

### **Fluconazole MBI 2mg/ml**

חברת אמ.בי.איי פארמה בע"מ מבקשת להודיע על עדכונים בעלון לרופא של התכשיר שבנדון.

#### **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.

**מרכיב פעיל:** fluconazole 2mg/ml

**צורת המתן של התכשיר:** Solution for infusion

בהודעה זו כלולים העדכונים המהותיים בלבד. החמרות מסומנות בצהוב, תוספת טקסט מסומנת בקו תחתון, מחיקת טקסט מסומנת בקו חוצה.

#### **4.5 Interaction with other medicinal products and other forms of interaction**

**HMG CoA reductase inhibitors:** The risk of myopathy and rhabdomyolysis increases (dose-dependent) when fluconazole is coadministered with HMG-CoA reductase inhibitors metabolised through CYP3A4, such as atorvastatin and simvastatin, or through CYP2C9, such as fluvastatin (decreased hepatic metabolism of the statin). If concomitant therapy is necessary, the patient should be observed for symptoms of myopathy and rhabdomyolysis and creatine kinase should be monitored. HMG-CoA reductase inhibitors should be discontinued if a marked increase in creatine kinase is observed or myopathy/rhabdomyolysis is diagnosed or suspected. Lower doses of HMG-CoA reductase inhibitors may be necessary as instructed in the statins prescribing information.

**Ivacaftor:** (alone or combined with drugs in the same therapeutic class): Coadministration with ivacaftor, a cystic fibrosis transmembrane conductance regulator (CFTR) potentiator, increased ivacaftor exposure by 3-fold and hydroxymethyl-ivacaftor (M1) exposure by 1.9-fold. A reduction of the ivacaftor (alone or combined) dose is necessary as instructed in the ivacaftor (alone or combined) prescribing information.

**Lurasidone:** Moderate inhibitors of CYP3A4 such as fluconazole may increase lurasidone plasma concentrations. If concomitant use cannot be avoided, reduce the dose of lurasidone as instructed in the lurasidone prescribing information.

#### **4.6 Fertility, pregnancy and lactation**

##### **Pregnancy**

Before becoming pregnant a washout period of approximately 1 week (corresponding to 5-6 half-lives) is recommended after a single-dose or discontinuation of a course of treatment (see section 5.2).

העלון מפורסם במאגר התרופות שבאתר משרד הבריאות: <https://data.health.gov.il/drugs/index.html#!/byDrug>  
לחילופין, ניתן לקבלו מודפס באמצעות פניה לבעל הרישום, חברת אמ.בי.איי פארמה, ת.ד. 5061, קדימה טל. 09-7719003

בברכה,

גלי קיסר

רוקחת ממונה