## Tygacil (tigecycline): Drug Safety Communication - Increased Risk of Death

**[Posted 09/27/2013]**

美國FDA提醒：Tygacil (tigecycline)以靜脈途徑用於FDA核准/非核准適應症時，死亡風險會提高。此訊息的來源，是美國FDA於2010年9月發出相關安全訊信後，為了FDA核准使用所進行的額外分析。

此分析顯示，使用Tygacil相較於使用它種抗生素，死亡率分別為：2.5% (66/2640) vs. 1.8% (48/2628)。效正後的死亡風險差異：0.6% (95CI 0.0%, 1.2%)。整體而言，死亡原因為感染惡化、感染併發症、其他潛在醫療因素。

**建議**

不適用其他替代治療的情況下，醫護人員應使用Tygacil。

**[Posted 09/27/2013]**

**AUDIENCE:** Infectious Disease, Critical Care, Pharmacy

**ISSUE:** FDA notified health professionals and their medical care organizations of a new Boxed Warning describing an increased risk of death when intravenous Tygacil is used for FDA-approved uses as well as for non-approved uses. These changes to the Tygacil Prescribing Information are based on an additional analysis that was conducted for FDA-approved uses after FDA issuing a Drug Safety Communication about this safety concern in September 2010.

This analysis showed a higher risk of death among patients receiving Tygacil compared to other antibacterial drugs: 2.5% (66/2640) vs. 1.8% (48/2628), respectively. The adjusted risk difference for death was 0.6% with corresponding 95% confidence interval (0.0%, 1.2%). In general, the deaths resulted from worsening infections, complications of infection, or other underlying medical conditions.

**BACKGROUND:** Tygacil is FDA-approved to treat complicated skin and skin structure infections (cSSSI), complicated intra-abdominal infections (cIAI), and community-acquired bacterial pneumonia (CABP).

**RECOMMENDATION:** Health care professionals should reserve Tygacil for use in situations when alternative treatments are not suitable.

## Tygacil (tigecycline): Label Change - Increased Mortality Risk

**[Posted 09/01/2010]**

**AUDIENCE:** Infectious Disease, Critical Care Medicine, Internal Medicine

**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.