הודעה על החמרה (מידע בטיחות) בעלון לרופא

(מעודכן 05.2013)

אושר – 10.16

תאריך 09.10.2016

שם תכשיר באנגלית ומספר הרישום

Tygacil 136.43.31352.01

שם בעל הרישום פייזר פי אף אי פרמצבטיקה ישראל בע"מ

טופס זה מפרט ההחמרות בלבד !

ההחמרות המבוקשות		
טקסט חדש	**טקסט נוכחי**	**פרק בעלון**
…. The following adverse reactions were reported (<2%) in patients receiving TYGACIL in clinical studies: … *Hemic and Lymphatic System*: prolonged activated partial thromboplastin time (aPTT), prolonged prothrombin time (PT), eosinophilia, increased international normalized ratio (INR), thrombocytopenia	… The following adverse reactions were reported (<2%) in patients receiving TYGACIL in clinical studies: … *Hemic and Lymphatic System*: partial thromboplastin time (aPTT), prolonged prothrombin time (PT), eosinophilia, increased international normalized ratio (INR), thrombocytopenia	**Adverse reactions**
8.1 Pregnancy **Teratogenic Effects—Pregnancy Category D *[see Warnings and Precautions (5.6)]*** Tigecycline was not teratogenic in the rat or rabbit. In preclinical safety studies, ^{14}C-labeled tigecycline crossed the placenta and was found in fetal tissues, including fetal bony structures. The administration of tigecycline was associated with ~~slight~~ reductions in fetal weights and an increased incidence of ~~minor~~ skeletal anomalies (delays in bone ossification) at exposures of 5 times and 1 times the human daily dose based on AUC in rats and rabbits, respectively (28 mcg·hr/mL and 6 mcg·hr/mL at 12 and 4 mg/kg/day).	**8.1 Pregnancy** **Teratogenic Effects—Pregnancy Category D *[see Warnings and Precautions (5.6)]*** Tigecycline was not teratogenic in the rat or rabbit. In preclinical safety studies, ^{14}C-labeled tigecycline crossed the placenta and was found in fetal tissues, including fetal bony structures. The administration of tigecycline was associated with slight reductions in fetal weights and an increased incidence of minor skeletal anomalies (delays in bone ossification) at exposures of 5 times and 1 times the human daily dose based on AUC in rats and rabbits, respectively (28 mcg·hr/mL and 6 mcg·hr/mL at 12 and 4 mg/kg/day).	**Use In Specific Populations**

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… 11.3 Pharmacokinetics … **Drug Interaction Studies** … Tigecycline is a substrate of P-gp based on an in vitro study using a cell line overexpressing P-gp. The potential contribution of P-gp-mediated transport to the in vivo disposition of tigecycline is not known. Coadministration of P-gp inhibitors (e.g., ketoconazole or cyclosporine) or P-gp inducers (e.g., rifampicin) could affect the pharmacokinetics of tigecycline.	… 11.3 Pharmacokinetics … **Drug Interaction Studies** …	**Clinical Pharmacology**

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............09.10.2016....

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