

PATIENT INFORMATION LEAFLET (PIL)

Cefepime

1 g powder for solution for injection or infusion

Cefepime (as cefepime dihydrochloride monohydrate)

- 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, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

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1. SERIOUS SIDE EFFECTS

Get emergency medical help if you have any of these signs of severe allergic reaction:

- severe rash, itching or hives on the skin
- swelling of the face, lips, tongue or other parts of the body
- shortness of breath, wheezing or trouble breathing.

You must contact your doctor immediately if you notice any of the following:

- inflammation of the bowels, called colitis (or antibiotic-associated colitis), causing severe long-lasting watery diarrhea with stomach cramps and fever.
- convulsions (fits).
- destruction and inability to form red blood cells, which can cause weakness, bruising, frequent infections, pale skin, tiredness, breathlessness and dark urine
- lack of white blood cells, which can cause sudden high fever, severe sore throat and ulcers in the mouth

- coma, reduced consciousness or difficulty in thinking
- various conditions affecting the brain, symptoms of which may cause paralysis of part or all of the body, stiff neck, abnormal speech and eye movements
- sudden muscle contraction
- peeling and blistering of the skin, mouth, eyes and genitals
- kidney failure, resulting in severely decreased urine output.

2. WHAT CEFEPIME IS AND WHAT IS USED FOR

Cefepime 1 g powder for solution for injection or infusion (hereinafter referred to as Cefepime) belongs to a group of antibiotics called ‘cephalosporins’. These antibiotics are fairly similar to penicillin. It works by killing bacteria, which can cause serious or life-threatening infections:

- infections of lung (pneumonia) and bronchi (bronchitis)
- bladder and kidney infections (urinary tract infections)
- skin infections and infections of the layers beneath the skin
- fever in patients with a moderate or severe reduction in the number of certain white blood cells
- abdominal infections including inflammation of the peritoneum (peritonitis)
- biliary tract infections (gallbladder and bile duct infections)
- infections of genital tract
- infection of blood stream (septicemia).

Cefepime may also be used to help prevent infections following abdominal surgery.

It is suitable for the treatment of infections in infants and children such as:

- brain infections (bacterial meningitis)
- lung infections (pneumonia)
- bladder and kidney infections (urinary tract infections)
- skin infections and infections of the layers beneath the skin
- fever in patients with a moderate or severe reduction in the number of certain white blood cells.

3. WHAT YOU NEED TO KNOW BEFORE YOU TAKE CEFEPIME

a. Do not use Cefepime if:

- you are allergic (hypersensitive) to cefepime or L-arginine or any of the other ingredients of this medicine (listed in section 7)
- you are allergic (hypersensitive) to any other cephalosporin type of antibiotic
- you have ever had a severe allergic reaction to any penicillin or any other beta-lactam antibiotics (penicillins, monobactams and carbapenems), because this could mean you might also be allergic to cefepime.

If you are not sure, ask your doctor or healthcare professional.

b. Talk to your doctor, pharmacist or nurse before using Cefepime if:

- you have ever had an allergic reaction to penicillin or other medicines from the penicillin family (beta-lactam-antibiotics)
- you have serious kidney problems
- you have ever had a bowel problem with diarrhea called colitis, or any serious problem affecting your intestines.

If any of these apply to you, your doctor may want to change your treatment or give you special advice.

c. Tell your doctor if you are taking any other medicines, especially:

- an antibiotic such as amikacin, gentamicin, kanamycin, neomycin, netilmicin, streptomycin, or tobramycin; or
- a diuretic (water pill) such as furosemide, bumetanide, torsemide, or ethacrynic acid.

This list is not complete and other drugs may interact with cefepime. Tell your doctor about all medications you use. This includes prescription, over-the-counter, vitamin, and herbal products. Do not start a new medication without telling your doctor.

d. Pregnancy, breast-feeding and fertility

- If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.
- Do not use this medicine during pregnancy, unless absolutely necessary and specifically directed by your doctor.
- Cefepime can be transferred to breast milk, and this medicine should therefore be used during breastfeeding with great care and only after discussing with your doctor.

e. Driving and using machines

No studies on the effects on the ability to drive and use machines have been performed. However, you may experience disturbed consciousness, dizziness and confusion, which may compromise the ability to drive and use machines.

4. HOW TO TAKE CEFEPIME

Always use this medicine exactly as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

Your doctor will decide the correct dose of Cefepime for you. The dose will depend on the severity and type of infection; whether you are on any other antibiotics; your weight and age; how well your kidneys and liver are working.

Use in adults and children over 12 years old and/or weighing ≤ 40 k g, with normal renal function:

- The usual adult dose is 2 to 4 gram (g) daily. In severe infections the dose may go up to 6 g daily.

Lower doses may be needed for children or anyone with kidney problems. Your doctor will decide this.

Use in infants and children from 1 month up to 12 years old:

- The usual dose for children aged two months to twelve years and weighing ≤ 40 kg is 50 mg per kg body weight every 12 hours; in more severe infections, the 8 hours interval between the intakes should be done.
- Experience in children under 2 months of age is limited. Children of this age should be monitored carefully during administration of Cefepime.

For children weighing > 40 kg dosage recommendations for adults are applicable.

People with kidney problems:

- You may be given a different dose to the usual dose. Your doctor will decide how much Cefepime you will need and will check you closely depending on the severity of the kidney disease.

How to use Cefepime:

Cefepime must be mixed with a liquid (diluent) before using it.

