הודעה על החמרה (מידע בטיחות) בעלון לרופא

(מעודכן 05.2013)

תאריך 06.10.2014

שם תכשיר באנגלית ומספר הרישום

ERAXIS 139.84.31584

שם בעל הרישום: <u>פייזר פרמצבטיקה בע"מ</u>

טופס זה מיועד לפרוט ההחמרות בלבד !

ההחמרות המבוקשות		
טקסט חדש	**טקסט נוכחי**	**פרק בעלון**
		Indication
		contraindications
Treatment with ERAXIS should be initiated by a physician experienced in the management of invasive fungal infections. Specimens for fungal culture should be obtained prior to therapy. Therapy may be initiated before culture results are known and can be adjusted accordingly once they are available. <u>Posology</u> A single 200 mg loading dose should be administered on Day 1, followed by 100 mg daily 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. **Duration of treatment** **There are insufficient data to support the 100 mg dose for longer than 35 days of treatment.**	Candidemia and other Candida infections (intra-abdominal (abscess, and peritonitis The recommended dose is a single 200 mg loading dose of ERAXIS on Day 1, followed by 100 mg daily dose 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.	**Posology, dosage & administration**
<u>Infusion-related reactions</u> Infusion-related adverse events have been reported with anidulafungin, including rash, urticaria, flushing, pruritus, dyspnea, bronchospasm and hypotension. Infusion-related adverse events are infrequent when the rate of anidulafungin infusion does not exceed 1.1 mg/min. **Exacerbation of infusion-related reactions by co-administration of anaesthetics has been seen in a non-clinical (rat) study (see section 5.3). The clinical relevance of this is unknown. Nevertheless, care should be taken when co-administering anidulafungin and anaesthetic agents.** **<u>Fructose content</u>** **Patients with rare hereditary problems of fructose intolerance should not take this medicine**	PRECAUTIONS Anaphylactic reactions Anaphylactic reactions, including shock, were reported with the use of anidulafungin. If these reactions occur, anidulafungin should be discontinued and appropriate treatment administered. Infusion-related reactions Infusion-related adverse events have been reported with anidulafungin, including rash, urticaria, flushing, pruritus, dyspnea, bronchospasm and hypotension. Infusion-related adverse events are infrequent when the rate of anidulafungin infusion does not exceed 1.1 mg/minute	**Special Warnings and Special Precautions for Use**
		Interaction with Other Medicaments and Other Forms of Interaction
<u>Pregnancy</u> <u>Pregnancy Category C</u>	Pregnancy Pregnancy Category C	**pregnancy Fertility,**

There are no data regarding the use of anidulafungin in pregnant women. Slight developmental effects have been observed in rabbits administered anidulafungin during pregnancy, in the presence of maternal toxicity (see section 5.3). The potential risk for humans is unknown. **Therefore anidulafungin is not recommended in pregnancy.** Breast-feeding Animal studies have shown excretion of anidulafungin in breast milk. It is not known whether anidulafungin is excreted in human breast milk. A decision on whether to continue/discontinue breast-feeding or therapy with anidulafungin should be made taking into account the benefit of breast-feeding to the child and the benefit of anidulafungin to the mother. **Fertility** **For anidulafungin, there were no effects on fertility in studies conducted in male and female rats (see section 5.3).**	Embryo-fetal development studies were conducted with doses up to 20 mg/kg/day in rats and rabbits (equivalent to 2 and 4 times, respectively, the proposed therapeutic maintenance dose of 100 mg/day on the basis of relative body surface area). Anidulafungin administration resulted in skeletal changes in rat fetuses including incomplete ossification of various bones and wavy, misaligned or misshapen ribs. These changes were not dose-related and were within the range of the laboratory's historical control database. Developmental effects observed in rabbits (slightly reduced fetal weights) occurred in the high dose group, a dose that also produced maternal toxicity. Anidulafungin crossed the placental barrier in rats and was .detected in fetal plasma There are no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, ERAXIS should be used during pregnancy only if the potential benefit justifies the risk .to the fetus	**and Lactation**

System Organ Class	Very Common	System Organ Class	Very Common	System Organ Class	Very Common
Hepatobiliary Disorders		**Alanine aminotransferase increased, blood alkaline phosphatase increased, aspartate aminotransferase increased, blood bilirubin increased, cholestasis**		**Gamma-glutamyltransferase increased**	
Skin and Subcutaneous Tissue Disorders		**Rash, pruritus**	**Urticaria**		

Hepatobiliary: abnormal liver function tests NOS, cholestasis, hepatic necrosis

Skin and Subcutaneous Tissue: angioneurotic edema, erythema, pruritus generalized, sweating increased, urticaria, urticaria NOS

Adverse events

No studies on the effects on the ability to drive and use machines have been performed.		**Effects on ability to drive and use machines**

מצ"ב העלון, שבו מסומנות ההחמרות המבוקשות על רקע צהוב.
שינויים שאינם בגדר החמרות סומנו (בעלון) בצבע שונה. יש לסמן רק תוכן מהותי ולא שינויים במיקום הטקסט.

הועבר בדואר אלקטרוני בתאריך 02.10.2014