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Fetroja[®] (cefiderocol): A Unique Siderophore Cephalosporin for the Treatment of Difficult-to-Treat Infections Due to Susceptible Gram-Negative Pathogens



SPEAKER
David Ritchie, PharmD,
FCCP, BCIDP
Barnes-Jewish Hospital
St. Louis, MO

Wednesday, August 13, 2025 Time: 6:00 PM CT

J.Gilbert's Wood Fired Steaks And Seafood 8901 Metcalf Ave Overland Park, Kansas, 66212

SPACE IS LIMITED. Visit the link below or scan the QR code to RSVP.





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INDICATIONS

Fetroja[®] (cefiderocol) is indicated in patients 18 years of age or older for the treatment of complicated urinary tract infections (cUTIs), including pyelonephritis caused by the following susceptible Gram-negative microorganisms: *Escherichia coli, Klebsiella pneumoniae, Proteus mirabilis, Pseudomonas aeruginosa,* and *Enterobacter cloacae* complex.

Fetroja is indicated in patients 18 years of age or older for the treatment of hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP), caused by the following susceptible Gram-negative microorganisms: *Acinetobacter baumannii* complex, *Escherichia coli*, *Enterobacter cloacae* complex, *Klebsiella pneumoniae*, *Pseudomonas aeruginosa*, and *Serratia marcescens*.

USAGE

To reduce the development of drug-resistant bacteria and maintain the effectiveness of Fetroja and other antibacterial drugs, Fetroja should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

Fetroja is contraindicated in patients with a known history of severe hypersensitivity to cefiderocol or other beta-lactam antibacterial drugs, or any other component of Fetroja.

Please see additional Important Safety Information continued on the next page and accompanying Full Prescribing Information for Fetroja.



IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS

Increase in All-Cause Mortality in Patients with Carbapenem-Resistant Gram-Negative Bacterial Infections

An increase in 28-Day all-cause mortality was observed in Fetroja-treated nosocomial pneumonia, bloodstream infections, or sepsis patients compared to those treated with best available therapy (BAT) in a clinical study (NCT02714595). Most BAT regimens contained colistin. All-cause mortality remained higher in patients treated with Fetroja than in patients treated with BAT through Day 49.

Generally, deaths were in patients with infections caused by Gram-negative organisms, including non-fermenters such as *Acinetobacter baumannii* complex, *Stenotrophomonas maltophilia*, and *Pseudomonas aeruginosa*, and were the result of worsening or complications of infection, or underlying comorbidities. The cause of the increase in mortality has not been established.

Closely monitor the clinical response to therapy in patients with cUTI and HABP/VABP.

Hypersensitivity Reactions

Serious and occasionally fatal hypersensitivity (anaphylactic) reactions and serious skin reactions have been reported in patients receiving beta-lactam antibacterial drugs. Hypersensitivity was observed with Fetroja. Before Fetroja is instituted, inquire about previous hypersensitivity to cephalosporins, penicillins, or other beta-lactam drugs. If an allergic reaction occurs, discontinue Fetroja.

Clostridioides difficile-associated Diarrhea (CDAD)

CDAD has been reported with nearly all systemic antibacterial agents, including Fetroja. Careful medical history is necessary because CDAD has been reported to occur more than 2 months after the administration of antibacterial agents. If CDAD is suspected or confirmed, antibacterial drugs not directed against *C. difficile* may need to be discontinued.

Seizures and Other Central Nervous System (CNS) Adverse Reactions

Cephalosporins, including Fetroja, have been implicated in triggering CNS adverse reactions such as seizures. Encephalopathy, coma, asterixis, and neuromuscular excitability have been reported with cephalosporins particularly in patients with a history of epilepsy and/or when recommended dosages of cephalosporins were exceeded due to renal impairment. Adjust Fetroja dosing based on creatinine clearance. If focal tremors or seizures occur, evaluate patients to determine whether Fetroja should be discontinued.

Development of Drug-Resistant Bacteria

Prescribing Fetroja in the absence of a proven or strongly suspected bacterial infection or a prophylactic indication is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

ADVERSE REACTIONS

The most common adverse reactions occurring in $\geq 2\%$ of patients receiving Fetroja in the cUTI trial were: diarrhea (4%), infusion site reactions (4%), constipation (3%), rash (3%), candidiasis (2%), cough (2%), elevations in liver tests (2%), headache (2%), hypokalemia (2%), nausea (2%), and vomiting (2%). The most common adverse reactions occurring in $\geq 4\%$ of patients receiving Fetroja in the HABP/VABP trial were: elevations in liver tests (16%), hypokalemia (11%), diarrhea (9%), hypomagnesemia (5%), and atrial fibrillation (5%).

Please see accompanying Full Prescribing Information for Fetroja.

