Fetroja® – Maximum Concentration and Range of Volume of Diluted Infusion Solution

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**.

Maximum Concentration



- The in-use stability data for the diluted cefiderocol infusion solution supports a concentration of 7.5 mg/mL up to 20 mg/mL[1]

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Range of Volume in Phase 2 and Phase 3 Clinical Studies



≥100 mL

- **In the APEKS-NP and CREDIBLE-CR Phase 3 clinical trials, solution volume for infusion was required to be at least 100 mL**. Investigators were permitted to use dilution volumes >100 mL for cefiderocol, if needed, to reduce any emerging symptoms related to nausea and infusion site issues[2,3]



Up to 200 mL

- **In the Phase 2 clinical trial, APEKS-cUTI, investigators were allowed to adjust dilution volumes** for cefiderocol, if needed, to reduce any emerging symptoms related to nausea and infusion site issues. It was **possible to further dilute cefiderocol up to 200 mL for infusion of subsequent doses** to minimize patient discomfort[4]

- An analysis of Phase 2 and Phase 3 studies evaluating the outcomes based on volume of dilution has not been performed[2–4]

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Retrospective Study

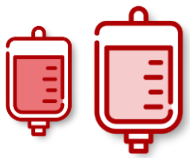


- **Rando et al (2022)** described a retrospective study of 13 patient cases in Italy with CRAB pneumonia treated with cefiderocol[5]



1 or 2 g IV

- Patients received cefiderocol 1 or 2 g IV every 6 or 8 h as an extended 3 h infusion adjusted for renal function[5]



100 or 250 mL

- The reconstituted cefiderocol was further diluted in either 100 mL or 250 mL of normal saline for administration[5]

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Relevant Prescribing Information

Fetroja® is indicated in patients 18 years of age or older for the treatment of:[6]

- 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:[6]

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

As stated in **Section 2.3** of the **Fetroja Full Prescribing Information**:[6]

- **Fetroja** is supplied as a sterile, lyophilized powder that must be reconstituted and subsequently diluted using aseptic technique prior to intravenous infusion
- To prepare the required doses, withdraw the appropriate volume of reconstituted solution from the vial according to Table 3 of the **Full Prescribing Information**. Add the withdrawn volume to a 100 mL infusion bag containing 0.9% sodium chloride injection, USP or 5% dextrose injection, USP

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

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Literature Search

Oct 2025

As of October 2025, a computerized search of the published medical literature using internal and external databases (ie, Medline® and Embase®) has failed to identify any relevant references regarding the maximum concentration and/or range of volume of dilution for cefiderocol.

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

CRAB	carbapenem-resistant *Acinetobacter baumannii*	HABP	hospital-acquired bacterial pneumonia
cUTIs	complicated urinary tract infections	IV	intravenous
FDA	US Food and Drug Administration	USP	United States Pharmacopeia
g	gram	VABP	ventilator-associated bacterial pneumonia
h	hours		

References

1. Data on File 78. Shionogi Inc.
2. Data on File 3. Shionogi Inc.
3. Data on File 4. Shionogi Inc.
4. Data on File 1. Shionogi Inc.
5. Rando E, Segala FV, Vargas J, et al. Cefiderocol for severe carbapenem-resistant *A. baumannii* pneumonia: towards the comprehension of its place in therapy. *Antibiotics*. 2021;11(1):3. [Web Link]
6. Fetroja® (cefiderocol) for injection, for intravenous use [Prescribing Information]. Shionogi Inc.

Enclosure

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