

## **SECTION 1: PATIENT INFORMATION LEAFLET (PIL)**

### **Ceftazidime**

**1 g powder for solution for injection**

Ceftazidime (as Ceftazidime Sodium)

- **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 an allergic reaction:

- hives;
- difficulty breathing;
- swelling of your face, lips, tongue, or throat.

Call your doctor at once if you have a serious side effect such as:

- diarrhea that is watery or bloody;
- swelling, pain, or irritation where the injection was given;
- cold feeling, discoloration, or skin changes in your fingers;

- seizure (black-out or convulsions), tremors and, in some cases coma. These have occurred in people when the dose they are given is too high, particularly in people with kidney disease.
- white patches or sores inside your mouth or on your lip;
- jaundice (yellowing of the eyes or skin); or
- severe skin reaction -- fever, sore throat, swelling in your face or tongue, burning in your eyes, skin pain, followed by a red or purple skin rash that spreads (especially in the face or upper body) and causes blistering and peeling.

## **2. WHAT CEFTAZIDIME IS AND WHAT IS USED FOR**

Ceftazidime belongs to a group of medicines called cephalosporins which are antibiotics. These medicines work by killing bacteria that cause infections.

Ceftazidime is used in adults and children (including newborn babies) to treat many kinds of severe or life-threatening bacterial infections of:

- the lungs or chest
- the lungs and bronchi in patients suffering from cystic fibrosis
- the brain (meningitis)
- the ear
- the urinary tract
- the skin and soft tissues
- the abdomen and abdominal wall (peritonitis)
- the bones and joints.

Ceftazidime is also used:

- to prevent infections during prostate surgery in men
- to treat patients with low white blood cell counts (neutropenia) who have a fever due to a bacterial infection.

## **3. WHAT YOU NEED TO KNOW BEFORE YOU TAKE CEFTAZIDIME**

*a. You must not be given Ceftazidime 1 g powder for solution for injection if:*

- You are allergic to ceftazidime or any other cephalosporin.
- You have previously had a severe allergic reaction to penicillin or any other beta-lactam antibiotic as you may also be allergic to Ceftazidime.

If any of the above applies to you, you should not be given Ceftazidime for Injection.

b. Talk to your doctor, pharmacist or nurse before using Ceftazidime 500 mg & 1 g powder for solution for injection if:

- you have previously had an allergic reaction to penicillin or other antibiotics of this type. Not all people who are allergic to penicillins are also allergic to cephalosporins. Before you are given this medicine your doctor should check whether you have previously had an allergic reaction to such drugs.
- you have kidney problems. You will be carefully monitored throughout your treatment.
- you are taking aminoglycosides such as streptomycin and gentamicin. Your kidney function will be carefully monitored.

If you are not sure if any of the above applies to you, talk to your doctor or nurse before using Ceftazidime.

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

- Aminoglycoside antibiotics such as streptomycin, streptomycin, kanamycin or gentamicin
- Furosemide or other strong diuretics, used to get rid of excess water from the body
- An antibiotic called chloramphenicol

This may not be a complete list of all interactions that may occur. Ask your doctor if Ceftazidime may interact with other medicines that you take. Check with your doctor before you start, stop, or change the dose of any medicine.

d. Pregnancy, breast-feeding and fertility

You should let your doctor or nurse know if you are pregnant or wish to become pregnant or are breast-feeding before this medicine is administered.

e. Driving and using machines

Ceftazidime for injection may cause side effects that affect your ability to drive, such as dizziness. If you are affected you should not drive or operate machinery.

f. Ceftazidime contains sodium

This medicinal product contains approximately

- 29 mg of sodium per 500 mg dose
- 52 mg of sodium per 1 g dose

It should be taken into consideration by patients on a controlled sodium diet.

#### **4. HOW TO TAKE CEFTAZIDIME**

Your doctor or nurse will prepare your injection by dissolving the ceftazidime powder in a suitable fluid for injection. The mixture is usually injected intramuscularly (into a muscle) or given intravenously (into a vein) either by injection or infusion (drip).

The usual dose

Your doctor will decide the correct dose of Ceftazidime 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 are working.

Adults and adolescents who weigh 40 kg or more:

- The usual adult (including the elderly) dose by intramuscular or intravenous injection is 1 to 2 g of Ceftazidime three times daily. Maximum of 9 g per day.

Patients over 65:

- The daily dose should not normally exceed 3 g per day, especially if you are over 80 years of age.

