



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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## Fetroja (*cefiderocol*)

An overview of Fetroja and why it is authorised in the EU

### What is Fetroja and what is it used for?

Fetroja is an antibiotic used in adults to treat infections caused by bacteria classed as aerobic Gram-negative bacteria. It is for use when other treatments might not work.

Fetroja contains the active substance cefiderocol.

### How is Fetroja used?

Fetroja can only be obtained with a prescription. It should only be used after taking advice from a doctor with appropriate experience of managing patients with infectious diseases.

Fetroja is given by infusion (drip) into a vein over 3 hours. The usual dose is 2 g given every 8 hours and the duration of treatment depends on the nature of the infection.

For more information about using Fetroja, see the package leaflet or contact your doctor or pharmacist.

### How does Fetroja work?

The active substance in Fetroja, cefiderocol, belongs to the cephalosporin class of antibiotics. It uses the bacteria's own system for importing iron to enter the bacterial cell, where it blocks the formation of the bacterial cell wall, killing the bacteria.

### What benefits of Fetroja have been shown in studies?

Fetroja was tested in 2 main studies involving patients with various infections caused by Gram-negative bacteria.

In the first study, involving 452 adults with complicated urinary tract infection, 73% of patients treated with Fetroja were cured (based on lack of symptoms and tests for bacteria in the urine) compared with 55% of patients treated with imipenem and cilastatin given together.

The second study involved 152 adults with various serious infections caused by bacteria that were resistant to carbapenems (could not be killed by antibiotics called carbapenems). For lung infections, 50% of patients treated with Fetroja were cured based on a lack of symptoms, compared with 53% of

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those treated with the best alternative treatment. For bloodstream infections, these figures were 44% and 43%, respectively. For complicated urinary tract infections, 53% of patients treated with Fetcroja were cleared of disease-causing bacteria in the urine compared with 20% of patients receiving the best alternative treatment.

### **What are the risks associated with Fetcroja?**

The most common side effects (which may affect up to 1 in 10 people) were diarrhoea, vomiting, nausea (feeling sick) and cough. For the full list of side effects with Fetcroja, see the package leaflet.

Fetcroja must not be used in patients who are hypersensitive (allergic) to any cephalosporin antibiotic or who have had a severe reaction to the broader class of beta-lactam antibiotics (such as penicillins or carbapenems). For the full list of restrictions, see the package leaflet.

### **Why is Fetcroja authorised in the EU?**

The European Medicines Agency noted that the number of patients in the main studies was small. However, taken together with laboratory studies and studies on how the medicine works in the body, there was sufficient evidence that Fetcroja is effective against infections caused by aerobic Gram-negative bacteria. The Agency therefore decided that Fetcroja's benefits are greater than its risks and it can be authorised for use in the EU.

### **What measures are being taken to ensure the safe and effective use of Fetcroja?**

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Fetcroja have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Fetcroja are continuously monitored. Side effects reported with Fetcroja are carefully evaluated and any necessary action taken to protect patients.

### **Other information about Fetcroja**

Fetcroja received a marketing authorisation valid throughout the EU on 23 April 2020.

Further information on Fetcroja can be found on the Agency's website:

[ema.europa.eu/medicines/human/EPAR/fetcroja](https://ema.europa.eu/medicines/human/EPAR/fetcroja)