Fetroja® – Bone Penetration and Use in Osteomyelitis/Bone/Joint Infections

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.**

Summary

Clinical Studies

- Clinical studies evaluating the bone penetration of cefiderocol in humans have not been conducted

Retrospective Studies

- **Diarra et al (2024)** conducted a retrospective, observational, multicenter study evaluating the use of cefiderocol in 45 patients across 22 centers mostly in France between January 2019 and December 2023[1]
  - Osteomyelitis occurred in 25 (56%) patients, while implant-related infection occurred in 20 (44%) patients
  - Clinical remission occurred in 23 (51%) cases, infection control involved surgery in 37 (82%) patients
  - 7 (16%) patients experienced cefiderocol-related ADRs, the majority of which were mild in severity, and 10 (22%) deaths were reported during the course of the study
- **Clancy et al (2024)** performed the PROVE (Retrospective Cefiderocol Chart Review) study, a multicenter, medical chart review study in 1075 patients treated with cefiderocol in the US and European hospitals from November 2020 to February 2024. Of the 1075 patients enrolled, 54 (5%) patients had bone/joint infections[2]
  - Of the 54 patients with bone/joint infections, clinical cure at EOT was achieved in 83.3% of patients and clinical response at EOT was achieved in 88.9% of patients
- **Clancy et al (2024)** conducted an interim analysis of the PROVE study in US patients (N=244), which included 14 (5.7%) patients with bone/joint infections[3]
  - Clinical response at EOT was achieved by 12 (85.7%) patients and clinical cure was achieved by 10 (71.4%) patients
  - 14-Day and 30-Day ACM in patients with bone/joint infections occurred in 0 and 2 (14.3%) patients, respectively

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Summary

Patient Reports, Case Series, and Compassionate Use

- In individual patients, case series, and compassionate use cases, cefiderocol has been shown to be effective and well tolerated as treatment for osteomyelitis or bone/joint infections[4–15]
  - Across cases, infections were caused by *Pseudomonas aeruginosa*, *Klebsiella pneumoniae*, *Stenotrophomonas maltophilia*, *Proteus mirabilis*, *Morganella morganii*, *Acinetobacter baumannii*, *Enterococcus faecalis*, *Cornynebacterium striatum*, *Enterobacter cloacae*, and *Enterobacter hormaechei*
  - Pathogens displayed various degrees of antibiotic resistance and several harbored resistance genes, including ESBL, IMP, OXA, KPC, VIM, and NDM
  - All cases resulted in successful treatment with cefiderocol administered either as monotherapy or in combination with other antibiotics (1 patient was treated via OPAT)

Pre-Clinical PK Studies

- In a pre-clinical PK study of cefiderocol, quantifiable radioactivity was observed in the bone marrow (0.078 µg/g) 120 h after a single IV bolus of radiolabeled cefiderocol (30 mg/kg)[16]

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Clinical Studies

Studies evaluating the bone penetration of cefiderocol in humans have not been conducted.

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Retrospective, Observational, Multicenter Study

Diarra et al (2025) published the results of a retrospective, observational, multicenter study designed to evaluate the use of cefiderocol across 22 centers mostly in France between January 2019 and December 2023.[1]

Results[1]

- A total of 45 patients were included in the analysis, 73% were male, median (IQR) age was 62 (29) years and the median (IQR) CCI was 3 (5)
- Osteomyelitis was the most frequent infection, reported in 25 (56%) patients, while implant-related infection occurred in 20 (44%) patients
- Carbapenemase-producing Gram-negative bacilli were involved in 17 out of 23 (74%) of cases where data regarding mechanism of resistance mechanisms were available, of which 38% were *P. aeruginosa* infections
  - Of the 17 carbapenemase-producing Gram-negative bacilli, there were 5 NDM, 4 VIM, and 4 OXA isolates
- Most patients received 6 g of cefiderocol per day, and the median duration of cefiderocol treatment was 34 days (see **Table 1**)
- Cefiderocol was used in combination with another antibiotic in 40 cases (89%)

Table 1. Cefiderocol Use and Monitoring[1]

