Fetroja Product Ordering
Fact Sheet

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, 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 susceptible 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 Important Safety Information throughout this brochure and accompanying Full Prescribing Information for Fetroja, or visit Fetroja.com.
How supplied

**DESCRIPTION**
Fetroja 1 gram (cefiderocol) for injection is supplied as a white to off-white sterile lyophilized powder for reconstitution in single-dose, clear glass vials sealed with a rubber stopper (not made with natural rubber latex) and an aluminum seal with flip-off cap. Each vial is supplied in cartons containing 10 single-dose vials.

**NDC NUMBER**
59630-266-10: 1 gram/vial, 10 vials/carton

**DIMENSIONS**
175 mm x 70.5 mm x 60.5 mm (6.9” x 2.8” x 2.4”)

**WAC**
$1833.33

Storage and handling

**UNRECONSTITUTED VIALS**
- Store refrigerated at 2°C to 8°C (36°F to 46°F)
- Protect from light
- Store in carton until time of use

**RECONSTITUTED SOLUTIONS**
- Upon reconstitution with appropriate diluent, immediately transfer and dilute Fetroja into the infusion bag
- Reconstituted vials can be stored for up to 1 hour at room temperature
- Diluted Fetroja infusion solution in infusion bags is stable for up to 6 hours at room temperature
- The diluted Fetroja infusion solution in the infusion bag may also be refrigerated at 2°C to 8°C (36°F to 46°F) for up to 24 hours, protected from light, and then the infusion should be completed within 6 hours at room temperature.
- Discard any unused reconstituted solution

NDC=National Drug Code; WAC=wholesale acquisition cost.

**IMPORTANT SAFETY INFORMATION**

**WARNINGS AND PRECAUTIONS**

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

An increase in all-cause mortality was observed in patients treated with Fetroja as compared to best available therapy (BAT) in a multinational, randomized, open-label trial in critically ill patients with carbapenem-resistant Gram-negative bacterial infections (NCT02714595). Patients with nosocomial pneumonia, bloodstream infections, sepsis, or cUTI were included in the trial. BAT regimens varied according to local practices and consisted of 1 to 3 antibacterial drugs with activity against Gram-negative bacteria. Most of the BAT regimens contained colistin.

The increase in all-cause mortality occurred in patients treated for nosocomial pneumonia, bloodstream infections, or sepsis. The 28-Day all-cause mortality was higher in patients treated with Fetroja than in patients treated with BAT [25/101 (24.8%) vs 9/49 (18.4%), treatment difference 6.4%, 95% CI [-8.6, 19.2]]. All-cause mortality remained higher in patients treated with Fetroja than in patients treated with BAT through Day 49 [34/101 (33.7%) vs 10/49 (20.4%), treatment difference 13.3%, 95% CI [-2.5, 26.9]].

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Ordering Fetroja

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<thead>
<tr>
<th>Wholesalers</th>
<th>Customer Service Number</th>
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<tr>
<td>Cardinal Health</td>
<td>800-926-3161</td>
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<td>McKesson</td>
<td>855-625-6285</td>
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<td>AmerisourceBergen</td>
<td>844-222-2273</td>
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<td>Henry Schein</td>
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<td>Morris &amp; Dickson Co.</td>
<td>800-388-3833</td>
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<td>Smith Drug Company</td>
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<td>Anda</td>
<td>800-331-2632</td>
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<td>Value Drug</td>
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<td>RDC</td>
<td>800-333-0538 [ext. 5307, 5277, 5315, or 5338]</td>
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<td>Louisiana Wholesale Drug</td>
<td>337-662-1040</td>
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<tr>
<td>Dakota Drug</td>
<td>800-437-2018</td>
</tr>
</tbody>
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- Fetroja can be obtained through all common wholesale channels for hospital products
- Shionogi plans to work with major GPOs to support hospital acquisition

Fetroja is available through open distribution

GPO=group purchasing organization.

**IMPORTANT SAFETY INFORMATION**

**WARNINGS AND PRECAUTIONS (cont’d)**

**Increase in All-Cause Mortality in Patients with Carbapenem-Resistant Gram-Negative Bacterial Infections (cont’d)**

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 in Fetroja-treated patients in clinical trials. These reactions are more likely to occur in individuals with a history of beta-lactam hypersensitivity and/or a history of sensitivity to multiple allergens. There have been reports of individuals with a history of penicillin hypersensitivity who have experienced severe reactions when treated with cephalosporins.

Before therapy with Fetroja is instituted, inquire about previous hypersensitivity reactions to cephalosporins, penicillins, or other beta-lactam antibacterial drugs. Discontinue Fetroja if an allergic reaction occurs.

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IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS (cont’d)

Clostridioides difficile-associated Diarrhea (CDAD)

Clostridioides difficile-associated diarrhea (CDAD) has been reported for nearly all systemic antibacterial agents, including Fetroja. CDAD may range in severity from mild diarrhea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon and may permit overgrowth of C. difficile.

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. Manage fluid and electrolyte levels as appropriate, supplement protein intake, monitor antibacterial treatment of C. difficile, and institute surgical evaluation as clinically indicated.

Seizures and Other Central Nervous System (CNS) Adverse Reactions

Cephalosporins, including Fetroja, have been implicated in triggering seizures. Nonconvulsive status epilepticus (NCSE), encephalopathy, coma, asterixis, neuromuscular excitability, and myoclonia 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. Anticonvulsant therapy should be continued in patients with known seizure disorders. If CNS adverse reactions including seizures occur, patients should undergo a neurological evaluation 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 [≥2%] of patients receiving Fetroja compared to imipenem/cilastatin in the cUTI trial were: diarrhea [4% vs 6%], infusion site reactions [4% vs 5%], constipation [3% vs 4%], rash [3% vs <1%], candidiasis [2% vs 3%], cough [2% vs <1%], elevations in liver tests [2% vs <1%], headache [2% vs 5%], hypokalemia [2% vs 3%], nausea [2% vs 4%], and vomiting [2% vs 1%]. The most common adverse reactions occurring in [≥4%] of patients receiving Fetroja compared to meropenem in the HABP/VABP trial were: elevations in liver tests [16% vs 16%], hypokalemia [11% vs 15%], diarrhea [9% vs 9%], hypomagnesemia [5% vs <1%], and atrial fibrillation [5% vs 3%].


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