

# CEFAXONE® 1g

Ceftriaxone sodium

Powder for preparation for I.M. injection / I.V. injection / I.V. infusion

Read this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, health care provider or your pharmacist.
- This medication has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any side effect gets serious, or if you notice any side effect not listed in this leaflet; please tell your doctor, health care provider or your pharmacist.

**In this leaflet:**

1. What CEFAXONE® 1g is and what it is used for
2. Before you use CEFAXONE® 1g
3. How to use CEFAXONE® 1g
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**1. What CEFAXONE® 1g is and what it is used for:**

CEFAXONE® 1g 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 medications called cephalosporins.

CEFAXONE® 1g is used to treat infections of:

- The brain (meningitis).
- The lungs.
- The middle ear.
- The abdomen and abdominal wall (peritonitis).
- The urinary tract and kidneys.
- Bones and joints.
- The skin or soft tissues.
- The blood.
- The heart.

It can be given:

- To treat 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.

**2. Before you use CEFAXONE® 1g**

**a. Do not use CEFAXONE® 1g in the following cases:**

**You must not be given CEFAXONE® 1g if:**

- You are allergic to ceftriaxone or any of the other ingredients of this medication.
- 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 breathe or swallow, sudden swelling of the hands, feet and ankles, and a severe rash that develops quickly.
- You are allergic to lidocaine and you will be receiving CEFAXONE® 1g as an injection into a muscle.

**CEFAXONE® 1g 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 the whites of the eyes).
- Ceftriaxone and products containing calcium should be administered sequentially in infants more than 28 days by washing the injection device with sodium chloride solution 0.9 % between the administrations of both products.

**b. Warnings and precautions of use:**

- Talk to your doctor or pharmacist or nurse before you are given CEFAXONE® 1g if:
  - You have recently received or are about to receive products that contain calcium.
  - You have recently had diarrhea after having an antibiotic medication. You have ever had problems with your gut, in particular colitis (inflammation of the bowel).
  - You have liver or kidney stones.
  - You have gall stones or kidney stones.
  - You have other illnesses, such as hemolytic anaemia (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 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").
- This medicine contains sodium. This medicine contains 83 mg of sodium per vial. To be taken into account in patients controlling their sodium dietary intake.

**If you need a blood or urine test**

If you have had CEFAXONE® 1g for a long time, you may need to have regular blood tests. CEFAXONE® 1g can affect the results of urine tests for sugar and you test known as the Coombs test. If you are having tests:

- Tell the person taking the sample that you have had CEFAXONE® 1g.

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.

• **Children**

**Ceftriaxone and products containing calcium should be administered sequentially in infants more than 28 days by washing the injection device with sodium chloride solution 0.9 % between the administrations of both products.**

Talk to your doctor or pharmacist or nurse before giving CEFAXONE® 1g to your child if:

He/She has recently received or will receive a product that contains calcium by IV way.

**c. Taking other medications, herbal or dietary supplements:**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medications.

In particular, tell your doctor or pharmacist if you are taking any of the following medications:

- A type of antibiotic called an aminoglycoside.
- An antibiotic called chloramphenicol (used to treat infections, particularly of the eyes).

**d. Pregnancy and breast-feeding:**

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 medication.

The doctor will consider the benefit of treating you with CEFAXONE® 1g against the risk to your baby.

**e. Driving and using machines:**

CEFAXONE® 1g 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.

**3. How to use CEFAXONE® 1g**

CEFAXONE® 1g is usually given by a doctor or nurse. It can be given:

- **Through intravenous infusion or slow IV infusion:** by dissolving 50 - 100 ml of sodium chloride 0.9 % or glucose 5% solutions following doctor's instructions.
- **Through intravenous direct injection:** by dissolving the powder in 10 ml of the solvent water for injection: the injection lasts 3 - 5 minutes. Do never use the solvent lidocaine hydrochloride by IV way.
- **Through intramuscular way:** by dissolving the powder in 4 ml of the solvent lidocaine hydrochloride.