		N=45
Cefiderocol dosage, n (%)	0.75 g BID 1 g TID 1.5 g TID 2 g TID 2 g QID	1 (2) 1 (2) 2 (4) 40 (89) 1 (2)
Duration of treatment	Duration of cefiderocol (median±IQR) [Unknown] Range	34±47 [6] 4–122
Cefiderocol monitoring	Blood monitoring, n (%) Plasma trough concentration, mg/L (median±IQR)	6 (14) 17.4±10

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Retrospective, Observational, Multicenter Study

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		N=45
Cefiderocol dosage, n (%)	0.75 g BID 1 g TID 1.5 g TID 2 g TID 2 g QID	1 (2) 1 (2) 2 (4) 40 (89) 1 (2)
Duration of treatment	Duration of cefiderocol treatment, days (median±IQR) [Unknown] Range	34±47 [6] 4–122
Cefiderocol monitoring	Blood monitoring, n (%) Plasma trough concentration, mg/L (median±IQR)	6 (14) 17.4±10

Abbreviations: BID, twice daily; IQR, interquartile range; QID, four times daily; TID, three times daily.
Table adapted from Diarra et al. *Antibiotics (Basel)*. 2025.

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Retrospective, Observational, Multicenter Study (Cont.)

Results (Cont.)[1]

- The median (IQR) duration of follow-up in this study was 291 (339) days (35 days was the minimum)
- Clinical failure occurred in 22 (49%) cases, while infection control involved surgery in 37 (82%) patients
  - Pathogens similar to the initial pathogen (eg, species and antibiotic susceptibility pattern) were identified in half of the 14 cases in which microbiological documentation was available
- 5 superinfections as a result of *Staphylococcus* spp. occurred despite specifically targeted antibiotic therapy in 4 of these 5 cases
- In cases where cefiderocol susceptibility data were available, the emergence of resistance to cefiderocol was only identified in 1 of these 6 cases
- Clinical remission occurred in 23 (51%) cases, with a median (IQR) follow-up of 350 (326) days
- There were no statistically significant differences between clinical failures and remission in terms of infection type, comorbidities, clinical presentation, microbiology, antibiotic regimen, or surgery (see **Table 2**)

Table 2. Details of Patient Outcomes – Comparison Between Clinical Failure and Remission[1]

		Failure (49%) (n=22)	Remission (51%) (n=23)	*P* Value
Infection Type	Infection involving orthopedic device, n (%)	11 (50)	9 (39)	0.6
Comorbidities	Age, years (median, Q1, Q3)	62 (36–74)	62 (49–68)	0.8
	Male/female, n (%)	15 (68)/7 (32)	18 (78)/ 5 (22)	0.4
	BMI, kg/m² (median, Q1, Q3)	24 (20–31)	26 (24–32)	0.2
	CCI (median, Q1, Q3)	4 (2–6)	3 (1–7)	0.7
Clinical Presentation	Local signs of inflammati	16)	15 (65)	0.1
	Duration between sym days (median, Q1, Q	7)	26 (6–61)	0.2
Microbiology	Enterobacterales, n		12 (18)	0.7
	Non-fermenters, n (%		25 (38)	0.7
	Fungi, n (%)		2 (3)	0.7
	Carbapenemase-prod	)	10/13 (77)	0.7
	Polymicrobial infection, n	8)	17 (74)	0.7
Antibiotic regimen	Combined anti-GNB therapy, n	11 (19)	15 (22)	0.8
	Duration of cefiderocol treatment, days (median, Q1, Q3)	42 (14–65)	22 (9–49)	0.2
Surgery	Removal of the implant device, n/19 (%)	7 (70)	5 (56)	0.6
	Bone resection, n/18 (%)	1 (10)	3 (38)	0.3
	Delay between infection onset and surgery, days (median, Q1, Q3)	29 (9–631)	78 (21–411)	0.5

Safety[1]

- 7 (16%) patients experienced cefiderocol-related ADRs (GI disorders [n=4], acute renal insufficiency [n=1], rhabdomyolysis [n=1], and skin reaction [n=1])
  - In 4 cases, ADRs were experienced when cefiderocol was used in combination with colistin, and in combination with both colistin and tigecycline in another case
- The majority of ADRs were considered mild in severity (grade 2)
  - The most severe ADR (grade 4 diarrhea) occurred in a patient receiving cefiderocol in combination with daptomycin
- Cefiderocol treatment was withdrawn in 3 (7%) patients, due to grade 4 diarrhea, grade 2 hypereosinophilia, and acute kidney failure (grade not disclosed)
- 10 (22%) deaths were reported during the study (during follow-up of up to 2 years), with deaths occurring a median (IQR) of 67 (247) days following the initiation of cefiderocol treatment

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Retrospective, Observational, Multicenter Study (Cont.)

