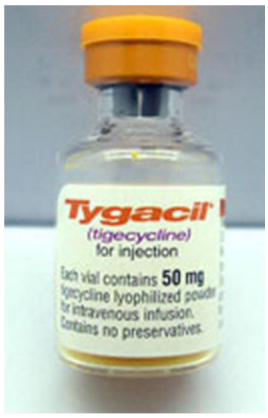
Tigecycline (*Tygacil*; Wyeth Pharmaceuticals) is linked to an increased risk for death in patients with certain severe infections, and clinicians should consider alternative intravenous antibiotics, the US Food and Drug Administration (FDA) announced today.



Tygacil

The agency stated that the increased mortality risk is most apparent in patients treated for hospital-acquired pneumonia, particularly ventilator-associated pneumonia. The agency also has discerned the increased risk in patients with complicated intra-abdominal infections, complicated skin and skin-structure infections, and diabetic foot infections.

Tigecycline is not approved for diabetic foot infections or hospital-acquired pneumonia. It is approved for complicated intra-abdominal infections and complicated skin and skin-structure infections, as well as for community-acquired pneumonia.

In a pooled analysis of 13 trials with patients given tigecycline for both approved and unapproved indications, death occurred in 4% of patients receiving tigecycline compared with 3% of patients receiving other antibiotics.

"The cause of the excess deaths in these trials is often uncertain, but it is likely that most deaths in patients with these severe infections were related to progression of the infection," the agency stated.

The FDA noted that tigecycline is generally considered to be a bacteriostatic drug; that is, it inhibits the growth of bacteria as opposed to killing them outright. However, it has demonstrated bactericidal activity against isolates of *Streptococcus pneumonia* and *Legionella pneumophila*. "One possible reason for the mortality difference," said the agency, "is that in certain severe infections, Tygacil's bacteriostatic mechanism may put it at some disadvantage, although for approved indications, cure rates with Tygacil were generally similar to that seen with the bactericidal active control agents."

More information about today's announcement is available on the FDA's Web site.

To report adverse events related to tigecycline, contact MedWatch, the FDA's safety information and adverse event reporting program, by telephone at 1-800-FDA-1088, by fax at 1-800-FDA-0178, online at http://www.fda.gov/medwatch, or by mail to MedWatch, FDA, 5600 Fishers Lane, Rockville, Maryland 20852-9787.