**It should be noted that the reconstituted solution must be made with shaking rigorously the solution for at least 2 minutes then letting it rest in order to clear air bubbles.**

CEFAXONE® 1g 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.

**Ceftriaxone should not be mixed with solutions containing calcium as Ringer or Hartman or any other intravenous solutions containing calcium.**

**The usual dose:**

Your doctor will decide the correct dose of CEFAXONE® 1g 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. The number of days or weeks that you are given CEFAXONE® 1g depends on what sort of infection you have.

• **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.

• **Newborn babies, infants and children aged 15 days to 12 years with a body weight of less than 50 kg:**

50 - 80 mg CEFAXONE® 1g 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 with a body weight of 50 kg or more should be given the usual adult dose.

• **Newborn babies (0-14 days)**

20 - 50 mg CEFAXONE® 1g 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 receive a different dose to the usual one. Your doctor will decide how much CEFAXONE® 1g you will need and you will be monitored closely in terms of the severity of the liver and kidney disease.

**a. If you are given more CEFAXONE® 1g than you should:**

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

**b. If you forget to use CEFAXONE® 1g:**

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 doubling dose (two injections at the same time) to make up for a missed dose.

**4. Possible side effects:**

Like all medications, this medication can cause side effects, although not everybody gets them.

The following side effects may happen with this medication:

**Severe allergic reactions (not known, frequency cannot be estimated from the available data)**

If you have a severe allergic reaction, tell a doctor straight away.

The signs may include:

- 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.

**Severe skin reactions (not known, frequency cannot be estimated from the available data)**

If you get a severe skin reaction, tell a doctor straight away.

The signs may include:

- A 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 that 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 CEFAXONE® 1g treatment for infections with spirochete such as Lyme disease.

**Other possible side effects:**

**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 eosinophil) 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 (anaemia).
- 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 CEFAXONE® 1g 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):**

- A secondary infection that may not respond to the antibiotic previously prescribed
- Form of anaemia where red blood cells are destroyed (hemolytic anaemia).
- 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).
- CEFAXONE® 1g may interfere with some types of blood glucose tests - please check with your doctor.

**IF YOU GET ANY SIDE EFFECTS, TALK TO YOUR DOCTOR, PHARMACIST OR NURSE. THIS INCLUDES ANY POSSIBLE SIDE EFFECTS NOT LISTED IN THIS LEAFLET.**

**5. How to store CEFAXONE® 1g**

- Store at less than 30°C temperature and away from light.
- After reconstitution: the solution should be used as soon as reconstituted. However, it can be stored for 6 hours at less than 30°C temperature.

The color of the reconstituted solution can vary from slightly yellow to yellow-brown solution in the above indicated storage conditions.

**6. Further information:**

- a. What CEFAXONE® 1g contains:**
  - Each bottle contains ceftriaxone sodium equivalent to 1g.
  - Sodium content: 83 mg for 1 g.

For one ampoule of solvent: water for injections 10 ml or 4 ml of lidocaine hydrochloride.

**b. What CEFAXONE® 1g looks like and contents of the pack:**

- CEFAXONE® 1g IV: box containing one vial of powder and a bottle of solvent: EPPI 10 ml.
- CEFAXONE® 1g IM: box containing one vial of powder and a bottle of solvent: 4 ml of lidocaine hydrochloride.

**c. Marketing Authorization Holder and Manufacturer:**

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**d. This leaflet was last approved in {12/2023} ; version number {03}.**

**e. Prescription Only Medicine**

**f. Approved in Iraq.**

## THIS IS A MEDICINE

- This is a product that affects your health and not following the method of administration puts you at risk.
- Follow carefully the doctor's prescription, the directions for use and the pharmacist's advice.
- The doctor and the pharmacist are the experts on the medicine and know its benefits and risks.
- Do not stop taking the medicine on your own.
- Do not renew the supply of this medicine without consulting the doctor.
- Keep medicines away from children.

Council of Arab Health Ministers

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Titre :	Notice CEFAXONE® 1g
Version :	03
Date de réalisation :	01/12/2023
Dimension :	190 x 345 mm
Destination (Pays....) :	IRAK