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		Failure (49%) (n=22)	Remission (51%) (n=23)	*P* Value
Infection Type	Infection involving orthopedic device, n (%)	11 (50)	9 (39)	0.6
Comorbidities	Age, years (median, Q1, Q3) Male/female, n (%) BMI, kg/m^2 (median, Q1, Q3) CCI (median, Q1, Q3)	62 (36–74) 15 (68)/7 (32) 24 (20–31) 4 (2–6)	62 (49–68) 18 (78)/ 5 (22) 26 (24–32) 3 (1–7)	0.8 0.4 0.2 0.7
Clinical Presentation	Local signs of inflammation, n (%) Duration between symptoms and diagnosis, days (median, Q1, Q3)	19 (86) 12 (3–27)	15 (65) 26 (6–61)	0.1 0.2
Microbiology	Enterobacterales, n (%) Non-fermenters, n (%) Fungi, n (%) Carbapenemase-producing GNB, n (%) Polymicrobial infection, n (%)	5 (10) 22 (44) 0 (0) 7/10 (70) 15 (68)	12 (18) 25 (38) 2 (3) 10/13 (77) 17 (74)	0.7 0.7 0.7 0.7 0.7
Antibiotic Regimen	Combined anti-GNB therapy, n (%) Duration of cefiderocol treatment, days (median, Q1, Q3)	11 (19) 42 (14–65)	15 (22) 22 (9–49)	0.8 0.2
Surgery	Removal of the implant device, n/19 (%) Bone resection, n/18 (%)	7 (70) 1 (10)	5 (56) 3 (38)	0.6 0.3
	Delay between infection onset and surgery, days (median, Q1, Q3)	29 (9–631)	78 (21–411)	0.5

Abbreviations: BMI, body mass index; CCI, Charlson Comorbidity Index; GNB, Gram-negative bacilli; Q, quartile.
Table adapted from Diarra et al. *Antibiotics (Basel)*. 2025.

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PROVE (Retrospective Cefiderocol Chart Review) Study

PROVE was an international, multicenter, retrospective chart review study investigating clinical and microbiological outcomes with cefiderocol treatment in US and European hospitals.[2,3]

- This real-world study included patients with Gram-negative bacterial infection, documented ≥72 h before treatment, along with information on doses, type of infection, and clinical and safety outcomes[2,3]
  - Patients included were required to have received cefiderocol treatment for the first time and continuously for ≥72 h
- Patients receiving cefiderocol before local commercial availability were excluded from the study[2,3]
- Data from an interim analysis of 244 patients from only the US is also available below[3]

Outcome Measures[2,3]

- Patient characteristics
- Infection type (Gram-negative pathogen, susceptibility, infection site, monomicrobial or polymicrobial)
- Cefiderocol treatment course: time from culture collection to first dose of cefiderocol, daily dose, treatment duration
  - Positive culture: defined as the sample collected prior to starting cefiderocol that resulted in cefiderocol prescription. The index culture may have been collected and tested in the outpatient setting prior to hospitalization
- Efficacy endpoints:
  - Clinical cure (signs/symptoms resolved or improved at the EOT and no relapse/recurrence any time afterward)
  - Clinical response (signs/symptoms improved or resolved at the EOT, excluding patients who died during therapy)
  - ACM at Day 14, Day 30, and in-hospital mortality
- ADRs associated with cefiderocol were evaluated

Results (Global Dataset)[2]

- Data were assessed from a total of 1075 patients from the US (47.3%), Spain (14.8%), France (11.9%), Italy (11.3%), UK (7.5%), and Germany (7.3%)
- 65.6% of patients were male, the median age was 60 years (IQR: 46–69), and the median CCI was 2 (IQR: 1–4)
- The most common reported comorbidities included chronic pulmonary disease (20.4%), uncomplicated diabetes (18.5%), COVID-19 (17%), moderate-severe renal disease (16.9%), and congestive heart failure (14%)
- 88.7% of patients had ≥1 risk factor for CR infections
- Of the 1075 patients included, 54 (5%) had a bone/joint infection

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PROVE (Retrospective Cefiderocol Chart Review) Study (Cont.)

