Fetroja® – Shelf Life

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**.

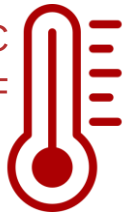
Summary | Relevant Prescribing Information | Abbreviations/Reference

Summary



- The shelf-life of the un-reconstituted Fetroja vials is confidential
- The FDA recognizes the confidentiality of this information, which is not disclosed publicly
- Shionogi releases Fetroja into marketing and distribution channels with adequate time remaining for the product to be used
- All vials are labeled with an expiration date
- Fetroja is safe and effective when stored and used according to the product labeling

2°C to 8°C
36°F to 46°F



- Un-reconstituted Fetroja vials should be stored in the carton until time of use, refrigerated at 2°C to 8°C (36°F to 46°F), and protected from light[1]

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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*
  - *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*
  - *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**

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Abbreviations

cUTIs	complicated urinary tract infections	HABP	hospital-acquired bacterial pneumonia
FDA	US Food and Drug Administration	VABP	ventilator-associated bacterial pneumonia

Reference

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

Enclosure

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