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

מרץ 2011

רופא/ה, רוקח/ת נכבד/ה,

ברצוננו להודיעך על עדכון בעלונים לרופא של **Eraxis Solution for infusion** ממרץ 2011:
קו תחתי משמעו תוספת טקסט, קו חוצה משמעו מחיקת טקסט, הדגשה משמעה החמרה.

Anidulafungin 100mg

Indicated for:
Eraxis is indicated for use in the treatment of the following fungal infections : Candidemia and other forms of Candida infections (intra- abdominal abscess and peritonitis).

להלן העדכונים העיקריים בעלון לרופא:

Mechanism of action
Anidulafungin is a semi-synthetic echinocandin with antifungal activity. Anidulafungin inhibits glucan synthase, an enzyme present in fungal, but not mammalian cells. This results in inhibition of the formation of 1,3-β-D-glucan, an essential component of the fungal cell wall.

Activity in vitro
Anidulafungin is active in vitro against Candida albicans, C. glabrata, C. parapsilosis, and C. tropicalis (see Indications And Usage, Clinical Studies).

MICs were determined according to the Clinical and Laboratory Standards Institute (CLSI) approved standard reference methods M27 and M38 for susceptibility testing of yeasts. However, no correlation between in vitro activity (MIC) as determined by this method and clinical outcome has been established.

There have been reports of Candida isolates with reduced susceptibility to echinocandins including anidulafungin, but the clinical significance of this observation is unknown

Contraindications

ERAXIS is contraindicated in persons with known hypersensitivity to anidulafungin, any component of ERAXIS, or other echinocandins.

Precautions

Hepatic Effects
Laboratory abnormalities in liver function tests have been seen in healthy volunteers and patients treated with ERAXIS. In some patients with serious underlying medical conditions who were receiving multiple concomitant medications along with ERAXIS, clinically significant hepatic abnormalities have occurred. Isolated cases of significant hepatic dysfunction, hepatitis, or ~~worsening~~ hepatic failure have been reported in patients; a causal relationship to ERAXIS has not been established. Patients who develop abnormal liver function tests during ERAXIS therapy should be monitored for evidence of worsening hepatic function and evaluated for risk/benefit of continuing ERAXIS therapy.

Drug Interactions
Pre-clinical in vitro and in vivo and clinical studies demonstrated that anidulafungin is not a clinically relevant substrate, inducer, or inhibitor of cytochrome P450 isoenzymes. Anidulafungin has negligible renal clearance (< 1%) . Minimal interactions are expected from the concomitant medications (see CLINICAL PHARMACOLOGY –Drug Interaction Studies).

Adverse Reactions

General
Possible histamine-mediated symptoms have been reported with ERAXIS, including rash, urticaria, flushing, pruritus, dyspnea, bronchospasm and hypotension. These events are infrequent when the rate of ERAXIS infusion does not exceed 1.1 mg/minute.

The following events occurred in either < 2% of patients treated for candidemia/other Candida infections, and were judged by investigators to be at least possibly related to ERAXIS:

Blood and Lymphatic: coagulopathy, thrombocytopenia
Cardiac: atrial fibrillation, bundle branch block (right), sinus arrhythmia, ventricular extrasystoles
Eye: eye pain, vision blurred, visual disturbance
Gastrointestinal: abdominal pain upper, constipation, diarrhea NOS, dyspepsia, fecal incontinence, nausea, vomiting
General and Administration Site: infusion related reaction, peripheral edema, rigors
Hepatobiliary: abnormal liver function tests NOS, cholestasis, hepatic necrosis
Infections: candidiasis, clostridial infection, fungemia, oral candidiasis
Investigations: amylase ↑, bilirubin ↑, CPK ↑, creatinine ↑, electrocardiogram QT prolonged, electrocardiogram early transition, gamma-glutamyl transferase ↑, lipase ↑, magnesium ↓, platelet count ↑, platelet count ↓, potassium ↓, prothrombin time prolonged, urea ↑
Metabolism and Nutrition: hypercalcemia, hyperglycemia, hyperkalemia, hypernatremia, hypomagnesemia
Musculoskeletal and Connective Tissue: back pain
Nervous System: convulsion, dizziness, headache
Respiratory, Thoracic and Mediastinal: cough, bronchospasm
Skin and Subcutaneous Tissue: angioneurotic edema, erythema, pruritus generalized, sweating increased, urticaria, urticaria NOS
Vascular: flushing, hot flushes, hypertension, hypotension, thrombophlebitis superficial

~~For~~ Authorization Holder:
Pfizer Pharmaceutical Israel Ltd, 9 Shenkar st., Herzeliya 46725

העלונים לרופא נשלחו למשרד הבריאות לצורך פרסומם במאגר התרופות שבאתר משרד הבריאות:
http://www.health.gov.il/units/pharmacy/trufot/index.asp.

לחילופין, לקבלת עלון מלא מודפס ניתן לפנות לחברת פייזר פרמצבטיקה ישראל בע"מ
שנקר 9, ת.ד. 12133
הרצליה פיתוח, 46725.

בברכה,

ענת גולדבוים
רוקחת ממונה