

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S4**

CEFEPIME 1 g FRESENIUS powder for injection or infusion

CEFEPIME 2 g FRESENIUS powder for injection or infusion

Cefepime

Sugar free

Read all of this leaflet carefully before you are given CEFEPIME FRESENIUS.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse or other health care provider

What is in this leaflet

1. What CEFEPIME FRESENIUS is and what it is used for
2. What you need to know before you use CEFEPIME FRESENIUS
3. How to use CEFEPIME FRESENIUS
4. Possible side effects
5. How to store CEFEPIME FRESENIUS
6. Contents of the pack and other information

1. What CEFEPIME FRESENIUS is and what it is used for

CEFEPIME FRESENIUS is a cephalosporin type of antibiotic.

CEFEPIME FRESENIUS is indicated in adults for the treatment of infections caused by bacteria susceptible to cefepime, namely:

- Certain lung infections;
- Certain urinary tract infections;

- Skin infections;
- Abdominal infections;
- Low level of white blood cells in patients with fever that is suspected to be due to a bacterial infection. Your doctor may prescribe an additional antibiotic in severe infections.

CEFEPIME FRESENIUS is indicated in children (2 months and older) for the treatment of infections caused by bacteria susceptible to cefepime, namely:

- Certain lung infections;
- Certain urinary tract infections;
- Skin infections;
- Low level of white blood cells in patients with fever that is suspected to be due to a bacterial infection. Your doctor may prescribe an additional antibiotic in severe infections.

2. What you need to know before you use CEFEPIME FRESENIUS

Do not use CEFEPIME FRESENIUS:

- if you are hypersensitive (allergic) to cefepime, any other cephalosporin antibiotics or any of the other ingredients of CEFEPIME FRESENIUS (listed in section 6);
- if you have history of severe allergic reaction to any other type of beta-lactam antibiotics (penicillins, monobactams and carbapenems).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before being given the injection.

Special care should be taken with CEFEPIME FRESENIUS:

- if you have some kind of allergy, particularly to medicines. If you develop an allergic reaction during treatment with CEFEPIME FRESENIUS, you should

contact your doctor immediately, this might be serious. In this case the doctor may discontinue the treatment immediately. See section 4;

- if you have diarrhoea. During treatment with CEFEPIME FRESENIUS you may also develop severe and persistent watery or bloodstained diarrhoea. This may be a sign of an inflammation of the large bowel and needs urgent medical intervention;
- if you have kidney problems. Serious side effects (including renal failure) have been reported in patients with kidney problems (see section 4). The dosage of CEFEPIME FRESENIUS may need to be adjusted;
- if you take other medicines. Side effects may be enhanced by medicines that also have an adverse effect on the kidneys, such as aminoglycoside antibiotics (see “Other medicines and CEFEPIME FRESENIUS”).

Tell your doctor if you develop a new infection during prolonged use of CEFEPIME FRESENIUS. This may be overgrowth of micro-organisms which are insensitive to CEFEPIME FRESENIUS and may require interruption of treatment.

Other medicines and CEFEPIME FRESENIUS

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Tell your doctor if you are taking:

- bacteriostatic antibiotics (antibiotics that limit the growth of bacteria, such as tetracyclines, sulphonamides) since they may interfere with the action of CEFEPIME FRESENIUS.
- medicines that have an adverse effect on the kidneys, such as aminoglycoside antibiotics (for example, gentamicin), “water tablets” (diuretics, for example furosemide). Your renal function may need to be monitored;
- medicines used to prevent your blood from clotting (such as warfarin);

- probenecid (a medicine used in treating gout).

If you need to have any blood or urine tests done during treatment with CEFEPIME FRESENIUS, tell the laboratory staff that you are receiving CEFEPIME FRESENIUS. It may alter the results of some tests.

Pregnancy and breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant, or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before using CEFEPIME FRESENIUS.

Pregnancy

The safety of CEFEPIME FRESENIUS during pregnancy has not been established.

If you become pregnant during treatment with CEFEPIME FRESENIUS tell your doctor.

Breastfeeding

CEFEPIME FRESENIUS can be transferred to breastmilk. The safety of breastfeeding during use of CEFEPIME FRESENIUS has not been established.

Fertility

No information available.

Driving and using machines

CEFEPIME FRESENIUS may cause disturbed consciousness, confusion and hallucination, dizziness and may affect your vision (see section 4). If you have these

reactions, or feel unwell, do not drive or operate machines, or perform any tasks that need your full attention.

3. How to use CEFEPIME FRESENIUS

You will not be expected to give yourself CEFEPIME FRESENIUS. It will be given to you by a person who is qualified to do so.

After reconstitution CEFEPIME FRESENIUS can be administered into a vein (IV) or a muscle (IM). Your doctor may prefer the IV route of administration if you have severe infections, are in shock or have a life-threatening condition.

The dose and duration of therapy depends on the type of infection you have and how severe it is. The dose also depends on your age, your weight, and how well your kidneys are working. Your doctor will explain this to you.

- The usual dose for adults and children weighing more than 40 kg is 1 – 2 g intravenously every 12 hours. The maximum intramuscular dose is 1 g every 12 hours.
- The usual dose for babies and children 2 months to 12 years and weighing less than 40 kg is 50 mg/kg twelve hourly or eight hourly. Experience with the intramuscular route in children is limited.