Clinical Outcomes[2]

- Clinical cure at EOT and clinical response at EOT was achieved by 67.5% of patients and 75.1% of patients, respectively, in the overall population
- Among patients with bone/joint infections (n=54):
  - Clinical cure rate at EOT was 83.3%
  - Clinical response rate at EOT was 88.9%

Safety[2]

- In the overall study population, 25 patients had a total of 29 ADRs, of which 3 were classed as serious ADRs (ie, interstitial nephritis and acute kidney injury, elevation of liver enzymes, and hepatic cytolysis)
- Cefiderocol treatment was discontinued for 16 events (in 13 patients)

US Interim Results[3]

- N=244 patients were enrolled from US hospitals
  - Median age was 56 years
  - 69.3% (n=170) were treated for monomicrobial infections
  - 30.7% (n=75) were treated for polymicrobial infections
- Of the 244 patients included, 14 (5.7%) had a bone/joint infection

Clinical Outcomes[3]

- Clinical response was achieved in 181 (74.2%) patients, while clinical cure was achieved by 158 (64.8%) patients in the total study population
  - Among patients with bone/joint infections (n=14), clinical response at EOT was achieved in 12 (85.7%) patients and clinical cure by 10 (71.4%) patients
- Overall, 23 (9.4%) patients died by Day 14 and 45 (18.4%) died at Day 30
  - No patients with bone and joint infections died by Day 14; 2 (14.3%) died by Day 30

Safety[3]

- Cefiderocol was generally well tolerated
- In the overall population, 5 (2%) patients experienced a total of 6 ADRs
  - Rash, elevated hepatic function test, urticarial rash (n=1 each), diarrhea (n=2)
  - 1 patient, who experienced the urticarial rash, also experienced a serious ADR (interstitial nephritis, acute kidney injury)
  - Cefiderocol was discontinued in 2 patients due to 2 events

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Patient Reports, Case Series, and Compassionate Use

Use of cefiderocol for the treatment of bone/joint infections as monotherapy and in combination with other antibiotics has been reported in individual case studies, case series, and compassionate use.[4–15]

For more information, please refer to **Table 3** below:

Table 3. Case Studies[4–15]

Case Author	Age y/sex	Infection Type	Pathogen	Treatment	AEs	Patient Outcomes
Schellong et al (2024)[4]	Mid-30s /M	Infection-related pseudarthrosis of left tibia following a blast causing an open comminuted fracture	MDR *P. aeruginosa* harboring NDM MIC=0.5 mg/L	**First hospitalization:** **Cefiderocol:** 2 g q6h for 14 days **Second hospitalization:** **Cefiderocol:** 2 g q8h for 23 days, followed by an additional 63 days via outpatient parenteral antibiotic therapy **Additional procedure:** Cefiderocol powder (4g) was applied to a bone graft **Total cefiderocol:** 169 days	Iron deficiency anemia which occurred 10 days after stopping cefiderocol. Potentially related to prolonged treatment	Eradication of *P. aeruginosa*
Fischer et al (2024)[5]	23/M	Acetabular and hip joint fracture-related infection	MDR *K. pneumoniae* harboring OXA-48 XDR *K. pneumoniae* harboring OXA-48 and NDM	**Cefiderocol:** Dose and duration not provided Concomitant antibiotics: Piperacillin–tazobactam, colistin Cemented filler containing antibiotics, including cefiderocol, was implanted	Not reported	Eradication of *K. pneumoniae* harboring OXA-48 occurred shortly after cefiderocol initiation Successful eradication of *K. pneumoniae* harboring OXA-48 and NDM occurred following cefiderocol treatment with drug-eluting cemented filler

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Patient Reports, Case Series, and Compassionate Use (Cont.)

