FDA adds most severe warning to Pfizer's Tygacil

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Regulators are putting their harshest warning on Pfizer's antibiotic Tygacil, saying the drug is associated with an increased risk of death.

The Food and Drug Administration said Friday Tygacil, or tigecycline, should only be used in situations when other treatments aren't suitable. The intravenous drug is approved as a treatment for complicated skin and skin structure infections and community-acquired bacterial pneumonia. The FDA will add a boxed warning to the drug label, its most serious type of warning.

In 2010 the FDA said Tygacil was associated with a greater risk of death than other antibacterial drugs. It says a new analysis confirmed that conclusion. The risk was greatest in patients with ventilator-associated pneumonia. Tygacil hasn't been approved for that condition.

The agency said it's not clear why the drug is associated with a higher risk of death compared to other drugs.

The New York drugmaker reported $335 million in Tygacil revenue last year, including $152 million in U.S. sales.

Shares of Pfizer Inc. rose 37 cents to $28.89 in afternoon trading.