Tygacil (tigecycline): Label Change - Increased Mortality Risk

U.S. Food & Drug Administration

ISSUE: FDA reminded healthcare professionals of an increased mortality risk associated with the use of the intravenous antibacterial Tygacil (tigecycline) compared to that of other drugs used to treat a variety of serious infections. The increased risk was seen most clearly in patients treated for hospital-acquired pneumonia, especially ventilator-associated pneumonia, but was also seen in patients with complicated skin and skin structure infections, complicated intra-abdominal infections and diabetic foot infections. FDA has updated sections of the Tygacil drug label to include information regarding increased mortality risk of Tygacil.

BACKGROUND: Tygacil is approved by FDA for the treatment of complicated skin and skin structure infections, complicated intra-abdominal infections, and community acquired pneumonia. Tygacil is not approved for the treatment of hospital-acquired pneumonia (including ventilator-associated pneumonia) or diabetic foot infection. The increased risk was determined using a pooled analysis of clinical trials. See the Data Summary section of the FDA Drug Safety Communication for additional details.

RECOMMENDATION: Alternatives to Tygacil should be considered in patients with severe infections. Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of this product to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report.htm [1]
- Download form [2] or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

[09/01/2010 - Drug Safety Communication [3] - FDA]

SOURCE [4]

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http://www.mdtmag.com/news/2010/09/tygacil-tigecycline-label-change-increased-mortality-risk

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[1] http://www.fda.gov/MedWatch/report.htm
[2] http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm
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