

Fetcroja® (cefiderocol) 1 g powder for concentrate for solution for infusion

Please refer to the full Summary of Product Characteristics (SmPC) before prescribing

Pharmaceutical Form: Fetcroja is available in packs containing 10 vials. Each vial contains cefiderocol sulfate tosylate equivalent to 1 g of cefiderocol. White to off-white powder for concentrate for solution for infusion.

Indication(s): Fetcroja is indicated for the treatment of infections due to aerobic Gram-negative organisms in adults with limited treatment options.

Dosage and administration: Intravenous use. Follow reconstitution instructions exactly as per SmPC. Fetcroja is administered by intravenous infusion over 3 hours. This medicinal product must not be mixed with other medicinal products except those mentioned in section 6.6 of the SmPC. If treatment with a combination of another medicinal product and Fetcroja is unavoidable, administration should not occur in the same syringe or in the same infusion solution. It is recommended to adequately flush intravenous lines between administration of different medicinal products. Normal renal function (CrCL ≥ 90 to < 120 mL/min): 2 g every 8 hours. Augmented renal clearance (CrCL ≥ 120 mL/min): 2 g every 6 hours. Duration of treatment is in accordance with the site of infection. For complicated UTIs including pyelonephritis and complicated intra-abdominal infections the recommended treatment duration is 5 to 10 days. For hospital acquired pneumonia including ventilator-associated pneumonia the recommended treatment duration is 7 to 14 days. Treatment up to 21 days may be required.

Special populations: *Renal impairment:* Mild renal impairment (CrCL ≥ 60 to < 90 mL/min): 2 g every 8 hours. Moderate renal impairment (CrCL ≥ 30 to < 60 mL/min): 1.5 g every 8 hours. Severe renal impairment (CrCL ≥ 15 to < 30 mL/min): 1 g every 8 hours. End stage renal disease (CrCL < 15 mL/min): 0.75 g every 12 hours. Intermittent haemodialysis (administer Fetcroja at the earliest possible time after completion of haemodialysis-on-haemodialysis days): 0.75 g every 12 hours. *Hepatic impairment:* No dose adjustment is required in patients with hepatic impairment. *Elderly:* No dose adjustment is required. *Paediatric:* No data are available. The safety and efficacy of Fetcroja in children below 18 years of age has not yet been established.

Contraindications: Severe hypersensitivity (e.g. anaphylactic reaction, severe skin reaction) to any other type of beta lactam antibacterial agent (e.g. penicillins, monobactams or carbapenems). Hypersensitivity to the active substance or to any of the excipients. Hypersensitivity to any cephalosporin antibacterial medicinal product.

Special warnings and precautions: Hypersensitivity has been reported with Fetcroja. Before initiating therapy with Fetcroja, careful inquiry should be made concerning previous hypersensitivity reactions to beta lactam antibiotics. If a severe allergic reaction occurs, treatment with Fetcroja must be discontinued immediately and adequate emergency measures must be initiated. *Clostridioides difficile*- associated diarrhoea (CDAD) has been reported with Fetcroja. Discontinuation of therapy with Fetcroja and the use of supportive measures together with the administration of specific treatment for *Clostridioides difficile* should be considered. Medicinal products that inhibit peristalsis should not be given. Patients with known seizure disorders should continue anticonvulsant therapy. Patients who develop focal tremors, myoclonus, or seizures should be evaluated neurologically and placed on anticonvulsant therapy if not already instituted. If necessary, the dose of Fetcroja should be

adjusted based on renal function or alternatively, Fetcroja should be discontinued. In clinical trials, Fetcroja has only been used to treat patients with the following types of infection: complicated urinary tract infections (cUTI); hospital-acquired pneumonia (HAP), ventilator-associated pneumonia (VAP), healthcare-associated pneumonia (HCAP); sepsis and patients with bacteraemia (some with no identified primary focus of infection). A higher all-cause mortality rate was observed in patients treated with Fetcroja as compared to best available therapy (BAT) in a randomised, open-label trial in critically ill patients with infections known or suspected to be due to carbapenem-resistant Gram-negative bacteria. The cause of the increase in mortality has not been established. In the Fetcroja group there was an association between mortality and infection with *Acinetobacter* spp., which accounted for the majority of infections due to non-fermenters. In contrast, mortality was not higher in Fetcroja vs. BAT patients with infections due to other non-fermenters. Fetcroja has little or no activity against most Gram-positive organisms and anaerobes. Additional antibacterial medicinal products should be used when these pathogens are known or suspected to be contributing to the infectious process. The use of Fetcroja may result in the overgrowth of non-susceptible organisms, which may require interruption of treatment or other appropriate measures. Fetcroja may result in false-positive results in urine dipstick tests (urine protein, ketones, or occult blood). Alternative methods of testing should be used by the clinical laboratories to confirm positive tests. A positive direct or indirect Coombs test may develop during treatment with Fetcroja.

Drug interactions: Based on in vitro studies and one two phase 1 clinical evaluation studies no significant drug-drug interactions are anticipated between Fetcroja and substrates, or inhibitors or inducers of cytochrome P450 enzymes (CYPs) or transporters (see section 5.2 of the SmPC).

Pregnancy, breast-feeding and fertility: There are no or limited data (less than 300 pregnancy outcomes) from the use of Fetcroja in pregnancy. As a precautionary measure, it is preferable to avoid the use of Fetcroja during pregnancy. It is unknown whether Fetcroja is excreted in human milk. Risk/benefit ratio should be considered, considering the benefit of breast-feeding for the child and the benefit of therapy for the woman. The effect of Fetcroja on fertility in humans has not been studied.

Undesirable effects: See SmPC for full list of side effects. Common ($\geq 1/100$, $< 1/10$): Candidiasis, *Clostridioides difficile* colitis, cough, diarrhoea, nausea, vomiting, rash, infusion site reaction, abnormal hepatic function and blood creatinine increased.

Prescribing information & SmPC:

<https://www.medicines.ie/active-ingredients/cefiderocol-26197>

ATC code: J01DI04 cefiderocol. **Legal supply status:** Product subject to prescription which may not be renewed (A) **Marketing Authorisation Number(s):** EU/1/20/1434/001.

Marketing Authorisation Holder: Shionogi B.V, Herengracht 464, 1017 CA Amsterdam, Netherlands.

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Adverse events should be reported.

If you wish to make a medical information inquiry or report an adverse event, please contact Shionogi on +44 (0) 2030534190 or email contact@shionogi.eu.

Report an adverse event to your national reporting system (<http://www.hpra.ie/homepage/about-us/report-an-issue>)