Fetroja® – Use with Elastomeric Devices

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 US 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 | Retrospective Study | Published Case Reports | External Stability Studies | Relevant Prescribing Information | Literature Search, Abbreviations & References

Summary

- **Shionogi has not conducted studies assessing the stability or administration of cefiderocol with elastomeric devices (eg, pumps, diffusers). The published case reports below were described by external authors. Shionogi does not recommend the administration of cefiderocol using elastomeric pumps**

- **Parra-Plaza et al (2025)** conducted a retrospective, multicenter, real-world observational study describing the use of cefiderocol in a HaH/OPAT setting in 27 patients with CR Gram-negative infections in Spain[1]
  - ADRs occurred in 7.4% of patients
- **Babich et al (2025)** reported a patient with NDM-producing *Klebsiella pneumoniae* otomastoiditis who successfully received cefiderocol 6 g/day for 62 days administered as a 24 h continuous infusion using an elastomeric pump[2]
- **Schellong et al (2024)** reported a patient with NDM-producing *Pseudomonas aeruginosa* osteomyelitis who successfully received cefiderocol for a total of 169 days, including 63 days through OPAT from an elastomeric pump[3]
  - The patient experienced manifest iron deficiency anemia possibly due to the extended treatment duration of cefiderocol

- **Stability studies were conducted by external investigators (see reference list). Shionogi does not recommend the use of cefiderocol in elastomeric devices based on these findings**

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Retrospective Study

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Parra-Plaza et al (2025) conducted a retrospective, multicenter, real-world observational study describing the use of cefiderocol in a HaH/OPAT setting for CR Gram-negative infections across 6 centers in Spain between January 2023 and December 2024.[1]

Methods[1]

- Adult patients with documented CR Gram-negative infections treated with cefiderocol for ≥4 doses were included
- Clinical success was defined by resolution of infection that led to treatment with cefiderocol and attributable mortality was defined by death related directly to the underlying infectious process
- This was designed as a descriptive study with no statistical correlation or formal inferential analyses

Results[1]

- 27 patients were included with a median age of 69 years (IQR, 53–80.6 years). 70.4% of patients were male, 40.7% were immunosuppressed, and the median CCI was 3 (IQR, 2.5–7)
- A majority of infections were nosocomial (65.4%), with the most common infection sites being skin/soft tissue (37%), intra-abdominal (22.2%), urinary tract (18.5%), and respiratory tract (14.8%)
- The most frequent pathogens were *P. aeruginosa* (66.7%) and *K. pneumoniae* (14.8%)
- Among cases with available resistance data (n=20), the predominant resistance mechanism was VIM (50%), with additional mechanisms including OXA-48 (15%) and NDM (10%)
- Cefiderocol was administered using a standard daily dose of 6000 mg (consistent with 2 g q8h), with center-specific delivery either as extended infusions every 8–12 h or a continuous 24 h infusion
  - Infusions were administered via electronic infusion pumps (52%) or elastomeric devices (48%). 3 patients self-administered the full cefiderocol course after training and monitoring
  - Venous access included PICC (33.3%), peripheral venous catheter (29.6%), midline (22.2%), and central venous catheter (11.1%)
- In patients with renal impairment, cefiderocol dosing was reduced as follows:
  - 4500 mg/day (consistent with 1.5 g q8h) for eGFR 30–60 mL/min (n=2)
  - 3000 mg/day (1 g q8h) for eGFR 15–20 mL/min (n=3)
- The mean cefiderocol treatment duration was 21.7 days, and the mean treatment HaH duration was 16.37 days
- ADRs occurred in 2 patients (7.4%): renal failure and cutaneous mycosis, which resulted in treatment discontinuation in 1 case

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Published Case Reports

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Babich et al (2025) described a 31-year-old male patient who developed right-sided otomastoiditis caused by NDM-producing *K. pneumoniae* and successfully received cefiderocol 6 g/day administered as a 24 h continuous infusion using an elastomeric pump for 62 days, in conjunction with TDM.[2]

- During a previous hospitalization, he developed purulent right otitis media caused by NDM-producing *K. pneumoniae* and was treated with IV ceftazidime–avibactam plus aztreonam for 10 days
- 11 months later, the patient developed a new episode of right-sided otitis complicated by mastoiditis. Middle ear pus cultures resulted in NDM-producing *K. pneumoniae*
  - Cefiderocol MIC=1 µg/mL and was resistant to ceftazidime–avibactam
- Cefiderocol was initiated at 6 g/day as a 24 h continuous infusion using an elastomeric pump (INFUSOR LV; product code 2C2063K, 10 mL/h; Baxter), diluted in 240 mL of NS

Schellong et al (2024) described a male patient who presented to a hospital in Germany with osteomyelitis due to NDM-producing *P. aeruginosa* that received cefiderocol for a total of 169 days, including 63 days through OPAT.[3]

