



Bundesinstitut
für Arzneimittel
und Medizinprodukte

Per Postzustellungsurkunde
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**Antrag vom 30.09.2020 auf Erteilung einer Gestattung gemäß §§ 10 Absatz 1a und 11 Absatz 1c
Arzneimittelgesetz -
Einfuhr und Inverkehrbringen von Fetcroja, Pulver für ein Konzentrat zur Herstellung einer
Infusionslösung**

Arzneimittelbezeichnung	Zulassungsinhaber	Zulassungs-Nr.
Fetcroja, Pulver für ein Konzentrat zur Herstellung einer Infusionslösung	Shionogi B.V.	EU/1/20/1434/00

Anlagen

Sehr geehrte Damen und Herren,

in der vorbezeichneten Angelegenheit ergeht der folgende

BESCHEID:

1. Es wird gemäß § 10 Absatz 1a und § 11 Absatz 1c AMG gestattet, das o.g. Arzneimittel mit einer (aus der Anlage dieses Bescheides ersichtlichen) Kennzeichnung und Packungsbeilage in englischer Sprache in den Verkehr zu bringen.
2. Diese Gestattung ist befristet bis zum 31. Dezember 2020.
3. Die Gestattung unter Ziffer 1 erfolgt unter der Maßgabe, dass die Abgabe dieser Arzneimittel ausschließlich an krankenhausversorgende Apotheken oder Krankenhausapotheken erfolgt

Begründung:

Zu 1.

Gemäß § 10 Absatz 1a und § 11 Absatz 1c Arzneimittelgesetz (AMG) kann die zuständige Bundesoberbehörde im Fall eines drohenden oder bestehenden versorgungsrelevanten Lieferengpasses auf Antrag des Zulassungsinhabers im Einzelfall gestatten, dass das Arzneimittel abweichend von § 10 Absatz 1 Satz 1 AMG befristet mit einer Kennzeichnung und Packungsbeilage in einer anderen als der deutschen Sprache in den Verkehr gebracht wird.

Dem o.g. Antrag wird stattgegeben, da die Voraussetzungen für eine Gestattung vorliegen.

Das Arzneimittel wird durch Ärzte unmittelbar an Patienten angewendet.

Im Rahmen der durch das BfArM aktuell durchgeführten Sachverhaltsermittlung unter Einbeziehung der Fachkreise wurde ein drohender versorgungsrelevanter Lieferengpass festgestellt.

Das Inverkehrbringen der in Rede stehenden Ware dient der Sicherstellung der Patientenversorgung.

Wir machen darauf aufmerksam, dass jeder Lieferung von Fetroja® in englischer Aufmachung ein Ausdruck der zugelassenen Produktinformationstexte in deutscher Sprache in entsprechender Anzahl beizufügen ist und die Ware entsprechend der zugelassenen EU Spezifikation freigegeben werden muss.

Zu 2.

Die nach § 10 Abs. 1a und § 11 Absatz 1c AMG zwingend erforderliche Befristung erfolgt antragsgemäß.

Zu 3.

Die Beschränkung der Gestattung auf die Abgabe des Arzneimittels an Krankenhausapotheken oder krankenhausversorgende Apotheken erfolgt antragsgemäß.

Hinweis:

Es wird empfohlen, aus Gründen der Nachvollziehbarkeit und Transparenz ein offizielles Informationsschreiben jeder bestellenden Klinik zur Verfügung zu stellen.

Rechtsbehelfsbelehrung:

Gegen diesen Bescheid kann innerhalb eines Monats nach Bekanntgabe Widerspruch erhoben werden. Der Widerspruch ist bei dem Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) in Bonn einzulegen.

