Fetroja® – Beyond-Use Date with Mini-Bag Plus and Vial-Mate Adaptors

SHIONOGI

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**.

Clinical Studies

- Mini-Bag Plus Container Systems and Vial-Mate Adaptors were not used during the administration of Fetroja in either the Phase 2 or Phase 3 clinical studies

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Background Information

- A study demonstrated that the Fetroja vial was physically compatible with the Mini-Bag Plus Container System (Baxter Healthcare Co.) and the Vial-Mate Adaptor (Baxter Healthcare Co.)[1]

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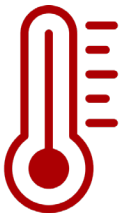
Information on Beyond-Use Dates

- Studies have not been conducted to determine the chemical stability of Fetroja vials when used with the Mini-Bag Plus Container System and Vial-Mate Adaptor[2,3]
- Therefore, a beyond-use date (BUD) for Fetroja with these systems has not been established[2]

Attached and Not Activated

(cefiderocol drug powder is not in contact with the diluent)

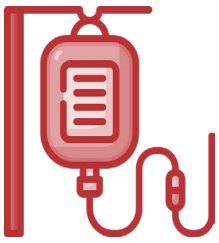
2°C to 8°C
36°F to 46°F



- Unreconstituted Fetroja vials should be stored refrigerated at 2°C to 8°C (36°F to 46°F) and protected from light[4]
- The same storage recommendations apply to Fetroja vials that are attached to the Mini-Bag Plus or Vial-Mate Adaptor, but are not activated[3]

Attached and Activated

(cefiderocol drug powder is dissolved)



- Once the attached Fetroja vial is activated with the Mini-Bag Plus Container System, the diluted Fetroja intravenous (IV) solution must be administered to the patient immediately[3]
- The Fetroja solution for administration is compatible with components in commonly available IV bags and IV infusion sets, such as polyolefin (eg, polyethylene, polypropylene) or polyvinyl chloride (PVC) with di(2-ethylhexyl) phthalate (DEHP) or DEHP-free[5]
- The Baxter Mini-Bag Plus Container System consists of specially formulated PVC (PL 146 Plastic)[6,7]

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Relevant Prescribing Information

Fetroja® is indicated in patients 18 years of age or older for the treatment of:[4]

- 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:[4]

- 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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Literature Search

As of July 2026, a computerized search of the published medical literature using internal and external databases (i.e. Medline® and Embase®) has failed to identify any relevant references regarding information on beyond-use dates of cefiderocol with Mini-Bag Plus and/or Vial-Mate Adaptor systems.

Please keep in mind that medical literature databases, while considered a major source of biomedical information, are selective in their sources, and the information derived from them should not be considered all-inclusive.

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Abbreviations

BUD	beyond-use date	HABP	hospital-acquired bacterial pneumonia
cUTIs	complicated urinary tract infections	IV	intravenous
DEHP	di(2-ethylhexyl) phthalate	PVC	polyvinyl chloride
FDA	US Food and Drug Administration	VABP	ventilator-associated bacterial pneumonia

References

1. Rathod D, Chen Z, Slover CM, et al. Cefiderocol for injection: compatibility testing using the MINI-BAG Plus container system and the VIAL-MATE adaptor. *J Pharm Technol*. 2023;39(4):159-163. [Web Link]
2. Data on File 74. Shionogi Inc.
3. Data on File 76. Shionogi Inc.
4. Fetroja® (cefiderocol) for injection, for intravenous use [Prescribing Information]. Shionogi Inc.
5. Data on File 71. Shionogi Inc.
6. 0.9% Sodium Chloride Injection, USP in Mini-Bag Plus Container [Prescribing Information]. Baxter Healthcare Corporation.
7. Dextrose Injection 5%, USP Container [Prescribing Information]. Baxter Healthcare Corporation.

Enclosure

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