- During a prior hospitalization, NDM-producing *P. aeruginosa* and *Enterococcus faecalis* was isolated from multiple bone cultures and was treated with ampicillin–sulbactam 3 g q8h for 28 days, and was subsequently treated with cefiderocol 2–3 g q6h for 14 days
- During the patient's current hospitalization, multiple cultures from the tibial medullary cavity revealed NDM-producing *P. aeruginosa* with a cefiderocol MIC of 0.5 mg/L as tested by the Etest method on Mueller-Hinton agar
- Cefiderocol 2 g q8h was started and after 23 days of therapy, the patient was discharged and switched to outpatient cefiderocol treatment via a PICC line for 63 days
- The OPAT service utilized an elastomeric pump (EASYPUMP II ST 400-4-S, B. Braun, Melsungen, Germany) to provide cefiderocol over the 3 h infusion duration
  - There were no reported complications during OPAT
- Planned readmission occurred after OPAT, where the patient underwent autogenous cancellous bone grafting with 4 g of cefiderocol followed by IV cefiderocol 3 g q8h for 83 days
  - Investigators utilized TDM to guide dosing
- Manifest iron deficiency anemia was observed 10 days after cefiderocol cessation, which could possibly be related to the extended therapy duration
  - Hemoglobin was 5.1 mmol/L (normal range, 8.7–10.9 mmol/L), serum iron was 1.5 µmol/L (normal range, 6.3–30.1 µmol/L), transferrin saturation was 2% (normal range, 16–45%), and ferritin was 11.4 µg/L (normal range, 30–400 µg/L)

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External Stability Studies

The stability studies listed below were conducted by external investigators. Shionogi does not recommend the use of cefiderocol in elastomeric devices based on these findings.

- d'Huart E, Boutouha I, Berardi C, Vigneron J, Demore B, Charmillon A. Stability of nine time-dependent antibiotics for outpatient parenteral antimicrobial therapy (OPAT) use. *Antibiotics (Basel)*. 2025;14(5):466. [Web Link]
- Fernández-Rubio B, Herrera-Hidalgo L, de Alarcón A, et al. Stability studies of antipseudomonal beta lactam agents for outpatient therapy. *Pharmaceutics*. 2023;15(12):2705. [Web Link]
- Loeuille G, D'Huart E, Vigneron J, et al. Stability studies of 16 antibiotics for continuous infusion in intensive care units and for performing outpatient parenteral antimicrobial therapy. *Antibiotics (Basel)*. 2022;11(4):458. [Web Link]

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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**

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Literature Search

As of June 2026, a computerized search of the published medical literature using internal and external databases (ie, Medline® and Embase®) has identified an additional relevant reference regarding cefiderocol and elastomeric devices. For your review, this reference is listed in the bibliography that follows:

- Babich S, Di Bella S, De Rivo R, et al. Continuous infusion OPAT via elastomeric pumps: effectiveness, safety, and cost-saving potential in a real-world Italian cohort. *Infection*. 2026;54(1):365-375. [Web Link]

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.

Abbreviations

ADR	adverse drug reaction	L	liter
CCI	Charlson Comorbidity Index	MIC	minimum inhibitory concentration
CR	carbapenem-resistant	NDM	New Delhi metallo-β-lactamase
cUTIs	complicated urinary tract infections	NS	normal saline
eGFR	estimated glomerular filtration rate	OPAT	outpatient parenteral antimicrobial therapy
FDA	US Food and Drug Administration	OXA	oxacillinase
g	grams	PICC	peripherally inserted central catheter
h	hours	q6h	every 6 hours
HABP	hospital-acquired bacterial pneumonia	q8h	every 8 hours
HaH	Hospital at Home	TDM	therapeutic drug monitoring
IQR	interquartile range	VABP	ventilator-associated bacterial pneumonia
IV	intravenous	VIM	Verona integron-encoded metallo-β-lactamase

References

1. Parra-Plaza A, Ugarte A, Benavent E, et al. Use of cefiderocol for carbapenem-resistant Gram-negative infections in hospital at home: multicentric real-world experience. *Antibiotics (Basel)*. 2025;14(12):1216. [Web Link]
2. Babich S, Cojutti PG, Gatti M, Pea F, Di Bella S, Monticelli J. Feasibility of 24 h continuous-infusion cefiderocol administered by elastomeric pump in attaining an aggressive PK/PD target in the treatment of NDM-producing *Klebsiella pneumoniae* otomastoiditis. *JAC Antimicrob Resist*. 2025;7(3):dlaf066. [Web Link]
3. Schellong P, Wennek-Klose J, Spiegel C, Rödel J, Hagel S. Successful outpatient parenteral antibiotic therapy with cefiderocol for osteomyelitis caused by multi-drug resistant Gram-negative bacteria: a case report. *JAC Antimicrob Resist*. 2024;6(1):dlae015. [Web Link]
4. Fetroja® (cefiderocol) for injection, for intravenous use [Prescribing Information]. Shionogi Inc.

Enclosure

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