

ספטמבר 2019

רופא/ה נכבד/ה,
רוקח/ת נכבד/ה,

הנדון:

Vortimal (Voriconazole 200 mg/vial)

Powder for Concentrate for Solution for Infusion

ברצוננו להודיע על עדכון בעלון לרופא של התכשיר שבנדון.
הודעה זו מתייחסת רק לסעיפים בהם נעשה שינוי המהווה החמרה או שינוי בתנאי הרישום: טקסט מודגש **בצהוב** משמעו החמרה.

ההתוויה המאושרת:

Vortimal is a broad spectrum, triazole antifungal agent and is indicated as follows:

- Treatment of invasive aspergillosis.
- Treatment of candidaemia in non-neutropenic patients.
- Treatment of fluconazole-resistant serious invasive Candida infections (including C. krusei).
- Treatment of serious fungal infections caused by Scedosporium spp. and Fusarium spp.

Vortimal should be administered primarily to immunocompromised patients with progressive, possibly lifethreatening infections.

Prophylaxis of invasive fungal infections in high risk allogeneic hematopoietic stem cell transplant (HSCT) Recipients.

העדכונים המהותיים שנעשו בעלון לרופא הינם:

4.4 Special warnings and precautions for use

[...]

- Exfoliative cutaneous reactions

Severe cutaneous adverse reactions (SCARs) such as Stevens-Johnson syndrome (SJS), **toxic epidermal necrolysis (TEN), and drug reaction with eosinophilia and systemic symptoms (DRESS), which can be life-threatening or fatal, have been reported with the use of voriconazole.** If a patient develops a rash he should be monitored closely and Vortimal discontinued if lesions progress.

[...]

4.8 Undesirable effects

[...]

Skin and subcutaneous tissue disorders

Rare: toxic epidermal necrolysis, **drug reaction with eosinophilia and systemic symptoms (DRESS),**

angioedema, actinic keratosis, pseudoporphyria, erythema multiforme, psoriasis, drug eruption

[...]

Dermatological reactions

Dermatological reactions were very common in patients treated with voriconazole in clinical trials, but these patients had serious underlying diseases and were receiving multiple concomitant medicinal products. The majority of rashes were of mild to moderate severity. Patients have developed serious severe cutaneous adverse reactions (SCARs), including Stevens-Johnson syndrome (SJS) (uncommon), toxic epidermal necrolysis (TEN) (rare), **drug reaction with eosinophilia and systemic symptoms (DRESS) (rare)** and erythema multiforme (rare) during treatment with voriconazole (see section 4.4).

[...]

העלון לרופא מפורסם במלואו באתר האינטרנט של משרד הבריאות, להלן הקישור:

<https://www.old.health.gov.il/units/pharmacy/trufot/index.asp?safa=h>

ניתן לקבל את העלון המודפס במלואו באמצעות פניה לבעלת הרישום קיי.אס. קים אינטרנשיונל בע"מ, יגאל אלון 94, תל-אביב יפו, 6789139, טל. 03-6114543

בכבוד רב,

יוסי שמטרר
רוקח ממונה