



SFDA SAFTEY COMMUNICATION

26 July 2011

Saudi Food and Drug Authority (SFDA) PRESS RELEASE – Increased risk of death associated with use of (Tigecycline) Tygacil®

The Saudi Food and Drug Authority (SFDA) would like to provide healthcare professionals (HCPs) with an important safety information of an increased mortality risk associated with the use of tigecycline compared to other antibiotics used to treat similar infections.

There was a numerically more cases of death in tigecycline-treated patients in comparison to other antibiotics, particularly when tigecycline was used for hospital acquired pneumonia and ventilator associated pneumonia (unapproved indications). Although, the mortality difference was not statistically significant for each indication when analyzed separately, a pooled analysis showed that there was a statistically significant increase risk of death in tigecycline-treated patients compared to patients treated with other antibiotics. The SFDA concluded that the risk of death increases when tigecycline is used for unapproved indications.

Consideration for Healthcare Professionals:

1. Tigecycline should only be used when the use of alternative antibiotic is considered inappropriate.
2. Tigecycline should be used only for approved indications in Saudi Arabia as follows:
 - a. Complicated Skin Infection.
 - b. Soft Tissue Infection.
 - c. Complicated Intra-abdominal Infection.
- 3- Tigecycline **should not** be used for treatment of the following unapproved indications :
 - a. Community Acquired Pneumonia.
 - b. Hospital Acquired Pneumonia .
 - c. Ventilator Associated Pneumonia.
 - d. Diabetic Foot.

Report Adverse Drug Reactions (ADRs) to the Saudi FDA :

The SFDA urges both healthcare professionals and patients to cooperate with the National Pharmacovigilance and Drug Safety Center (NPC) through reporting any adverse drug reactions resulted from any medications by sending them through Email or regular mail to the following address :

National Pharmacovigilance and Drug Safety Center (NPC)

Saudi Food and Drug Authority-Drug sector

3292 Northern Ring Road

Al Nafal District

Riyadh 13312 – 6288

Kingdom of Saudi Arabia

Tel: 012759222 ext. 2334, 2317, 2353, 2354, 2356,5769

Fax: 012057662

Email: npc.drug@sfd.gov.sa

Website: www.sfd.gov.sa/npc