

Ceftriaxone 1g powder for solution for injection

What is Ceftriaxon 1g and what is it used for?

Ceftriaxon 1G is an antibiotic. It belongs to a group of antibiotics called cephalosporins, which are similar to penicillin. Ceftriaxon kills bacteria and can be used against various types of infections. Like all antibiotics, ceftriaxon is only effective against certain types of bacteria, so it is only suitable for the treatment of certain types of infections.

Ceftriaxon is used for treating:

- infections of the respiratory tract, throat, and nose
- ear infections
- infections of the kidneys and urinary tract
- infections of the skin and underlying layers, including wound infections
- infections of the genital organs, including gonorrhoea
- infections of the abdominal cavity; ceftriaxon should be administered in combination with a suitable antibiotic against anaerobic bacteria (bacteria that can live without oxygen).
- Infections of bones and joints
- sepsis
- inflammation of the meninges or spinal cord (meningitis)
- Lyme borreliosis (especially phase II and III) (tick-borne disease)
- Ceftriaxon can be administered prophylactically during surgeries if there is an increased risk of infection. In surgery involving the colon or rectum, ceftriaxon should be administered in combination with an antibacterial substance with additional anaerobic properties.

What you need to know before using Ceftriaxone 1g:

Do not use Ceftriaxone 1g if:

You are allergic to ceftriaxone or any of the other ingredients of this medicine. You are allergic to another type of cephalosporin antibiotic. You have ever had a severe allergic reaction to penicillin or another beta-lactam antibiotic, as you may also be allergic to this medicine. Ceftriaxone 1g should not be used in preterm infants up to a corrected age of 41 weeks (gestational weeks + weeks after birth) and in newborns (up to 28 days of age) with jaundice (icterus), or with hypo-albuminemia or acidosis (increased acidity of the body).

Ceftriaxone 1g should not be administered to newborns (up to 28 days old) who are being treated (or still need to be treated) with intravenous calcium or calcium-containing solutions because there is a risk of precipitation of ceftriaxone-calcium salt.

Ceftriaxone 1g should not be administered as an intramuscular injection (injection into the muscle):

- in children under 2 years of age, and;
- during pregnancy and breastfeeding.

You are allergic to lidocaine and you are given Ceftriaxone 1g as an injection into the muscle.

When should you be extra careful with Ceftriaxone 1.0 g Eberth?

Contact your doctor or pharmacist before using this medicine if:

- You have ever had an allergic reaction to an antibiotic, tell your doctor or pharmacist before taking this medicine.
- You have ever had another type of allergic reaction or asthma. Hypersensitivity reactions to ceftriaxone tend to occur more frequently in individuals with a tendency to allergic reactions and can occur in all degrees of severity up to anaphylactic shock.
- You are given an injection of calcium or a calcium-containing infusion intravenously (in a blood vessel), then you must tell your doctor or healthcare professional.
- You have been told that your kidneys and/or liver do not work so well .
- You have ever had gallbladder or kidney stones, or if you are being intravenously fed.
- You have ever had inflammation of your intestine, called colitis, or another serious intestinal disease.

If you get or have had one or more of the following symptoms: rash, red skin, blisters on the lips, eyes, and mouth, detachment of the skin, high fever, flu-like symptoms, increased liver enzyme levels detected by blood tests, and an increased number of white blood cells (eosinophils) and swollen lymph nodes (these may be symptoms of severe skin reactions, see also section 4 "Possible side effects").

This medicine can affect the results of some blood tests (such as the Coombs test). If you need to undergo one of these tests, it is important to inform your doctor of your use of this medicine.

Do you use any other medications?

Tell your doctor or pharmacist if you are using or have recently used any other medications, including those obtained without a prescription. This is particularly important for medications that are eliminated through the kidneys, as they may interact with this medication. There are many medications that can cause this interaction, so it is important to check with your doctor or pharmacist before taking this medication.

In particular, inform your doctor or pharmacist if you:

are using other antibiotics to treat infections, such as aminoglycosides, chloramphenicol, or vancomycin.
are using oral contraceptive pills. It is recommended to use additional non-hormonal contraceptive measures.
are using other active ingredients such as:

- probenecid (used to treat gout)
- amsacrine (a medication used to treat cancer),
- and fluconazole (an antifungal medication).

