

09.04.2023

רופא/ה נכבד/ה,

רוקח/ת נכבד/ה,

ברצוננו להביא לידיעתכם את העדכונים בעלון לצרכן של התכשיר הבא:

Posaconazole 100 mg Ofek Pharma

התכשיר מיועד להתוויה:

Treatment of the following fungal infections in adults: - Invasive aspergillosis in patients with disease that is refractory to amphotericin B or itraconazole or in patients who are intolerant of these medicinal products; - Fusariosis in patients with disease that is refractory to amphotericin B or in patients who are intolerant of amphotericin B.

Chromoblastomycosis and mycetoma in patients with disease that is refractory to itraconazole or in patient intolerant to itraconazole. - Coccidioidomycosis in patients with disease refractory to amphotericin B, itraconazole or fludonazole or in patient intolerant to these medicinal products. - Zygomycosis in patients intolerant of or with disease that is refractory to alternative therapy.

Refractoriness is defined as progression of infection or failure to improve after a minimum of 7 days of prior therapeutic doses of effective antifungal therapy. These are also indicated for prophylaxis of invasive fungal infections in the following patients: - Patients receiving remission-induction chemotherapy for acute myelogenous leukemia (AML) or myelodysplastic syndrome (MDS) expected to result in prolonged neutropenia who are at high-risk of developing invasive fungal infections. - Hematopoietic stem cell transplant (HSCT) recipients who are undergoing high-dose immunosuppressive therapy for graft versus host disease and who are at high-risk of developing invasive fungal infection

השינויים המהותיים בעלון לצרכן מופיעים בסעיפים הבאים:

שם היצרן וכתובתו:

Haimen Pharma Inc.,
No. 163, Zhuhai Rd., Binjiang Street,
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בברכה,

מירי חזן

רוקחת ממונה

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