

SECTION 1: PATIENT INFORMATION LEAFLET (PIL)

Ceftriaxone

1 g powder for solution for injection or infusion

Ceftriaxone (as Ceftriaxone 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**
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1. SERIOUS SIDE EFFECTS

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

- severe rash, itching or hives on the skin
- sudden swelling of the face, throat, lips or mouth. This can make it difficult to breathe or swallow
- sudden swelling of the hands, feet and ankles
- shortness of breath, wheezing or trouble breathing.

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

- diarrhea that is watery or bloody
- sudden weakness or ill feeling, fever, chills, cold or flu symptoms, mouth sores
- white patches or sores inside your mouth or on your lips

- unusual bleeding (nose, mouth, vagina, or rectum), purple or red pinpoint spots under your skin
- skin rash, bruising, severe tingling, numbness, pain, muscle weakness
- pale or yellowed skin, dark colored urine
- severe pain in your upper stomach that comes and goes or spreads to your back
- pain in your side or lower back spreading to your groin, blood in your urine, painful or difficult urination, little or no urine
- seizure (convulsions)
- swelling, pain, or irritation where the injection was given
- chalky-colored stools, stomach pain just after eating a meal, nausea, heartburn, bloating, and severe upper stomach pain that may spread to your back; or
- severe skin reaction - severe rash that develops quickly, with blisters or peeling of the skin and possibly blisters in the mouth (Stevens-Johnson syndrome and toxic epidermal necrolysis which are also known as SJS and TEN)
- a combination of any of the following symptoms: widespread rash, high body temperature, liver enzyme elevations, blood abnormalities (eosinophilia), enlarged lymph nodes and other body organs involvement (Drug Reaction with Eosinophilia and Systemic Symptoms which is also known as DRESS or drug hypersensitivity syndrome).
- Jarisch-Herxheimer reaction which causes fever, chills, headache, muscle pain, and skin rash that is usually self-limiting. This occurs shortly after starting Ceftriaxone treatment for infections with spirochete such as Lyme disease.

2. WHAT CEFTRIAZONE IS AND WHAT IS USED FOR

Ceftriaxone 1 g powder for solution for injection or infusion (hereinafter referred to as Ceftriaxone) is an antibiotic given to adults and children (including newborn babies). It works by killing bacteria that cause infections. It belongs to a group of medicines called cephalosporins.

Ceftriaxone is used to treat infections of:

- the brain (meningitis)
- the lungs
- the middle ear
- the abdomen and abdominal wall (including peritonitis)
- the urinary tract and kidneys
- bones and joints
- the skin or soft tissues
- the blood

- the heart.

It can be given:

- to treat specific sexually transmitted infections (gonorrhea and syphilis)
- to treat patients with low white blood cell counts (neutropenia) who have fever due to bacterial infection
- to treat infections of the chest in adults with chronic bronchitis
- to treat Lyme disease (caused by tick bites) in adults and children including newborn babies from 15 days of age
- to prevent infections during surgery.

3. WHAT YOU NEED TO KNOW BEFORE YOU TAKE CEFTRIAZONE

a. You must not be given Ceftriazone if:

- You are allergic to ceftriazone or any of the other ingredients of this medicine
- You have had a sudden or severe allergic reaction to penicillin or similar antibiotics (such as cephalosporins, carbapenems or monobactams). The signs include sudden swelling of the throat or face which might make it difficult to breath or swallow, sudden swelling of the hands, feet and ankles, and a severe rash that develops quickly
- You are allergic to lidocaine and you are to be given ceftriazone as an injection into a muscle.

Ceftriazone must not be given to babies if:

- The baby is premature;
- The baby is newborn (up to 28 days of age) and has certain blood problems or jaundice (yellowing of the skin or whites of the eyes) or is about to be given a product that contains calcium into their vein.