This medication can also affect the results of certain blood tests, such as the Coombs test or galactose determination in your blood. If you need to undergo any of these tests, it is important to inform your doctor of your use of this medication. This medication can also affect the results of non-enzymatic urine tests for the determination of sugar levels. If you have diabetes and usually perform a urine test, inform your doctor. Other tests may need to be used to monitor your diabetes while you are taking this medication.

Pregnancy and breastfeeding

- Are you pregnant or do you think you may be pregnant? Although it is not known to be harmful to the unborn child, this medication will only be administered to a pregnant woman if absolutely necessary.
- Are you breastfeeding? This medication should not be given to women who are breastfeeding. This is because small amounts of the medication can pass into breast milk and therefore into the infant.
- During pregnancy, this medication should not be administered intramuscularly if used in combination with lidocaine.

If you are pregnant, think you may be pregnant, want to become pregnant, or are breastfeeding, contact your doctor or pharmacist before using this medication.

Driving and using machines

You may feel dizzy when using this medication. This can affect your ability to drive or operate machinery. If you experience this, do not drive or use machinery.

How to use Ceftriaxone 1g?

Follow the advice of your doctor closely when using this medicine. If in doubt, consult your doctor or pharmacist.

Ceftriaxone is usually administered by a doctor or nurse.

- It is administered as an injection.
- The injection is given as a slow injection into a vein or a deep injection into a large muscle.

The dose your doctor will give you depends on the type of infection and the severity of the infection. It also depends on your weight and kidney function. Your doctor will explain this to you. The usual doses are:

Adults, elderly people, and children over 12 years of age weighing more than 50 kg

- 1 to 2 g once a day
- For severe infections, this can be increased to 4 g per day, injected into a vein.

Special dosage information:

- For meningitis infection, 100 mg per kg is first administered once a day (but not more than 4 g per day). In newborn babies (up to 14 days old), no more than 50 mg/kg should be given.
- For the treatment of gonorrhoea: Mild infections: 250 mg intramuscularly as a single dose. Complicated infections should be treated according to official guidelines. Syphilis (*Treponema pallidum*) must be ruled out using diagnostic measures (dark field microscopy and blood tests such as VDRL or RPR and FTA-ABS) before starting ceftriaxone.
- Treatment of Lyme Borreliosis: In adults and adolescents over 12 years of age, the therapeutic dose is 50 mg/kg with a maximum of 2 g ceftriaxone once daily for 14 days. Children up to 12 years of age receive 50-100 mg/kg body weight once daily up to a maximum daily dose of 2 g for at least 14 days.
- In case of administration for surgery, the normal daily dose is administered 30-90 minutes before the surgery. Usually, only one dose is given.
- In people with kidney problems, the dose should not be lowered if liver function is normal. If kidney function is very poor (creatinine clearance < 10 ml/min), the daily dose of ceftriaxone should not exceed 2 g in adult patients.
- In people with liver problems, it is not necessary to lower the dose unless they also have kidney problems.
- In concomitant severe renal and hepatic insufficiency, ceftriaxone blood levels should be regularly monitored, and the dosage adjusted accordingly for children and adults.
- If you are receiving dialysis, your doctor will perform tests to ensure that you are receiving the correct dose. Ceftriaxone is usually administered once a day.

- Treatment is usually continued at least 2 days after normalization of body temperature.
- Treatment may be continued for a total of 7 to 14 days.

Use in children and adolescents up to 18 years of age

Newborn babies (up to 14 days old)

- 20-50 mg per kg body weight once a day, injected into a vein
- More than 50 mg per kg should not be given, even in severe infections.

Children between 15 days and 12 years of age

- 20-80 mg per kg body weight once a day, injected into a vein
- More than 80 mg per kg should not be given, even in severe infections, except for meningitis.

If the patient is a child younger than 2 years old or a woman who is pregnant or breastfeeding, Ceftriaxone should only be administered through a slow injection into a vein.

What to do if you have used more Ceftriaxone 1g than you should have: If too much Ceftriaxone was used, immediately notify your doctor or go to the accident and emergency department of the nearest hospital. Take the medicine with you in the packaging so that the staff knows exactly what was used.

