

יוני 2021

רופא/ה נכבד/ה,  
רוקח/ת נכבד/ה,

### **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

עדכון בעלון לרופא, המהווה החמרה, נעשה בסעיף הבא:

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

Ibrutinib: Moderate inhibitors of CYP3A4 such as fluconazole increase plasma ibrutinib concentrations and may increase risk of toxicity. If the combination cannot be avoided, reduce the dose of ibrutinib to 280 mg once daily (two capsules) for the duration of the inhibitor use and provide close clinical monitoring.

בעלון נעשו שינויים נוספים שאינם מהווים החמרה.

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

בברכה,  
אבנר דור  
רוקח ממונה