Fetroja® – pH, Osmolarity, and Osmolality

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

Typical pH Range after Reconstitution



5.3–5.4
after reconstitution

- The typical pH range of Fetroja after it has been **reconstituted in normal saline** (0.9% sodium chloride) or 5% dextrose is 5.3–5.4[1]



5.1–5.3
after dilution

- The typical pH range of Fetroja after it has been **diluted in an intravenous (IV) bag** of normal saline or 5% dextrose is 5.1–5.3[1]

Osmolarity and Osmolality

- The osmolarity and osmolality of Fetroja solution diluted in an IV bag is 666 mOsm/L and 572 mOsm/kg, respectively, as a 2% solution in normal saline[1]
- The osmolarity of the solution diluted in the IV bags is 636 mOsm/L as a 2% solution in 5% dextrose solution. There are no data for the osmolality of Fetroja in 5% dextrose solution[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**

As stated in **Section 11 Description** of the **Fetroja Full Prescribing Information**:[2]

- The pH of the reconstituted solution of 1 gram cefiderocol (1 vial) dissolved in 10 mL water is 5.2 to 5.8

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

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Abbreviations

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

References

1. Data on File 90. 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.