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Saudi Arabia

Date 15th of October, 2011

Direct Health Care Professional Communication on increase in mortality with use of Tygacil® (tigecycline)

Dear Health Care Professional,

Pfizer is writing to inform you with updates related to the label of TYGACIL (tigecycline).
In Saudi Arabia, TYGACIL is not approved in clinical indications other than the treatment of complicated skin and skin structure infections (*cSSTI)* and complicated intra-abdominal infections (*cIAI)* caused by susceptible strains of designated microorganisms. The **special warning** and **precautions** for use section in the label now has been updated as following:

i. *"In clinical studies in complicated skin and soft tissue infections, complicated intra-abdominal infections, diabetic, foot infections, nosocomial pneumonia and studies in resistant pathogens, a numerically higher mortality rate among Tygacil treated patients has been observed as compared to the comparator treatment. The causes of these findings remain unknown, but poorer efficacy and safety than the study comparators cannot be ruled out."*

ii "*Patients who develop super-infections, in particular nosocomial pneumonia, appear to be associated with poorer outcomes. Patients should be closely monitored for the development of super-infection. If a focus of infection other than cSSTI or cIAI is identified after initiation of TYGACIL therapy, consideration should be given to instituting alternative antibacterial therapy that has been demonstrated to be efficacious* in *the treatment of the specific type of infection(s) present"*

iii *"Tygacil is not approved for clinical indications other than complicated skin and Soft tissue infections, and complicated intra-abdominal infections. The use of Tygacil in non-approved indications is not recommended".*

The numerically increased risk of mortality in tigecycline-treated patients was noticed 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 mortality in tigecycline-treated patients compared to patients treated with other antibiotics. The risk of mortality increases when tigecycline is used for unapproved indications. Pfizer is committed to ensuring that Tygacil is used safely and effectively and to providing you with the most current product information.

A call for reporting

Pfizer would like to encourage you to report all adverse drug reactions (ADRs) concerning Tygacil®, especially lack of efficacy, super-infection and fatal outcomes to:

Tel : + 966 2 653 7026
Fax : + 966 2 653 7016
Email : *Omar.Ahmed@Pfizer.com*

In addition, you can also report all ADRs to the Saudi Food and Drug Authority (SFDA) through either of the followings:

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. 2317, 2353, 2354, 2356, 5769
Fax : 012057662
Email: NPC.Drug@sfda.gov.sa
http://www.sfda.gov.sa/Ar/Drug/Topics/Organogram/NationalPharmacovigilanceCenter/

Country Medical Director
Kingdom Saudi Arabia

Full prescribing information is available upon request