Babies (over 2 months) and children who weigh less than 40 kg:

- For every 1 kg the baby or child weighs, they'll be given 100 to 150 mg of Ceftazidime per day divided in three doses. Maximum 6 g per day.

Newborn babies (0-2 months):

- For every 1 kg the baby weighs, they'll be given 25 to 60 mg Ceftazidime per day divided in two doses.

People with kidney problems:

- You may be given a different dose to the usual dose. The doctor or nurse will decide how much Ceftazidime you will need, depending on the severity of the kidney disease. Your doctor will check you closely and you may have more regular kidney function tests.

How to use Ceftazidime:

- Ceftazidime is usually given by a doctor or nurse. It can be given as an injection directly into a vein or into a muscle or as a drip intravenous infusion. Ceftazidime Injection is made up by the doctor, pharmacist or nurse.
- The number of days or weeks that you are given Ceftazidime depends on what sort of infection you have, your clinical condition and your response to treatment.
- You should normally have your injection or infusion at the same times each day.

a. If you forget to take Ceftazidime

- If you miss an injection, you should have it as soon as possible. Don't take a double dose (two injections at the same time) to make up for a missed dose.

b. If you take more Ceftazidime than you should

- If you accidentally use more than your prescribed dose, contact your doctor, nurse, pharmacist or nearest hospital.

c. If you stop using Ceftazidime:

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

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

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

## **5. POSSIBLE SIDE EFFECTS**

Like all other medicines Ceftazidime can cause side effects although not everybody gets them.

The following side effects may happen with this medicine:

### Common side effects

These may affect up to 1 in 10 people:

- diarrhea
- swelling and redness along a vein
- red raised skin rash which may be itchiness
- pain, burning, swelling or inflammation at the injection site.

Common side effects that may show up in blood tests:

- an increase in a type of white blood cell (eosinophilia)
- an increase in the number of cells that help the blood to clot
- an increase in liver enzymes.

### Uncommon side effects

These may affect up to 1 in 100 people:

- inflammation of the gut which can cause pain, or diarrhea which may contain blood
- thrush (fungal infections in the mouth or vagina)
- headache
- dizziness
- stomach ache
- feeling sick or being sick
- fever and chills.

Uncommon side effects that may show up in blood tests:

- a decrease in the number of white blood cells
- a decrease in the number of blood platelets (cells that help the blood to clot)
- an increase in the level of urea, urea nitrogen or serum creatinine in the blood.

### Other side effects

Other side effects have occurred in a small number of people but their exact frequency is unknown:

- inflammation or failure of the kidneys
- pins and needles (paraesthesia)
- unpleasant taste in the mouth
- yellowing of the whites of the eyes or skin.

Other side effects that may show up in blood tests:

- red blood cells destroyed too quickly
- an increase in a certain type of white blood cells
- severe decrease in the number of white blood cells.

### **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 CEFTAZIDIME AND OTHER INFORMATION**

### **Keep out of reach and sight of children**

- Do not use Ceftazidime 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.
- Once the powder has been dissolved; the solution 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 24hours under refrigeration.
- If the solution contains particles or is cloudy, it should not be used.
- Any unused solution should be discarded.

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 Ceftazidime 500 mg & 1 g powder for solution for injection contains**

- *Ceftazidime 500 mg powder for solution for injection:*  
The active substance is ceftazidime. Each vial contains 500 mg ceftazidime (present as ceftazidime pentahydrate).
- *Ceftazidime 1 g powder for solution for injection:*  
The active substance is ceftazidime. Each vial contains 1 g anhydrous ceftazidime (present as ceftazidime pentahydrate).
- The only other ingredient is sodium carbonate (anhydrous sterile).
- The sodium content per vial is approximately 29 mg of sodium per 500 mg dose or 52 mg of sodium per 1 g dose.

### **b. What Ceftazidime looks like**

Ceftazidime is a sterile white to cream powder. 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 Authorization 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 Authorization Holder:*

“KRASPHARMA” OJSC

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d. This leaflet was last approved \_\_\_\_\_; version number \_\_\_\_\_.

e. To report any side effect(s):

- \_\_\_\_\_:
  - \_\_\_\_\_
- Fax: \_\_\_\_\_
- Call \_\_\_\_\_ at \_\_\_\_\_, Exts: \_\_\_\_\_.
- Toll free phone: \_\_\_\_\_
- E-mail: \_\_\_\_\_ @ \_\_\_\_\_
- Website: \_\_\_\_\_

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 \_\_\_\_\_.