal candidiasis (including oropharyngeal candidiasis, oesophageal candidiasis, candiduria and chronic mucocutaneous candidiasis).
- Chronic oral atrophic candidiasis (denture sore mouth) if dental hygiene or topical treatment are insufficient.

Fluconazole is indicated in adults for the prophylaxis of:

- Relapse of cryptococcal meningitis in patients with high risk of recurrence.
- Relapse of oropharyngeal or oesophageal candidiasis in patients infected with HIV who are at high risk of experiencing relapse.
- Prophylaxis of candidal infections in patients with prolonged neutropenia (such as patients with haematological malignancies receiving chemotherapy or patients receiving Haematopoietic Stem Cell Transplantation (see section 5.1)).

Fluconazole is indicated in term newborn infants, infants, toddlers, children and adolescents aged from 0 to 17 years old:

Fluconazole is used for the treatment of mucosal candidiasis (oropharyngeal, oesophageal), invasive candidiasis, cryptococcal meningitis and the prophylaxis of candidal infections in immunocompromised patients. Fluconazole can be used as maintenance therapy to prevent relapse of cryptococcal meningitis in children with high risk of reoccurrence (see section 4.4).

Therapy may be instituted before the results of the cultures and other laboratory studies are known; however, once these results become available, anti-infective therapy should be adjusted accordingly.

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

בהודעה זו כלולים העדכונים המהותיים בלבד. תוספת טקסט מסומנת בקו תחתון, מחיקת טקסט מסומנת בקו חוצה. מידע בטיחותי חדש מודגש בצהוב.

## עדכונים שנעשו בעלון לרופא:

### 4.6 Fertility, pregnancy and lactation

#### Women of childbearing potential

Before initiating treatment, the patient should be informed of the potential risk to the foetus.

After single dose treatment, a washout period of 1 week (corresponding to 5-6 half-lives) is recommended before becoming pregnant (see section 5.2).

For longer courses of treatment, contraception may be considered, as appropriate, in women of childbearing potential throughout the treatment period and for 1 week after the final dose.

#### Pregnancy

Observational studies suggest an increased risk of spontaneous abortion in women treated with fluconazole during the first and/or second trimester compared to women not treated with fluconazole or treated with topical azoles during the same period.

Available epidemiological studies on cardiac malformations with use of fluconazole during pregnancy provide inconsistent results. However, a meta-analysis of 5 observational studies including several thousand pregnant women exposed to fluconazole during the first trimester finds a 1.8-2 fold increased risk of cardiac malformations when compared to no fluconazole use and/or topical azoles use.

העלון מפורסם במאגר התרופות שבאתר משרד הבריאות:  
<https://israel drugs.health.gov.il/#!/byDrug>

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בברכה,

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