Package leaflet: Information for the user

Fetcroja 1 g powder for concentrate for solution for infusion
cefiderocol

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects, you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Fetcroja is and what it is used for

Fetcroja contains the active substance cefiderocol. It is an antibiotic medicine that belongs to a group of antibiotics called cephalosporins. Antibiotics help to fight bacteria that cause infections.

Fetcroja is used in adults to treat infections caused by certain types of bacteria when other antibiotics cannot be used.

2. What you need to know before you are given Fetcroja

Do not use Fetcroja
- if you are **allergic to cefiderocol** or any of the other ingredients of this medicine (listed in section 6);
- if you are **allergic to other antibiotics** known as cephalosporins;
- if you have had a **severe allergic reaction to certain antibiotics**, such as penicillins or carbapenems. This can include severe skin peeling, swelling of the hands, face, feet, lips, tongue or throat; or difficulty swallowing or breathing.

➔ **Tell your doctor** if any of these apply to you.

Warnings and precautions
Talk to your doctor or nurse before you are given Fetcroja:
- if you have ever had any **allergic reaction to other antibiotics**. See also section above, "Do not use Fetcroja";
- if you have **kidney problems**. Your doctor will adjust your dose to ensure you don't get too much or too little medicine;
- if you suffer from **diarrhoea** during your treatment;
- if you are on a **low sodium diet;**
- if you have ever had **seizures**.

➔ **Talk to your doctor or nurse** before you are given Fetcroja.

New Infection
Although Fetcroja can fight certain bacteria, there is a possibility that you may get a different infection caused by another organism during or after your treatment. Your doctor will monitor you closely for any new infections and give you another treatment if necessary.

Blood/laboratory Tests
Tell your doctor that you are taking Fetcroja if you are going to have any blood/laboratory tests. This is because you may get an abnormal result. With something called a "Coombs test" this looks for the presence of antibodies that can destroy red blood cells or may be affected by the response of your immune system to Fetcroja. Fetcroja may also result in false-positive results in urine dipstick tests (urine protein or diabetes markers).

Children and adolescents
Fetcroja should not be given to children and adolescents under the age of 18. This is because it is not known if the medicine is safe to use in these age groups.

Other medicines and Fetcroja
Tell your doctor or nurse if you are taking, have recently taken or might take any other medicines.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Driving and using machines
Fetcroja does not affect your ability to drive or operate machinery.

Fetcroja contains sodium
This medicine contains 7.64 mmol (176 mg) of sodium per vial. The total daily dose is 2.1 g, just greater than the WHO recommend daily maximum of 2 g sodium for an adult. Talk to your doctor before you are given Fetcroja if you are on a low sodium diet.

3. How Fetcroja is used

Your doctor or nurse will give you this medicine as an infusion (a drip) into your vein over 3 hours, three times a day. The usual recommended dose is 2 g.

The number of days you will be given Fetcroja treatment depends on the type of infection you have and how well your infection is clearing.

If you get any pain where the Fetcroja infusion goes into your vein, tell your doctor or nurse.

People with kidney problems
If you have kidney problems, talk to your doctor before you are given Fetcroja. The doctor will adjust your dose of Fetcroja.

If you are given more Fetcroja than you should
Fetcroja will be given to you by a doctor or nurse, so it is unlikely you will be given the wrong dose. Tell your doctor or nurse straight away if you think you have been given more Fetcroja than you should have.

If you miss a dose of Fetcroja
If you think you have not been given a dose of Fetcroja, tell your doctor or nurse straight away.

If you have any further questions on the use of this medicine, ask your doctor or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious side effects
Tell your doctor straight away if you notice any of the following serious side effects – you may need urgent medical treatment:
- **Severe allergic reaction** – signs include sudden swelling of your lips, face, throat or tongue; a severe rash or other severe skin reactions; difficulty swallowing or breathing. This reaction may be life-threatening.
- **Diarrhoea** that gets worse or does not go away, or stools that contain blood or mucus. This may happen during treatment, or after it has been stopped. If this happens, do not take medicines that stop or slow bowel movement.

➔ **Tell your doctor** straight away if you notice any of the serious side effects above.

Other side effects
Tell your doctor or nurse if you notice any of the following side effects.

Common
(*may affect up to 1 in 10 people*)
- Feeling sick (nausea) or being sick (vomiting)
- Swelling, redness and/or pain around the needle where the medicine is given into a vein
- Yeast infections e.g. thrush
- Increase in levels of liver enzymes, shown in blood tests
- Cough
- Rash, with small raised bumps
- Severe gut infection known as *Clostridioides difficile* colitis. Symptoms include watery diarrhoea, abdominal pain, fever, etc.
- Increased blood creatinine values

Uncommon
(*may affect up to 1 in 100 people*)
- Increased blood urea values
- Allergy to Fetcroja

Not known
(frequency cannot be estimated from the available data)
- Reduced count of specific white blood cells (neutrophil granulocytes)

Reporting of side effects
If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.
By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Fetcroja

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

Store unopened vials in a refrigerator (2°C - 8°C).

Store in the original package in order to protect from light.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicnes you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Fetcroja contains
- The active substance is cefiderocol sulfate tosylate, equivalent to 1 g cefiderocol.
- The other excipients are sucrose, sodium chloride and sodium hydroxide.

What Fetcroja looks like and contents of the pack
Fetcroja is a white to off-white powder for concentrate for solution for infusion in a vial. It is available in packs containing 10 vials.

Marketing Authorisation Holder
Shionogi B.V.
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1017CA Amsterdam
Netherlands

Manufacturer
Shionogi B.V.
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For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

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This leaflet was last revised in 05/2024.

The following information is intended for healthcare professionals only:

Each vial is for single use only.

The powder should be reconstituted with 10 mL of either sodium chloride 9 mg/ml (0.9%) solution for injection or 5% dextrose injection taken from the 100 mL bags that will be used to prepare the final infusion solution and should be gently shaken to dissolve. The vial(s) should be allowed to stand until the foaming generated on the surface has disappeared (typically within 2 minutes). The final volume of the reconstituted solution in the vial will be approximately 11.2 mL (caution: the reconstituted solution is not for direct injection).

To prepare the required doses, the appropriate volume of reconstituted solution should be withdrawn

from the vial according to the table below. Add the withdrawn volume to the infusion bag containing the remainder of the 100 mL of sodium chloride 9 mg/ml (0.9%) solution for injection, or 5% dextrose injection, inspect the resulting diluted drug product solution in the infusion bag visually for particulate matter and discoloration prior to use. Do not use discoloured solutions or solutions with visible particles.

Preparation of cefiderocol doses

Cefiderocol dose	**Number of 1 g cefiderocol vials to be reconstituted**	**Volume to withdraw from reconstituted vial(s)**	**Total volume of cefiderocol solution required for further dilution in at least 100 mL of 0.9% sodium chloride injection or 5% dextrose injection**
2 g	2 vials	11.2 mL (entire contents) from both vials	22.4 mL
1.5 g	2 vials	11.2 mL (entire contents) from first vial AND 5.6 mL from second vial	16.8 mL
1 g	1 vial	11.2 mL (entire contents)	11.2 mL
0.75 g	1 vial	8.4 mL	8.4 mL

Standard aseptic techniques should be used for solution preparation and administration.

This medicinal product must not be mixed with other medicinal products except those mentioned above in this section. 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.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.