What to do if you forget to use Ceftriaxone 1.0 g Eberth: Do not take a double dose to make up for a missed dose.

If you stop using Ceftriaxone 1.0 g Eberth: It is important that this medicine is used in the prescribed course; you should not interrupt the course because you feel better again. If the treatment course is stopped too early, the infection may recur.

Possible Side Effects

Like any medication, this medication can have side effects, although not everyone experiences them. The side effects were classified according to frequency based on the following convention:

Very common: more than 1 in 10 people who take this medication

Common: less than 1 in 10, but more than 1 in 100 people who take this medication

Uncommon: less than 1 in 100, but more than 1 in 1000 people who take this medication

Serious side effects

If any of the following serious side effects occur, stop using this medication and immediately notify your doctor or go to the emergency department of the nearest hospital. The following side effects occur rarely (affect less than 1 in 1000 people):

Allergic reactions such as sudden shortness of breath and chest tightness, swelling of the eyelids, face or lips, severe skin rash with blisters that spread to the eyes, mouth, throat and genitals, loss of consciousness (fainting).

Diarrhea that is severe, long-lasting or contains blood, with stomach pain or fever. This can be a sign of a serious intestinal inflammation (so-called "pseudomembranous colitis") that can occur after taking antibiotics.

The following side effects occur very rarely (affect less than 1 in 10,000 people): precipitation of ceftriaxone-calcium salt in the lungs and kidneys in premature and newborn infants (up to 28 days of age) who were treated intravenously with ceftriaxone and calcium.

Other possible side effects

Common side effects (affect less than 1 in 10 people): decrease or increase in the number of white blood cells

a type of anemia that can be severe and caused by the breakdown of red blood cells. If you undergo a blood test for any reason, inform the person taking the blood sample that you are taking this medicine as it can affect the result.

- nausea, vomiting, stomach pain, diarrhea, loss of appetite.
- pain and hardening at the injection site in a muscle
- pain and redness at the injection site in a vein
- rash, itching, hives, swelling of the skin

Uncommon side effects (affect less than 1 in 100 people)

infections: A course of ceftriaxone may temporarily increase the risk of getting infections with other pathogens. For example, thrush may occur.

Rare side effects (affect less than 1 in 1,000 people)

- allergic reactions
- changes in blood tests that monitor liver function
- headache, dizziness
- fever, chills
- gallstones, precipitation of ceftriaxone-calcium salt in the gallbladder

kidney problems: changes in kidney function and decreased urine production

problems with the gallbladder and/or liver. This can lead to pain, nausea, vomiting, yellowing of the skin, itching, urine that is darker than usual, and stool with the same color as clay

If you experience severe skin reactions, tell a doctor immediately.

Symptoms may include:

a severe rash that develops rapidly and is accompanied by blisters on or detachment of the skin, and possibly blisters in the mouth (Stevens-Johnson syndrome and toxic epidermal necrolysis, also called SJS and TEN).

one or a combination of the following symptoms: extensive skin rash, elevated body temperature, elevated liver enzyme levels, abnormal blood values (eosinophils), swollen lymph nodes and other organs (drug rash with eosinophilia and systemic symptoms, also called DRESS or drug hypersensitivity syndrome).

Jarisch-Herxheimer reaction, which can cause fever, chills, headache, muscle pain, and rash, and usually goes away on its own. This reaction can occur shortly after starting treatment with Ceftriaxone 1g for spirochete infections such as Lyme disease.

Additional side effects that may occur in children.

How Do You Store Ceftriaxone 1g

- Keep out of the sight and reach of children.
- Do not use this medicine after the expiry date stated on the packaging. The expiry date refers to the last day of that month.
- Store the container in the outer packaging to protect it from light.
- The solutions must be used immediately after reconstitution. Only clear solutions may be used.
- The contents of the vial must be used immediately after opening.
- Any unused injection or infusion solution should be discarded.
- Do not flush medicines down the sink or toilet or throw them in the trash. Ask your pharmacist how to dispose of medicines you no longer use. They will be disposed of responsibly and not harm the environment.