Table 3. Case Studies[4–15]

Case Author	Age y/sex	Infection Type	Pathogen	Treatment	AEs	Patient Outcomes
Petrucci et al (2024)[6]	42/M	Left-leg fracture-related infection/soft tissue necrosis	XDR CRAB 2 additional Gram-positive pathogens also detected	**Cefiderocol:** 2 g q8h for 6 weeks	None	Hospital discharge after 6 weeks of treatment 3-years post-hospital discharge, patient achieved clinical cure and ability to return to normal function
Chambers et al (2023)[7]	52/F	Prosthetic joint infection	*S. maltophilia*	**Cefiderocol:** 2 g q8h for 8 weeks **Concomitant therapy:** Double-strength trimethoprim–sulfamethoxazole for 8 weeks	Hyperkalemia, with resolution upon discontinuation of lisinopril and nausea	Resolution of pain, erythema, and swelling at 2 months post-treatment Microbiological eradication at 20 months from last surgery
Simner et al (2022)[8]	25/M	Skull osteomyelitis following accidental electrocution	DTR *P. aeruginosa* expressing *bla*GES-1 and MexX and MexD efflux pumps MIC=0.5 µg/mL	**Cefiderocol:** Days 57–109 Concomitant therapy: Phage therapy on Days 79–109	None	Microbiological eradication was achieved (no additional isolates recovered) Patient discharged from hospital and no recurrent infections occurred 12 months post-treatment
Rose et al (2022)[9]	50/M	Right hip osteomyelitis	*Proteus mirabilis* *P. aeruginosa* CRAB harboring bla_{OXA-23}	**Cefiderocol:** 1 g q8h adjusted for acute renal insufficiency 2 g q8h once kidney function normalized, for a total of 6 weeks Concomitant therapy: Daptomycin	None	Achieved clinical cure of osteomyelitis at EOT

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Patient Reports, Case Series, and Compassionate Use (Cont.)

Table 3. Case Studies[4–15]

Case Author	Age y/sex	Infection Type	Pathogen	Treatment	AEs	Patient Outcomes
Chavda et al (2021)[10]	59/M	Surgical site infection complicated by osteomyelitis, left tibia	Pan-resistant *P. aeruginosa* harboring IMP *Morganella morganii*	**Cefiderocol:** Days 32–60 1.5 g q8h initial 2 g q8h once kidney function normalized Concomitant therapy: Ciprofloxacin	None	Hospital discharge Clinical response and no recurrent infection at 3-month follow-up
Mabayoje et al (2021)[11]	66/F	Discharging surgical wound, suspected distal humerus infection	MDR *A. baumannii* harboring NDM-1, OXA-23, OXA-69, ADC-25 MIC=4 µg/mL	**Cefiderocol:** 0.75 g q12h initial; 1.5 g q8h once renal function improved for a total of 25 days Concomitant therapy: Tigecycline for 6 weeks	No new AEs reported; renal function improved with treatment	Wounds healed, improved range of elbow movement
Alamarat et al (2020)[12]	15/M	Chronic osteomyelitis of left femur, following surgery for fracture	XDR *P. aeruginosa* harboring NDM-1 MIC=4 µg/mL ESBL-producing *K. pneumoniae* MIC=0.5 µg/mL	**Cefiderocol:** 2 g q8h over 3 h for 14 weeks Bone implant Concomitant therapy: Aztreonam	Intermittent episodes of reduced WBC count, spontaneously resolved	Hospital discharge, apparent clinical cure, and avoided amputation
Dagher et al (2020)[13]	57/M	Osteomyelitis	XDR *A. baumannii* *E. faecalis* *C. striatum*	**Cefiderocol:** 1g q8h over 3 h initial; 2g q8h over 3 h once renal function normalized for a total of 109 days, including treatment after discharge	None	Achieved microbiological response (no relapse or persistence of infection) Hospital discharge on Day 26 Treatment continued with PICC

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Patient Reports, Case Series, and Compassionate Use (Cont.)

Table 3. Case Studies[4–15]

Case Author	Age y/sex	Infection Type	Pathogen	Treatment	AEs	Patient Outcomes
Zingg et al (2020)[14]	29/M	Acute osteomyelitis	*A. baumannii* harboring OXA-23 *E. cloacae* harboring KPC *P. aeruginosa* harboring VIM	**Cefiderocol:** 2 g q8h for 14 days Zone diameter *A. baumannii* = 23 mm (susceptible) Zone diameter *E. cloacae* = 14 mm (resistant) Zone diameter *P. aeruginosa* = 24 mm (susceptible) Concomitant therapy: Ceftazidime–avibactam, colistin continued for 4 weeks	None	Achieved clinical cure
Siméon et al (2020)[15]	67/M	Prosthetic joint infection of right knee	XDR *E. hormaechei* harboring ACT-5, CTX-M-15, TEM-1B, OXA-1 MIC=1 µg/mL	**Cefiderocol:** 2 g q8h over 3 h for a total of 10 weeks, including treatment after discharge	None	Hospital discharge, clinical cure, and no recurrent infection 12 months from EOT