Experience in babies under 2 months of age is limited, CEFEPIME FRESENIUS is therefore not recommended for this age group.

You will normally be given CEFEPIME FRESENIUS for 7-10 days depending on what sort of infection you have.

If you use more CEFEPIME FRESENIUS than you should

Since a healthcare provider will administer CEFEPIME FRESENIUS, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to use CEFEPIME FRESENIUS

Since a healthcare provider will administer CEFEPIME FRESENIUS, it is unlikely that the dose will be missed.

4. Possible side effects

CEFEPIME FRESENIUS can have side effects.

Not all side effects reported for CEFEPIME FRESENIUS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking CEFEPIME FRESENIUS, please consult your doctor, pharmacist or other healthcare provider for advice.

If any of the following happens, tell your healthcare professional immediately:

- Swelling of the hands, feet, ankles, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- Severe skin reactions (rash, redness, swelling, itching, hives, blistering and peeling)
- Abdominal pain with watery diarrhoea, containing blood and mucous (see “Warnings and precautions”)
- Liver problems. Some signs of serious liver impairment may be abdominal pain and swelling, dark urine, nausea and yellow skin and eyes
- Problems with urination or pain on the kidneys (see “Warnings and precautions”)
- Fever (this may be a sign of recurrent infections due to low white blood cell count, infection in the bowel or injection site inflammation).

These are all very serious side effects. If you have them, you may have had a serious reaction to CEFEPIME FRESENIUS. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Anaemia (number of red blood cells). Some signs of anaemia may be pale skin, dizziness, fatigue
- Hypereosinophilia (very high numbers of certain white blood cells). Some signs of hypereosinophilia may be fever, mouth sores, shortness of breath
- Rash
- Pain, swelling and irritation at the intravenous injection site (phlebitis) and inflammation of the vein (thrombophlebitis).
- Diarrhoea
- Problems with the way your blood clots.

Less frequent side effects:

- Inflammation of the vagina, vaginal or oral thrush
- Low counts of various types white blood cells. Some signs may be sudden fever, chills, sore throat, mouth ulcers
- Low blood platelet count. Some signs may be easy or excessive bruising, point bleeding into the skin, prolonged bleeding from cuts
- Headache
- Seizures (having fits)
- Pins and needles sensation (paraesthesia)
- Dizziness
- Taste changes

- Shortness of breath
- Feeling cold and shivering
- Feeling sick (nausea) and being sick (vomiting)
- Abdominal pain, constipation
- Increase of some blood tests (urea and creatinine) which may point to a weaker kidney function
- Fever
- Itching of the genitals
- Inflammation at the injection site (redness, swelling, pain).

Frequency not known:

- Some specific types of anaemia (haemolytic anaemia or aplastic anaemia)
- Confusion, hallucinations
- Unconsciousness, brain disorders
- Spasmodic jerky contraction of groups of muscles
- False positive results in urine tests that detect glucose.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of CEFEPIME FRESENIUS.

Patients are asked to report any suspected adverse drug reactions to their healthcare provider or the Holder of the Certificate of Registration at the following email address: safety.fksa@fresenius-kabi.com and to the relevant medicine's regulatory authority in the country where the product is marketed.

5. How to store CEFEPIME FRESENIUS

Store all medicines out of reach of children.

Store at or below 25 °C. Protect from light (keep the vial in the carton).

Do not use CEFEPIME FRESENIUS after the expiry date which is stated on the carton and label after <EXP>. The expiry date refers to the last day of that month.

Return all unused medicines to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What CEFEPIME FRESENIUS contains

- The active substance is cefepime dihydrochloride monohydrate.

Each vial of CEFEPIME 1 g FRESENIUS, powder for solution for injection or infusion contains 1 g of cefepime (as dihydrochloride monohydrate).

Each vial of CEFEPIME 2 g FRESENIUS, powder for solution for injection or infusion contains 2 g of cefepime (as dihydrochloride monohydrate).

- The other ingredient is L-arginine.

What CEFEPIME FRESENIUS looks like and contents of pack

CEFEPIME 1 g FRESENIUS is a white to pale yellow powder for solution for injection/infusion.

Before CEFEPIME FRESENIUS is given to you, the healthcare provider will dissolve the powder by adding sterile liquid to the vial. He/she will then take the correct dose

out of the vial and inject you or add it to a bag of infusion solution which is given through a small tube into one of your veins.

CEFEPIME 1 g FRESENIUS is packed in 20 ml Type II or Type III clear glass vials closed with a rubber stopper with a blue aluminium cap.

CEFEPIME 2 g FRESENIUS is packed in 20 ml Type II or Type III clear glass vials closed with a rubber stopper with a red aluminium cap.

CEFEPIME FRESENIUS is supplied in packs of 1 or 10 vials per carton.

Not all pack sizes may be marketed.

Holder of the certificate of registration

FRESENIUS KABI SOUTH AFRICA (PTY) LTD

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Registration numbers

Cefepime 1 g Fresenius: 47/20.1.1/0005

Cefepime 2 g Fresenius: 47/20.1.1/0006

Access to the corresponding Professional Information

The professional information leaflet will be packed in the carton, together with the patient information leaflet.