Generic Name:
Cefiderocol
Trade Name:
Fetroja
Company:
Shionogi & Co.
Notes:

FDA approved cefiderocol, a cephalosporin antibacterial for treatment of patients ages 18 years or older with complicated urinary tract infections (cUTI), including kidney infections caused by susceptible Gram-negative microorganisms, who have limited or no alternative treatment options.

Cefiderocol's safety and effectiveness were demonstrated in a study of 448 patients with cUTIs. Of the patients who were administered the drug, 72.6% had resolution of symptoms and eradication of the bacteria approximately 7 days after completing treatment, compared with 54.6% of patients who received an alternative antibiotic. The clinical response rates were similar between the two treatment groups.

The recommended dosage is 2 g administered by injection every 8 hours by IV infusion over 3 hours in patients with creatinine clearance (CLcr) 60 to 119 mL/min. Dose adjustments are required for patients with CLcr less than 60 mL/min and for patients with CLcr 120 mL/min or greater.

The labeling includes a warning about the higher all-cause mortality rate observed in patients receiving cefiderocol compared with those treated with other antibiotics in a trial in critically ill patients with multidrug-resistant Gram-negative bacterial infections. The cause of the increase in mortality has not been established. Some of the deaths were a result of worsening or complications of infection or of underlying comorbidities. The higher all-cause mortality rate was observed in patients treated for hospital-acquired/ventilator-associated pneumonia (i.e.nosocomial pneumonia), bloodstream infections, or sepsis. The drug's efficacy has not been established for treatment of these types of infections.

The most common adverse reactions included diarrhea, constipation, nausea, vomiting, elevations in liver tests, rash, infusion site reactions, candidiasis, cough, headache, and hypokalemia. Cefiderocol should not be used in individuals with a known history of severe hypersensitivity to beta-lactam antibacterial drugs.

Medication Monitor Categories:
New Drug Approvals