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Pfizer Healthcare Ireland

IMPORTANT SAFETY INFORMATION 7th March 2011

Direct healthcare professional communication on increase in mortality in clinical trials of Tygacil (tigecycline)

Dear healthcare professional,

Summary

- Tygacil should only be used in situations where it is known or suspected that other drugs are not suitable.
- Tygacil is only approved for treatment of complicated skin and soft tissue infections and complicated intra-abdominal infections.
- A numerically higher mortality rate has been reported among patients in clinical studies in approved and not approved indications, compared to those subjects receiving comparator drugs.
- 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 medically indicated, these patients should be switched to alternative antibiotic treatment.

Further information on the safety concern

In the 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 was observed in subjects receiving tigecycline compared to those subjects receiving comparator anti-infective drugs.

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In all phase 3 and phase 4 complicated skin and soft tissue infections and complicated intra-abdominal infections studies, death occurred in 2.3 % (52/2216) of patients receiving tigecycline and 1.5% (33/2206) of patients receiving comparator drugs (section 4.8 of Summary of product characteristics).

The cause of these findings remains unknown, but poorer efficacy and safety than the study comparators cannot be ruled out.

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.

Tygacil is only indicated for the treatment of complicated skin and soft tissue infections and complicated intra-abdominal infections. Its use should be considered only when it is known or suspected that other alternatives are not suitable.

The Tygacil summary of product characteristics and risk management plan has been updated to reflect and further address these findings. Revisions have been made to sections 4.1 Indications and 4.4 Special warning and precautions for use of the Summary of Product Characteristics.

This information has been approved for distribution by the European Medicines Agency (EMA) and the Irish Medicines Board (IMB).

Call for reporting

You can assist us with monitoring the safety of Tygacil by reporting suspected adverse reactions (including any lack of efficacy, super-infections and fatal outcomes) to Pfizer at 1800 633363 and ask for Medical Information. Alternatively, this information may be reported to the Irish Medicines Board (IMB) by calling: (01) 6764971, using on-line reporting forms at: www.imb.ie or using post-paid Report Cards (Yellow Cards) e-mail: imbpharmacovigilance@imb.ie

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Communication information
For more information about Tygacil, please contact Pfizer Medical Information at Pfizer Limited, Walton Oaks, Dorking Road, Tadworth, Surrey, KT20 7NS or Tel: 1800 633363 and ask for Medical Information.

Yours sincerely,

Dr. Declan O'Callaghan
Director of Medical Affairs, Specialty Care Business Unit
Pfizer Healthcare Ireland