Abbreviations: ACT-5, AmpC type 5; ADC, *Acinetobacter*-derived cephalosporinase; AE, adverse event; CRAB, carbapenem-resistant *Acinetobacter baumannii*; CTX-M-15, Cefotaximase-Munich 15; DTR, difficult-to-treat; EOT, end of treatment; ESBL, extended spectrum β-lactamase; F, female; g, grams; h, hour; IMP, imipenemase; KPC, *Klebsiella pneumoniae* carbapenemase; M, male; MDR, multi-drug resistant; MIC, minimum inhibitory concentration; NDM, New Delhi metallo-β-lactamase; OXA, oxacillinase; PICC, peripherally inserted central catheter; q6h, every 6 hours; q8h, every 8 hours; q12h, every 12 hours; TEM-1B, Temoneira-1 β-lactamase; VIM, Verona integron metallo-β-lactamase; WBC, white blood cell; XDR, extensively drug resistant; y, years.

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Pre-Clinical PK Studies

The distribution of cefiderocol in the bone of animals has been evaluated:[16]

- The tissue distribution of cefiderocol was investigated using quantitative whole-body autoradiography after a single IV bolus of radiolabeled cefiderocol (30 mg/kg) in Long-Evans rats
- At 120 h post-dose, quantifiable radioactivity was observed in the bone marrow (0.078 µg/g)

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Relevant Prescribing Information

Fetroja® is indicated in patients 18 years of age or older for the treatment of:[17]

- 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:[17]

- 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**

Fetroja® – Bone Penetration and Use in Osteomyelitis/Bone/Joint Infections

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Literature Search

As of September 2025, a computerized search of the published medical literature using internal and external databases (ie, PubMed®) has identified several additional relevant references regarding the penetration of cefiderocol in the bone and/or the use of cefiderocol in osteomyelitis/bone/joint infections. For your review, these references are listed in the bibliography that follows:

- Melo e Silva J, Oliveira D, Louro JA, Monteiro E. Cefiderocol and intraventricular colistin for ventriculitis due to an extensively drug-resistant *Pseudomonas aeruginosa*. *J Crit Care Med (Targu Mures)*. 2024;10(2):183-187. [Web Link]
- El Ghali A, Coyne AJK, Lucas K, et al. Cefiderocol: early clinical experience for multi-drug resistant Gram-negative infections. *Microbiol Spectr*. 2024;12(2):e0310823. [Web Link]
- Buonomo AR, Scotto R, Esposito N, et al. Treatment of carbapenem-resistant *Acinetobacter baumannii* in real life (T-ACI): a prospective single-center observational study. *Antibiotics (Basel)*. 2024;13(11):1007. [Web Link]
- Palermo G, Medaglia AA, Pipitò L, et al. Cefiderocol efficacy in real-life setting: single-centre retrospective study. *Antibiotics (Basel)*. 2023;12(4):746. [Web Link]
- Meschiari M, Volpi S, Faltoni M, et al. Real-life experience with compassionate use of cefiderocol for difficult-to-treat resistant *Pseudomonas aeruginosa* (DTR-P) infections. *JAC Antimicrob Resist*. 2021;3(4):dlab188. [Web Link]
- Carney BW, Rizzo JA, Alderete JF, Cindass R, Markelz AE, Cancio LC. Carbapenem-resistant Enterobacterales infection after massive blast injury: use of cefiderocol based combination therapy. *Mil Med*. 2021;186(11-12):1241-1245. [Web Link]
- Cipko K, Gordon AK, Adhikari S, Konecny P. Cefiderocol treatment of *Pseudomonas aeruginosa* and extensively drug-resistant *Acinetobacter baumannii* retained spinal hardware infection causing reversible acute interstitial nephritis: Recto: Cefiderocol causing acute interstitial nephritis. *Int J Infect Dis*. 2021;109:108-111. [Web Link]
- Oliva A, Ceccarelli G, De Angelis M, et al. Cefiderocol for compassionate use in the treatment of complicated infections caused by extensively and pan-resistant *Acinetobacter baumannii*. *J Glob Antimicrob Resist*. 2020;23:292-296. [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.

