Fetroja® – Density of Reconstituted Vial

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



- Actual measurements for the density of the reconstituted Fetroja 1 gram vial are not available
- Based on theoretical values, calculations have been performed to determine the density of Fetroja 1 gram when reconstituted[1]

Density of the Reconstituted Vial



1.12 g/mL
in 0.9% sodium chloride

- The density of Fetroja 1 gram when **reconstituted with 10 mL of 0.9% sodium chloride injection** (0.089 g/mL) is 1.12 g/mL[1]



1.17 g/mL
in 5% dextrose

- The density of Fetroja 1 gram when **reconstituted with 10 mL of 5% dextrose injection** (0.089 g/mL) is 1.17 g/mL[1]

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Relevant Prescribing Information

Fetroja® is indicated in patients 18 years of age or older for the treatment of:[2]

- 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:[2]

- 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

References

1. Data on File 99. Shionogi Inc.
2. Fetroja® (cefiderocol) for injection, for intravenous use [Prescribing Information]. Shionogi Inc.

Enclosure

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