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

דצמבר 2023

רופא/ה, רוקח/ת נכבד/ה,

ברצוננו להודיעך על עדכון בעלון לרופא של התכשיר **Eraxis 100mg**

העדכון כולל תוספת התוויה, תוספת משטר מינון ותוספת של מידע בטיחותי

שם התכשיר :

Eraxis 100 mg

המרכיב הפעיל:

Anidulafungin

התוויה :

Treatment of invasive candidiasis in adults patients

להלן העדכונים העיקריים בעלון לרופא:

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Treatment of invasive candidiasis in adults and paediatric patients aged 1 month to < 18 years (see sections 4.4 and 5.1).

4.2 Posology and method of administration

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Paediatric population
(1 month to < 18 years) (dosing and treatment duration)
A single loading dose of 3.0 mg/kg (not to exceed 200 mg) should be administered on Day 1 followed by a daily maintenance dose of 1.5 mg/kg (not to exceed 100 mg) thereafter.

Duration of treatment should be based on the patient's clinical response.

In general, antifungal therapy should continue for at least 14 days after the last positive culture.

The safety and efficacy of ERAXIS® ~~in children below 18 years~~ have not been established in neonates (< 1 month old) (see section 4.4) . ~~Currently available data are described in section 5.2 but no recommendation on a posology can be made.~~

Method of administration
For intravenous use only.

ERAXIS® should be reconstituted with water for injection~~s~~ to a concentration of 3.33 mg/mL and subsequently diluted to a concentration of 0.77 mg/mL for the final infusion solution. For a paediatric patient, the volume of infusion solution required to deliver the dose will vary depending on the weight of the child. For instructions on reconstitution of the medicinal product before administration, see section 6.6.

4.3 Special warnings and precautions for use

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Paediatric population

Treatment with ERAXIS® in neonates (< 1 month old) is not recommended. Treating neonates requires consideration for coverage of disseminated candidiasis including central nervous system (CNS); nonclinical infection models indicate that higher doses of anidulafungin are needed to achieve adequate CNS penetration (see section 5.3), resulting in higher doses of polysorbate 80, a formulation excipient. High doses of polysorbates have been associated with potentially life-threatening toxicities in neonates as reported in the literature.

There is no clinical data to support the efficacy and safety of higher doses of anidulafungin than recommended in 4.2.

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Fructose content

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Babies and young children (below 2 years of age) may not yet be diagnosed with HFI. Medicines (containing fructose) given intravenously may be life threatening and should not be administered in this population unless there is an overwhelming clinical need and no alternatives are available.

A detailed history with regard to HFI symptoms has to be taken of each patient prior to being given this medicinal product.

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4.8 Undesirable effects

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Paediatric population

The safety of anidulafungin was investigated in 68 paediatric patients (1 month to < 18 years) with ICC in a prospective, open-label, non-comparative paediatric study (see section 5.1). The frequencies of certain hepatobiliary adverse events, including alanine aminotransferase (ALT) increased and aspartate aminotransferase (AST) increased appeared at a higher frequency (7-10%) in these paediatric patients than has been observed in adults (2%). Although chance or differences in underlying disease severity may have contributed, it cannot be excluded that hepatobiliary adverse reactions occur more frequently in paediatric patients compared to adults.

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השינויים המוצגים והמודגשים ברקע צהוב מהווים החמרה . כמו כן, בוצעו שינויים נוספים בעלון לרופא הכוללים תוספת מידע, השמטת מידע ועדכוני נוסח שאינם מהווים החמרה אשר אינם מוצגים בהודעה זו . בהודעה זו מצוינים רק העדכונים העיקריים המהווים החמרה. קיימים עדכונים נוספים. העלונים המעודכנים נשלחו למשרד הבריאות לצורך פרסומם במאגר התרופות שבאתר משרד הבריאות:
https://www.health.gov.il/Subjects/PharmAndCosmetics/DrugsRegistryDB/Pages/DrugsDatabase.aspx

לחילופין, לקבלת עלונים מלאים מודפסים ניתן לפנות לחברת פייזר פי אף אי פרמצבטיקה ישראל בע"מ שנקר 9, ת.ד. 12133 הרצליה פיתוח, 46725.

בברכה,
אנה רזניקוב
רוקחת ממונה