יוני 2024

רופא /ה, רוקח/ת נכבד/ה
חברת טבע מודיעה על העדכונים הבאים בעלון לרופא של התכשיר:

Anidulafungin Teva **אנידולפונגין טבע**

Contains:

Anidulafungin 100 mg/vail

עדכונים בעלון לרופא

התוויה כפי שאושרה בתעודת הרישום:

Treatment of invasive candidiasis in adult patients

ברצוננו להודיע שהעלון לרופא עודכן, בפירוט שלהלן כלולים העדכונים העיקריים בלבד (תוספות מסומנות באדום והסרות מידע כטקסט מחוק):

4.1 Therapeutic indications

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

4.2 Posology and method of administration

[…]

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 anidulafungin in have not been established in neonates (< 1 month old) (see section 4.4).

Method of administration

For intravenous use only.

Anidulafungin Teva should be reconstituted with water for injections 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.

[…]

4.4 Special warnings and precautions for use

[…]

Paediatric population

Treatment Anidulafungin Teva 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.

[…]

4.8 Undesirable effects

[…]

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.

[…]

4.9 Overdose

[…]

During a pediatric clinical trial, one subject received two doses of anidulafungin that were 143% of the expected dose. No clinical adverse reactions were reported.

[…]

העלונים נשלחו לפרסום במאגר התרופות שבאתר האינטרנט של משרד הבריאות
וניתן לקבלו מודפס ע"י פניה לחברת טבע. http://www.israeldrugs.health.gov.il