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אוקטובר 2021

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

צורת מינון: Solution For Injection

הרכב וחוזק:

Each ml contains 2 mg of fluconazole.

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, oesophageal candidiasis, candiduria and chronic mucocutaneous candidiasis.
- Chronic oral atrophic candidiasis (denture sore mouth) if dental hygiene or topical treatment are insufficient.
- Vaginal candidiasis, acute or recurrent; when local therapy is not appropriate.
- *Candidal balanitis* when local therapy is not appropriate.
- Dermatomycosis including *tinea pedis, tinea corporis, tinea cruris, tinea versicolor* and dermal *candida* infections when systemic therapy is indicated.
- *Tinea unguinium (onychomycosis)* when other agents are not considered appropriate.

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.
- To reduce the incidence of recurrent vaginal candidiasis (4 or more episodes a year).
- Prophylaxis of candidal infections in patients with prolonged neutropenia (such as patients with haematologicalmalignancies receiving chemotherapy or patients receiving Hematopoietic 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 and 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 העדכונים העיקרים בעלון לרופא:

Special warnings and precautions for use

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Dermatological reactions

Patients have rarely developed exfoliative cutaneous reactions, such as Stevens-Johnson syndrome and toxic epidermal necrolysis, during treatment with fluconazole. Drug reaction with eosinophilia and systemic symptoms (DRESS) has been reported. AIDS patients are more prone to the development of severe cutaneous reactions to many medicinal products. If a rash, which is considered attributable to fluconazole, develops in a patient treated for a superficial fungal infection, further therapy with this medicinal product should be discontinued. If patients with invasive/systemic fungal infections develop rashes, they should be monitored closely and fluconazole discontinued if *bullous* lesions or *erythema* multiforme develop.

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Candidiasis

Studies have shown an increasing prevalence of infections with *Candida* species other than *C. albicans*. These are often inherently resistant (e.g. *C. krusei* and *C. auris*) or show reduced susceptibility to fluconazole (*C. glabrata*). Such infections may require alternative antifungal therapy secondary to treatment failure. Therefore, prescribers are advised to take into account the prevalence of resistance in various *Candida* species to fluconazole.

Fertility, pregnancy and lactation

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Data from several thousand pregnant women treated with a cumulative dose of ≤ 150 mg of fluconazole, administered in the first trimester, show no increase in the overall risk of malformations in the foetus. In one large observational cohort study, first trimester exposure to oral fluconazole was associated with a small increased risk of musculoskeletal malformations, corresponding to approximately 1 additional case per 1000 women treated with cumulative doses ≤ 450 mg compared with women treated with topical azoles and to approximately 4 additional cases per 1000 women treated with cumulative doses over 450 mg. The adjusted relative risk was 1.29 (95% CI 1.05 to 1.58) for 150 mg oral fluconazole and 1.98 (95% CI 1.23 to 3.17) for doses over 450 mg fluconazole.

Undesirable effects

Summary of safety profile

Drug reaction with eosinophilia and systemic symptoms (DRESS) has been reported in association with fluconazole treatment.

השינויים המודגשים ברקע צהוב מהווים החמרה. כמו כן, בוצעו שינויים נוספים הכוללים תוספת מידע, השמטת מידע ועדכוני נוסח שאינם מהווים החמרה.
העלון לרופא נשלח למשרד הבריאות לצורך פרסומו 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,
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רוקחת ממונה