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Abbreviations

ACM	all-cause mortality	IV	intravenous
ACT-5	AmpC type 5	KPC	*Klebsiella pneumoniae* carbapenemase
ADC	*Acinetobacter*-derived cephalosporinase	M	male
ADR	adverse drug reaction	MDR	multi-drug resistant
AE	adverse event	MIC	minimum inhibitory concentration
BID	twice daily	NDM	New Delhi metallo-β-lactamase
BMI	body mass index	OPAT	outpatient parenteral antibiotic therapy
CCI	Charlson Comorbidity Index	OXA	oxacillinase
COVID-19	Coronavirus disease 2019	PICC	peripherally inserted central catheter
CR	carbapenem-resistant	PK	pharmacokinetics
CRAB	carbapenem-resistant *Acinetobacter baumannii*	Q	quartile
CTX-M-15	Cefotaximase-Munich 15	QID	four times daily
cUTI	complicated urinary tract infection	q6h	every 6 hours
DTR	difficult-to-treat resistant	q8h	every 8 hours
EOT	end of treatment	q12h	every 12 hours
ESBL	extended spectrum β-lactamase	TEM-1B	Temoneira-1 β-lactamase
F	female	TID	three times daily
FDA	US Food and Drug Administration	UK	United Kingdom
g	grams	US	United States
GI	gastrointestinal	VABP	ventilator-associated bacterial pneumonia
GNB	Gram-negative bacilli	VIM	Verona integron metallo-β-lactamase
h	hour	WBC	white blood cell
HABP	hospital-acquired bacterial pneumonia	XDR	extensively drug-resistant
IMP	imipenemase	y	years
IQR	interquartile range		

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2. Clancy C, Comely OA, Slover C, et al. Real-world effectiveness and safety of cefiderocol in the treatment of patients with serious Gram-negative bacterial infections: results of the PROVE Chart Review Study. Poster presented at IDWeek; October 16-19, 2024; Los Angeles, CA.
3. Clancy CJ, Cornely OA, Marcella SW, Nguyen ST, Gozalo L, Cai B. Effectiveness and safety of cefiderocol in clinical practice for treatment of patients with Gram-negative bacterial infections: US interim results of the PROVE study. *Infect Drug Resist*. 2024;17:4427-4443. [Web Link]
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6. Petrucci F, Perciballi B, Capparuccia MR, et al. Compassionate use of cefiderocol in a complex case of extensively drug-resistant *Acinetobacter baumannii* fracture-related infection: a comprehensive approach and multidisciplinary management. *Infection*. 2024;52(6):2487-2493. [Web Link]
7. Chambers MM, Gutowski CJ, Doktor K. Cefiderocol for *Stenotrophomonas maltophilia* prosthetic joint infection: a case report. *Ther Adv Infect Dis*. 2023;10:20499361231174292. [Web Link]
8. Simner PJ, Cherian J, Suh GA, et al. Combination of phage therapy and cefiderocol to successfully treat *Pseudomonas aeruginosa* cranial osteomyelitis. *JAC Antimicrob Resist*. 2022;4(3):dlac046. [Web Link]
9. Rose L, Lai L, Byrne D. Successful prolonged treatment of a carbapenem-resistant *Acinetobacter baumannii* hip infection with cefiderocol: a case report. *Pharmacotherapy*. 2022;42(3):268-271. [Web Link]
10. Chavda A, Gilchrist M, Samarasinghe D. Education: a compassionate use of cefiderocol to treat osteomyelitis caused by an XDR *Pseudomonas aeruginosa*. *JAC Antimicrob Resist*. 2021;3(Suppl 1):i18-i20. [Web Link]
11. Mabayoje DA, NicFhogartaigh C, Cherian BP, Tan MGM, Wareham DW. Compassionate use of cefiderocol for carbapenem-resistant *Acinetobacter baumannii* prosthetic joint infection. *JAC Antimicrob Resist*. 2021;3(Suppl 1):i21-i24. [Web Link]
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ENCLOSURE

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