Cefepime is given:

- by slow injection (for 3-5 minutes) or through a drip (for up to 30 minutes) into one of your veins (intravenous) or
- by deep injection into a large muscle of the buttock (intramuscular).

You should normally have your injections at the same times each day.

a. If you forget to take Cefepime

- If you think you have not been given a dose of Cefepime, tell your doctor immediately.

b. If you take more Cefepime than you should

- As you will be given Cefepime by a doctor or nurse, you are unlikely to be given the wrong dose. However, if you experience bad side effects or think you have been given too much, tell your doctor immediately. Overdose symptoms may include confusion, hallucinations, restless feeling, muscle stiffness, or seizure (convulsions).

c. If you stop using Cefepime:

Do not stop having Cefepime until your doctor tells you to.

If you still feel unwell at the end of your prescribed course of treatment, tell your doctor.

5. POSSIBLE SIDE EFFECTS

Like all other medicines Cefepime can cause side effects although not everybody gets them. If you have a severe allergic reaction (see section 1 of this leaflet), stop having Cefepime and see a doctor straight away. You may need urgent medical treatment.

The following side effects may happen with this medicine:

Very common side effect (may affect more than 1 in 10 people)

- false positive red blood cell status test (Coombs test).

Common side effects (may affect up to 1 in 10 people)

- low level of red blood cells
- increases in some types of white blood cells (eosinophilia)
- changes in blood coagulation parameters
- intravenous administration may result in inflammation of the blood vessel
- diarrhea
- increased levels of certain liver enzymes, high level of bilirubin in the blood
- rash
- reactions at the site of injection or infusion, pain and inflammation at the site of injection.

Uncommon side effect (may affect up to 1 in 100 people)

- inflammation of the bowels, called colitis (or antibiotic-associated colitis), causing severe long-lasting watery diarrhea with stomach cramps and fever
- oral thrush (yeast infection), vaginal infections
- serious blood problems, including changes in the numbers of some white blood cells and platelets (symptoms can include tiredness, new infections and easy bruising or bleeding)
- headache, feeling sick (nausea) and being sick (vomiting)
- skin rash (nettle rash), skin reddening and itchy skin
- abnormal kidney function test results
- fever.

Rare side effects (may affect up to 1 in 1 000 people)

- severe allergic reaction (sudden wheeziness, difficulty in breathing or dizziness, swelling of the eyelids, face, lips or throat)
- convulsions (fits)
- tingling or numbness in the hands or feet
- reduced consciousness or difficulty in thinking, dizziness
- altered sense of taste
- blood vessel dilatation
- difficulty breathing
- pain in your stomach (abdomen), constipation
- itching of genital organs
- shivering.

Side effects with unknown frequency (frequency cannot be estimated from the available data)

- destruction and inability to form red blood cells, which can cause weakness, bruising, frequent infections, pale skin, tiredness, breathlessness and dark urine

- lack of white blood cells, which can cause sudden high fever, severe sore throat and ulcers in the mouth
- a severe and rapid allergic reaction, with constriction of the airways which can prevent breathing
- coma, reduced consciousness or difficulty in thinking
- various conditions affecting the brain, symptoms of which may cause paralysis of part or all of the body, stiff neck, abnormal speech and eye movements
- sudden muscle contraction
- peeling and blistering of the skin, mouth, eyes and genitals
- kidney failure, resulting in severely decreased urine output
- false positive urinary glucose tests
- confusion, hallucinations, drowsiness
- bleeding disorder
- digestive complaints.

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.

6. HOW TO STORE CEFEPIME AND OTHER INFORMATION

Keep out of reach and sight of children

Do not use Cefepime after the expiry date which is stated on the vial and carton after EXP. The expiry date refers to the last day of that month.

Store the unopened vial below 30°C. Keep container in the outer carton.

After reconstitution:

The reconstituted solutions for injection should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 12 hours at room temperature or 24 hours under refrigeration.

If the solution is cloudy or has particles in it, it should not be used.

Any unused solution should be discarded.

Do not freeze the reconstituted solution.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

7. FURTHER INFORMATION

a. What Cefepime contains

The active substance is Cefepime. Each vial contains 1 g cefepime as cefepime dihydrochloride monohydrate.

The other ingredient is L-arginine.

b. What Cefepime looks like

Cefepime is a white to light yellow powder for solution for injection or infusion.

It is supplied in colorless glass vials sealed with an aluminum seal or flip-off aluminum seal with 1, 10, 1-50 or 50 vials in a carton.

Not all pack sizes may be marketed.

c. Marketing Authorisation Holder and Manufacturer

“KRASPHARMA” OJSC

Russia, 660042, 60 let Oktyabrya st. 2, Krasnoyarsk

Tel.: +7 (391) 261-25-90. Fax: +7 (391) 261-17-44

For any information about this medicinal product, please contact the local representative of the Marketing Authorisation Holder:

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d. This leaflet was last approved _____; version number 1.0.

e. To report any side effect(s):

f. Council of _____

THIS IS A MEDICAMENT

- **A medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.**
- **Follow strictly the doctor’s prescription, the method of use and the instructions of the pharmacist who sold the medicament.**
- **The doctor and the pharmacist are experts in medicine, its benefits and risks.**
- **Do not by yourself interrupt the period of treatment prescribed.**
- **Do not repeat the same prescription without consulting your doctor.**
- **Keep medicament out of reach of children**

g. This patient information leaflet is approved by the _____.