



Doribax (doripenem): Drug Safety Communication - Risk When Used to Treat Pneumonia on Ventilated Patients

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FDA做出結論：抗菌藥物Doribax (doripenem)治療呼吸器相關肺炎的患者，相較於imipenem/cilastatin注射劑，會增加死亡率且降低治癒率。

FDA分析資料來自一項三年的臨床試驗，此試驗因安全考量而在2011年提前終止。基於此分析，FDA核准修改Doribax的藥品仿單，以描述此風險。Doribax (doripenem)不被核准用於任何類型的肺炎。

背景

在這項提早終止的臨床試驗中，呼吸器相關肺炎的患者分別接受7天的Doribax治療，或10天的imipenem/cilastatin治療。在意圖治療族群中(intent-to-treat population)，Doribax組的28天死亡率(23.0%; n=31/135)，高於imipenem/cilastatin組(16.7%; n=22/132)。Doribax組的治癒率也較低。

建議

醫療人員應考量：呼吸器相關肺炎的患者使用Doribax，其治療益處是否高於風險。Doribax用於FDA核准適應症，仍被認為安全有效。FDA核准的適應症：治療成人的複雜性腹腔內感染、複雜性尿路感染，包括腎臟感染(腎盂腎炎)。

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AUDIENCE: Pulmonology, Infectious Disease, Pharmacy

ISSUE: The FDA has concluded that Doribax (doripenem), an antibacterial drug used to treat patients who develop pneumonia while on ventilators, carries an increased risk of death and lower clinical cure rates compared to use of imipenem and cilastatin for injection (marketed in the U.S. under the name Primaxin). Based on an FDA analysis of data from a three-year clinical trial that was prematurely stopped in 2011 due to these safety concerns, FDA approved changes to the Doribax drug label that describe these risks. The revised label includes a new warning about this unapproved use. Doribax is not approved to treat any type of pneumonia.

BACKGROUND: In the clinical trial that was stopped early, patients with ventilator-associated bacterial pneumonia received either 7-day Doribax treatment or 10-day treatment with imipenem and cilastatin. In the intent-to-treat population, the 28-day all-cause mortality was higher in the Doribax arm (23.0%; n=31/135) than in the imipenem and cilastatin arm (16.7%; n=22/132). Clinical cure rates were also lower in the Doribax arm.

RECOMMENDATION: Health care professionals should consider whether the benefits of Doribax treatment are likely to exceed its potential risks in patients who develop pneumonia while on ventilators. Doribax is still considered safe and effective for its FDA-approved indications - treatment of adults with complicated intra-abdominal infections and complicated urinary tract infections, including kidney infections (pyelonephritis).