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

- you are pregnant, planning to become pregnant, or are breast-feeding
- you have recently received or are about to receive products that contain calcium
- you have recently had diarrhea after having an antibiotic medicine. You have ever had problems with your gut, in particular colitis (inflammation of the bowel)
- you have liver or kidney problems
- you have gall stones or kidney stones
- you have other illnesses, such as hemolytic anemia (a reduction in your red blood cells that may make your skin pale yellow and cause weakness or breathlessness).
- you are on a low sodium diet

- you experience or have previously experienced a combination of any of the following symptoms: rash, red skin, blistering of the lips eyes and mouth, skin peeling, high fever, flu-like symptoms, increased levels of liver enzymes seen in blood tests and an increase in a type of white blood cell (eosinophilia) and enlarged lymph nodes (signs of severe skin reactions, see also section 4 “Possible side effects”).

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

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

- calcium-containing IV medicines (e.g., parenteral nutrition, Ringer's solution) because severe and sometimes fatal lung and kidney problems may occur, especially in newborns
- a type of antibiotic called an aminoglycoside (e.g., gentamicin) or anticoagulants (e.g., warfarin) because the risk of their side effects may be increased by ceftriaxone.

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

d. Children

Talk to your doctor or pharmacist or nurse before your child is administered Ceftriaxone if:

- he/she has recently been given or is to be given a product that contains calcium into their vein.

e. 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 for advice before taking this medicine. The doctor will consider the benefit of treating you with Ceftriaxone against the risk to your baby.

f. If you need a blood or urine test

If you are given Ceftriaxone for a long time, you may need to have regular blood tests. Ceftriaxone can affect the results of urine tests for sugar and a blood test known as the Coombs test. If you are having tests:

- Tell the person taking the sample that you have been given Ceftriaxone.

If you are diabetic or need to have your blood glucose level monitored you should not use certain blood glucose monitoring systems which may estimate blood glucose incorrectly while you are receiving ceftriaxone. If you use such systems check the instructions for use and tell your doctor, pharmacist or nurse. Alternative testing methods should be used if necessary.

g. Driving and using machines

Ceftriaxone can cause dizziness. If you feel dizzy, do not drive or use any tools or machines. Talk to your doctor if you experience these symptoms.

4. HOW TO TAKE CEFTRIAXONE

Ceftriaxone is usually given by a doctor or nurse. It can be given as

- a drip (intravenous infusion) or as an injection directly into a vein, or
- into a muscle.

Ceftriaxone is made up by the doctor, pharmacist or nurse and will not be mixed with or given to you at the same time as calcium-containing injections.

The usual dose

Your doctor will decide the correct dose of Ceftriaxone 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, older people and children aged 12 years and over with a body weight greater than or equal to 50 kilograms (kg):

- 1 to 2 g once a day depending on the severity and type of infection. If you have a severe infection, your doctor will give you a higher dose (up to 4 g once a day). If your daily dose is higher than 2 g, you may receive it as a single dose once a day or as two separate doses.

Use in newborn babies, infants and children aged 15 days to 12 years with a body weight of less than 50 kg:

- 50-80 mg Ceftriaxone for each kg of the child's body weight once a day depending on the severity and type of infection. If you have a severe infection, your doctor will give you a higher dose up to 100 mg for each kg of body weight to a maximum of 4 g once a day. If your daily dose is higher than 2 g, you may receive it as a single dose once a day or as two separate doses.
- Children who weigh over 50 kg will be given an adult dose.

Use in newborn babies (0-14 days):

- 20 – 50 mg ceftriaxone for each kg of the child's body weight once a day depending on the severity and type of infection.
- The maximum daily dose is not to be more than 50 mg for each kg of the baby's weight.

People with liver and kidney problems:

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

How to use Ceftriaxone:

- Ceftriaxone 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. Ceftriaxone injection is made up by the doctor, pharmacist or nurse and will not be mixed with or given to you at the same time as calcium-containing injections.
- The number of days or weeks that you are given Ceftriaxone 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 Ceftriaxone

- If you miss an injection, you should have it as soon as possible. However, if it is almost time for your next injection, skip the missed injection. Do not take a double dose (two injections at the same time) to make up for a missed dose.

b. If you take more Ceftriaxone than you should

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

c. If you stop using Ceftriaxone:

Do not stop having Ceftriaxone 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 Ceftriaxone can cause side effects although not everybody gets them. The following side effects may happen with this medicine:

Common (may affect up to 1 in 10 people)

- abnormalities with your white blood cells (such as a decrease of leucocytes and an increase of eosinophils) and platelets (decrease of thrombocytes).
- loose stools or diarrhea.
- changes in the results of blood tests for liver functions.
- rash.

