

FDA Approves New Antibiotic Avycaz



The FDA has approved the combination of ceftazidime-avibactam (CAZ-AVI). The antibiotic under the brand name of Avycaz will be marketed by Forest Laboratories and is indicated to treat adults with complicated intra-abdominal or urinary tract infections, including kidney infections.

Ceftazidime is a third generation of cephalosporin that was approved in 1985 while avibactam is a novel β -lactamase inhibitor that helps its chemical partner battle bacteria in the face of antibiotic resistance. The drug can be used in patients who have limited treatment options. For intra-abdominal infections, Avycaz is to be administered with metronidazole.

The FDA has approved Avycaz as a qualified infectious disease product. It is the fifth antibiotic okayed by the FDA as a qualified infectious disease product.

"The FDA is committed to making therapies available to treat patients with unmet medical need," said Edward Cox, MD, MPH, director of the Office of Antimicrobial Products in the FDA's Center for Drug Evaluation and Research, in a news release. "It is important that the use of [CAZ-AVI] be reserved to situations when there are limited or no alternative antibacterial drugs for treating a patient's infection."

The safety and efficacy data from Phase 2 trials of the combination drug and data on ceftazidime in the treatment of complicated intra-abdominal and urinary tract infections as well as data on avibactam from in-vitro studies and animal modes of infection were the basis for the approval from the FDA.

The most common adverse effects associated with the new drug include vomiting, nausea, constipation and anxiety. In addition, the drug may not be effective in patients with poor kidney function and they may experience seizures and other neurologic problems. Finally, patients with penicillin allergies can have serious skin reactions and anaphylaxis.

The use of the drug comes with a specific recommendation from the FDA which clearly states that the drug is to be used "when limited or no alternative treatments are available."

The drug has not been approved for treatment of gram-negative infections including hospital-acquired bacterial pneumonia; ventilator associated bacterial pneumonia and bacteraemia.

Source: Medscape

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