

Ceftazidime with β -lactamase inhibitor approved for complicated infections

FDA and Actavis plc on February 26 announced the approval of the antibacterial product ceftazidime–avibactam, or Avycaz, for the treatment of adults with complicated intraabdominal and urinary tract infections caused by certain bacteria.

The agency said its decision to approve Avycaz was made on the basis of findings from two Phase II studies of the combination product and earlier findings from studies of ceftazidime without avibactam, a β -lactamase inhibitor.

For that reason, the labeling for the combination product tells clinicians to reserve it for patients who have limited or no other treatment options.

The labeling recommends a dosage regimen of 2.5 g of ceftazidime–avibactam every eight hours by i.v. infusion over two hours in patients with an estimated creatinine clearance (CL_{cr}) of >50 mL/min. Patients with complicated intraabdominal infections should also receive metronidazole therapy.

Lower dosages are recommended by the labeling for patients whose estimated CL_{cr} is 50 mL/min or less. Patients whose renal function is changing should have it monitored at least daily, and clinicians should adjust the dosage of ceftazidime–avibactam accordingly.

The duration of treatment with ceftazidime–avibactam, the labeling states, depends on the type of infection: 5–14 days for complicated intraabdominal infections and 7–14 days for complicated urinary tract infections.

During the Phase II studies, the most common adverse reactions to ceftazidime–avibactam therapy were vomiting, nau-

sea, constipation, and anxiety, according to the labeling.

Patients should not receive probenecid and ceftazidime–avibactam concurrently, the labeling suggests. Avibactam is a substrate of two organic anion transporters. There is the potential for probenecid, a potent inhibitor of organic anion transporters, to decrease elimination of the β -lactamase inhibitor.

Avycaz will be available in single-use vials containing 2 g of ceftazidime and 0.5 g of avibactam. The formulation also contains sodium carbonate.

The vials should be stored at 25 °C and protected from light.

Preparation of a dose for administration involves making a solution in the vial and then transferring the drug solution to an infusion container. The total volume of the solution for infusion should be 50–250 mL. This solution, the labeling states, should be used within 12 hours when stored at room temperature. Initial storage at 2–8 °C should not exceed 24 hours.

The company said the new combination product will be available in the second quarter of 2015.

According to the product's labeling, Avycaz will be distributed by Forest Pharmaceuticals Inc.

Actavis bought Forest's parent company in mid-2014.

—Cheryl A. Thompson

DOI 10.2146/news150023

Prepare now for USP standard on handling hazardous drugs

No one knows exactly when health-care facilities will be required to meet the requirements for handling hazardous drugs specified in *United States Pharmacopeia (USP) chapter 800*.

But now is the time to plan for compliance with the chapter, said Patricia C. Kienle, director of accreditation and medication safety for Cardinal Health Innovative Delivery Solutions.

“Don't wait for it to be official. That's going to be too late,” said Kienle, who chairs the United States Pharmacopeial Convention's expert panel on com-

pounding with hazardous drugs, which wrote chapter 800.

Ryan Forrey, associate director of pharmacy and infusion services at The Ohio State University Comprehensive Cancer Center in Columbus, likewise said there are many “work practices, administrative controls, and procedures that can be changed now that are consistent with recommendations and guidelines that are already out there” for handling hazardous drugs.

“I do think that people should . . . start to implement what we can now, and then