Uncommon (may affect up to 1 in 100 people):

- fungal infections (for example, thrush).
- a decrease in the number of white blood cells (granulocytopenia).
- reduction in number of red blood cells (anemia).
- problems with the way your blood clots. The signs may include bruising easily and pain and swelling of your joints.

- headache.
- dizziness.
- feeling sick or being sick.
- pruritus (itching).
- pain or a burning feeling along the vein where Ceftriaxon has been given. Pain where the injection was given.
- a high temperature (fever).
- abnormal kidney function test (blood creatinine increased).

Rare (may affect up to 1 in 1 000 people):

- inflammation of the large bowel (colon). The signs include diarrhea, usually with blood and mucus, stomach pain and fever.
- difficulty in breathing (bronchospasm).
- a lumpy rash (hives) that may cover a lot of your body, feeling itchy and swelling.
- blood or sugar in your urine.
- edema (fluid build-up).
- shivering.

Not known (Frequency cannot be estimated from the available data):

- severe skin reactions (Stevens-Johnson syndrome and toxic epidermal necrolysis which are also known as SJS and TEN)
- Drug Reaction with Eosinophilia and Systemic Symptoms which is also known as DRESS or drug hypersensitivity syndrome
- Jarisch-Herxheimer reaction which causes fever, chills, headache, muscle pain, and skin rash
- a secondary infection that may not respond to the antibiotic previously prescribed
- severe allergic reaction (e.g., anaphylactic shock or severe angioedema)
- form of anemia where red blood cells are destroyed (hemolytic anemia).
- severe decrease in white blood cells (agranulocytosis).
- convulsions.
- vertigo (spinning sensation).
- inflammation of the pancreas (pancreatitis). The signs include severe pain in the stomach which spreads to your back.
- inflammation of the mucus lining of the mouth (stomatitis).
- inflammation of the tongue (glossitis). The signs include swelling, redness and soreness of the tongue.

- problems with your gallbladder, which may cause pain, feeling sick and being sick.
- a neurological condition that may occur in neonates with severe jaundice (kernicterus).
- kidney problems caused by deposits of calcium ceftriaxone. There may be pain when passing water (urine) or low output of urine.
- a false positive result in a Coombs' test (a test for some blood problems).
- a false positive result for galactosaemia (an abnormal build up of the sugar galactose).
- Ceftriaxone may interfere with some types of blood glucose tests - please check with your doctor.

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 CEFTRIAXONE AND OTHER INFORMATION

Keep out of reach and sight of children

Do not use Ceftriaxone after the expiry date which is stated on the vial and carton after «Exp.date».

The expiry date refers to the last day of that month.

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

Chemical and physical in-use stability of the reconstituted product has been demonstrated for at least 6 hours at or below 25°C or 24 hours at 2-8°C.

From a microbiological point of view, the product 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 not be longer than the times stated above for the chemical and physical in-use stability.

If the solution 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 Ceftriaxone contains

The active substance in Ceftriaxone 1 g powder for solution for injection or infusion is Ceftriaxone Sodium.

b. What Ceftriaxone looks like

Ceftriaxone consists of a powder for solution for injection. The powder is white to yellowish-orange. is a white to yellow powder. It is supplied in 10 ml colorless glass vials sealed with an aluminum seal or flip-off aluminum seal with 1 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; 204-014-77. Fax: +7 (391) 261-17-44

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

“KRASPHARMA” OJSC

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

Tel.: +7 (391) 261-25-90; 204-14-77. Fax: +7 (391) 261-17-44

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 _____.