



מאי 2021

פייזר פי אף אי פרמצבטיקה ישראל בע"מ
רח' שנקר 9, ת.ד. 12133
הרצליה פיתוח, ישראל 46725
טל: 972-9-9700500 פקס: 972-9-9700501

רופא/ה, רוקח/ת נכבד/ה,
ברצוננו להודיעך על עדכונים בעלון לרופא של התכשיר **Triflucan IV** :

Solution For Injection

צורת מינון:

Each ml contains 2 mg of fluconazole.

הרכב וחוזק:

התוויה:

Fluconazole is indicated in the following fungal infections.

Fluconazole is indicated in adults for the treatment of:

Cryptococcal meningitis. Coccidioidomycosis. 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).

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.

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.

להלן העדכון העיקרי בעלון לרופא:

Interaction with other medicinal products and other forms of interaction

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The effect of fluconazole on other medicinal products

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Tolvaptan: Exposure to tolvaptan is significantly increased (200% in AUC; 80% in Cmax) when tolvaptan, a CYP3A4 substrate, is co-administered with fluconazole, a moderate CYP3A4 inhibitor, with risk of significant increase in adverse reactions particularly significant diuresis, dehydration and acute renal failure. In case of concomitant use, the tolvaptan dose should be reduced as instructed in the tolvaptan prescribing information and the patient should be frequently monitored for any adverse reactions associated with tolvaptan.

השינוי המודגש ברקע צהוב מהווה החמרה.
העלון לרופא נשלח למשרד הבריאות לצורך פרסומם במאגר התרופות שבאתר משרד הבריאות:
<https://data.health.gov.il/drugs/index.html#!/byDrug>
לחילופין, לקבלת עלון מלא מודפס ניתן לפנות לחברת פייזר פי אף אי פרמצבטיקה ישראל בע"מ
רח' שנקר 9, ת.ד. 12133
הרצליה פיתוח, 46725.

בברכה,
גילי קבשה
רוקח/ת ממונה