Fetroja – Photostability

This medical response contains information in addition to that provided in the Fetroja® (cefiderocol) for injection, for intravenous use Full Prescribing Information approved by the U.S. Food and Drug Administration (FDA). Shionogi does not recommend the use of Fetroja in any manner other than as described in the Full Prescribing Information. **Please read the attached Fetroja Full Prescribing Information.**

1. RECOMMENDED STORAGE OF THE FETROJA SOLUTION

Reconstituted Fetroja[1]

Upon reconstitution with the appropriate diluent, the reconstituted Fetroja solution in the vial should be immediately transferred and diluted into the infusion bag. Reconstituted Fetroja can be stored for up to 1 hour at room temperature. Discard any unused reconstituted solution.

There is no requirement for reconstituted Fetroja vials to be protected from light.[2]

Diluted Fetroja Infusion Solution[1,3]

The diluted Fetroja infusion solution in the infusion bags is stable for up to 6 hours at room temperature. There is no requirement for the diluted infusion bag to be protected from light during the room temperature storage and administration period.

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.

Please read the attached Fetroja **Full Prescribing Information**.

2. RELEVANT PRESCRIBING INFORMATION

Fetroja® is indicated in patients 18 years of age or older for the treatment of:[1]

- 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

- 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*

Fetroja is contraindicated in:[1]

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

Please read the attached Fetroja **Full Prescribing Information**.

REFERENCES

1. Fetroja® (cefiderocol) for injection, for intravenous use [Prescribing Information]. Shionogi Inc.
2. Data on File 86. Shionogi Inc.
3. Data on File 108. Shionogi Inc.

ENCLOSURE

Fetroja® (cefiderocol) for injection, for intravenous use [Prescribing Information]. Shionogi Inc.