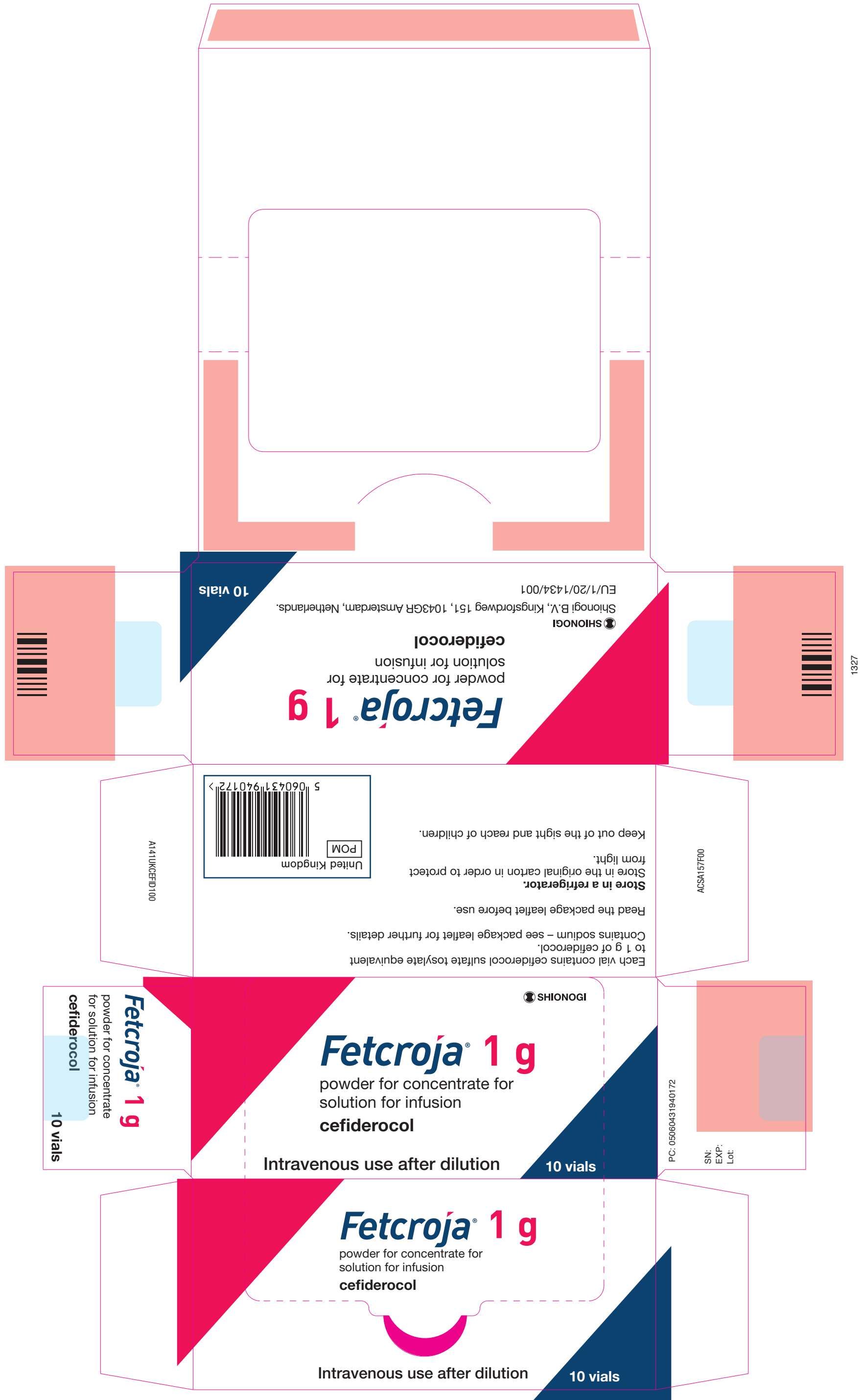
Mit freundlichen Grüßen

Im Auftrag

Dr. Michael Horn

Anlagen

- Äußere Umhüllung (Mock-Ups) in englischer Aufmachung
- Gebrauchsinformation (Package Leaflet) in englischer Sprache



Shionogi B.V.

Fetcroja	
Pharma Job No.:	Fetcroja
File Name:	Fetcoja1g-UK_ctn_v11.ai
QRD Doc Ref.:	N/A
Pharma Laetus:	1327
Tech Spec Code:	ACSA157F00
Artwork Code:	A141UKCFID100
Origination Date:	17 January 2019 - (as Issue 01)
Revision Date:	23 April 2020
Revised By:	AW01
Dimensions:	54,5 x 57,5 x 125mm
Market(s):	United Kingdom (UK)
Language(s):	English

Job: No. / Status / Ref.

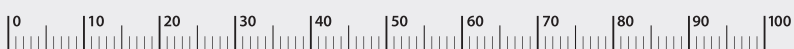
Version: 11



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• Body copy text = 9 pt



Measurement Tool (mm)
100 % scale



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Final Approval	Luis Casanova Regulatory Affairs 07-May-2020 14:07:05 GMT+0000
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Fetroja 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 Fetroja is and what it is used for
2. What you need to know before you are given Fetroja
3. How Fetroja is used
4. Possible side effects
5. How to store Fetroja
6. Contents of the pack and other information

1. What Fetroja is and what it is used for

Fetroja 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.

Fetroja 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 Fetroja

Do not use Fetroja

- 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 Fetroja:

- if you have ever had any **allergic reaction to other antibiotics**. See also section above, "Do not use Fetroja";
 - 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 Fetroja.

New Infection

Although Fetroja 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 Fetroja 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 Fetroja. Fetroja may also result in false-positive results in urine dipstick tests (urine protein or diabetes markers).

Children and adolescents

Fetroja 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 Fetroja

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

Fetroja does not affect your ability to drive or operate machinery.

Fetroja 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 Fetroja if you are on a low sodium diet.

3. How Fetroja 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 Fetroja treatment depends on the type of infection you have and how well your infection is clearing.

If you get any pain where the Fetroja 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 Fetroja. The doctor will adjust your dose of Fetroja.

If you are given more Fetroja than you should

Fetroja 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 Fetroja than you should have.

If you miss a dose of Fetroja

If you think you have not been given a dose of Fetroja, 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.

Uncommon

(may affect up to 1 in 100 people)

- Allergy to Fetroja

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 Fetroja

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 medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Fetroja contains

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

What Fetroja looks like and contents of the pack

Fetroja 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.
Kingsfordweg 151
1043GR Amsterdam
Netherlands

Manufacturer

Shionogi B.V.
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1043GR Amsterdam
Netherlands

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 06/2020

Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site: <http://www.ema.europa.eu>

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.

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

Fetroja 1 g powder for concentrate for solution for infusion cefiderocol

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ARTWORK DETAILS	
Customer	Shionogi B.V.
Product Name	Fetroja 1g
Market	United Kingdom (UK)
Language/s	English
Pharma Laetus:	1327
Tech Spec Code:	ACSI079F01
Artwork Code:	L141UKCEFID100
Our Ref	Fetroja-PIL_UK_ver14– (** to follow final proof)
Client Ref/Word doc used:	Fetroja Package leaflet_May20.docx
Issue	14
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