הודעה על החמרה (מידע בטיחות) בעלון לרופא
(מעודכן 05.2013)

אושר – 6.16

תאריך 18.04.2016

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**
… **2.3 Dosage in Pediatric Patients** … Avoild use of tigecycline in pediatric patients unless no alternative antibacterial drugs are available. Under these circumstances, the following doses are suggested:	…. **2.3 Pediatric Patients** … Tigecycline should not be used in pediatric patients unless no alternative antibacterial drugs are available. Under these circumstances, the following doses are suggested:	**Dosage and administration**
TYGACIL is contraindicated for use in patients who have known hypersensitivity to tigecycline. Reactions have included anaphylactic reactions [see Warnings and Precautions (5.3) and Adverse Reactions (6.2)].	TYGACIL is contraindicated for use in patients who have known hypersensitivity to tigecycline.	**Contraindications**
… **5.3 Anaphylactic Reactions** Anaphylactic reactions have been reported with nearly all antibacterial agents, including TYGACIL, and may be life-threatening. TYGACIL is structurally similar to tetracycline-class antibiotics and should be avoided in patients with known hypersensitivity to tetracycline-class antibiotics. **5.4 Hepatic Adverse Effects** … Patients who develop abnormal liver function tests during tigecycline therapy should be monitored for evidence of worsening hepatic function and evaluated for risk/benefit of continuing tigecycline therapy. Hepatic	… **5.2 Anaphylaxis/Anaphylactoid Reactions** Anaphylaxis/anaphylactoid reactions have been reported with nearly all antibacterial agents, including TYGACIL, and may be life-threatening. TYGACIL is structurally similar to tetracycline-class antibiotics and should be administered with caution in patients with known hypersensitivity to tetracycline-class antibiotics. **5.3 Hepatic Effects** … Patients who develop abnormal liver function tests during tigecycline therapy should be monitored for evidence of worsening hepatic function and evaluated for risk/benefit of	**Warnings and Precautions**

dysfunction may occur after the drug has been discontinued.	continuing tigecycline therapy. Adverse events may occur after the drug has been discontinued.	
… **5.9 Sepsis/Septic Shock in Patients with Intestinal Perforation** Monotherapy with tigecycline should be avoided in patients with complicated intra-abdominal infections (cIAI) secondary to clinically apparent intestinal perforation.	… **5.9 Patients with Intestinal Perforation** Caution should be exercised when considering TYGACIL monotherapy in patients with complicated intra-abdominal infections (cIAI) secondary to clinically apparent intestinal perforation. …	
The following serious adverse reactions are described elsewhere in the labeling: • All-Cause Mortality *[see Boxed Warning and Warnings and Precautions (5.1)]* • Mortality Imbalance and Lower Cure Rates in Hospital-Acquired Pneumonia *[see* Warnings *and Precautions (5.2)]* • Anaphylaxis *[Warning and Precautions (5.3)]* • Hepatic Adverse Effects *[Warnings and Precautions (5.4)]* • Pancreatitis *[Warnings and Precautions (5.5)]* …	…	**Adverse reactions**
… **11.4 Microbiology** … **Resistance** To date, there has been no cross-resistance observed between tigecycline and other antibacterials. Tigecycline is less affected by the two major tetracycline-resistance mechanisms, ribosomal protection and efflux. Additionally, tigecycline is not affected by resistance mechanisms such as beta-lactamases (including extended spectrum beta-lactamases), target-site modifications, macrolide efflux pumps or enzyme target changes (e.g. gyrase/topoisomerases). However, some ESBL-producing isolates may confer resistance to tigecycline via other resistance mechanisms.	… **11.4 Microbiology** … **Mechanism(s) of Resistance** To date, there has been no cross-resistance observed between tigecycline and other antibacterials. Tigecycline is not affected by the two major tetracycline-resistance mechanisms, ribosomal protection and efflux. Additionally, tigecycline is not affected by resistance mechanisms such as beta-lactamases (including extended spectrum beta-lactamases), target-site modifications, macrolide efflux pumps or enzyme target changes (e.g. gyrase/topoisomerases).	**Clinical Pharmacology**
• Advise patients, their families, or caregivers that diarrhea is a common problem caused by antibacterial drugs. Sometimes, frequent watery or bloody diarrhea may occur and may be a sign of a more serious intestinal infection. If severe watery or bloody diarrhea	• Diarrhea is a common problem caused by antibiotics which usually ends when the antibiotic is discontinued. Sometimes after starting treatment with antibiotics, patients can develop watery and bloody stools (with or	**Patient Counsuming Information**

develops, tell them to contact his or her healthcare provider *[see Warnings and Precautions (5.8)].*	without stomach cramps and fever) even as late as two or more months after having taken the last dose of the antibiotic. If this occurs, patients should contact their physician as soon as possible.	

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............18.04.2016....