

רופא/ה, רוקח/ת נכבד/ה,
 ברצוננו להודיעך על עדכון בעלון לרופא של התכשירים:

Vfend 40mg/ml powder for oral suspension, Vfend 200mg powder for solution for infusion, Vfend 50mg Film Coated Tablets, Vfend 200mg Film Coated Tablets

חוזק:

- Voriconazole 200mg powder for solution for infusion
- Voriconazole 50 mg film coated tablets
- Voriconazole 200 mg film coated tablets
- Voriconazole 40mg/ml powder for oral suspension

התוויה:

Treatment of invasive aspergillosis, fluconazole-resistant serious invasive Candida infections (including C. krusei), serious fungal infections caused by scedosporium spp. And fusarium spp.
 Vfend should be administered primarily to immunocompromised patients with progressive, possibly life-threatening infections.
 Treatment of candidemia in non neuropenic patients.
 Prophylaxis of invasive fungal infections in high risk allogeneic hematopoietic stem cell transplant (HSCT) recipients.

להלן העדכונים העיקריים בעלון לרופא:

4.4 Special warnings and precautions for use

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Serious dermatological adverse reactions

- Squamous cell carcinoma of the skin (SCC)
 Squamous cell carcinoma of the skin (including cutaneous SCC in situ, or Bowen's disease) has been reported in patients, some of whom have reported prior phototoxic reactions.

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Long-term treatment

Long term exposure (treatment or prophylaxis) greater than 180 days (6 months) requires careful assessment of the benefit-risk balance and physicians should therefore consider the need to limit the exposure to VFEND.

Squamous cell carcinoma of the skin (SCC) (including cutaneous SCC in situ, or Bowen's disease) has been reported in relation with long-term VFEND treatment.

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4.8 Undesirable effects

System Organ Class	Very common ≥ 1/10	Common ≥ 1/100 to < 1/10	Uncommon ≥ 1/1,000 to < 1/100	Rare ≥ 1/10,000 to < 1/1,000	Frequency not known (cannot be estimated from available data)
Infections and infestations		sinusitis	pseudomembranous colitis		
Neoplasms benign, malignant and unspecified (including cysts and polyps)					squamous cell carcinoma (including cutaneous SCC in situ, or Bowen's disease)*

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There have been reports of squamous cell carcinoma of the skin (including cutaneous SCC in situ, or Bowen's disease) in patients treated with VFEND for long periods of time; the mechanism has not been established (see section 4.4).

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השינויים המודגשים ברקע צהוב מהווים החמרה. כמו כן, בוצעו שינויים נוספים הכוללים תוספת מידע, השמטת מידע ועדכוני נוסח שאינם מהווים החמרה. העלונים לחפא ולצרכן נשלחו למשרד הבריאות לצורך פרסומם במאגר התחפופות שבאתר משרד הבריאות: <https://data.health.gov.il/drugs/index.html#!/byDrug> לחילופין, לקבלת עלון מלא מודפס ניתן לפנות לחברת פיזר פי אף אי פרמצבטיקה ישראל בע"מ רח' שנקר 9, ת.ד. 12133, הרצליה פיתוח, 46725.

בברכה,
גילי קבשה
רוקחת ממונה