

Cefotaxime 1 g powder for solution for injection/infusion  
Cefotaxime 2 g powder for solution for injection/infusion  
cefotaxime

**Read all of this leaflet carefully before you are given 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. See section 4.

**What is in this leaflet**

1. What Cefotaxime is and what it is used for
2. What you need to know before you are given Cefotaxime
3. How Cefotaxime is given
4. Possible side effects
5. How to store Cefotaxime
6. Contents of the pack and other information

**1. What Cefotaxime is and what it is used for**

Cefotaxime is an antibiotic, i.e. a medicine which is used for the treatment of bacterial infections of:

- the lungs (pneumonia)
- the skin and soft tissue
- the urinary tract
- the genitals (including gonorrhoea)
- the heart valves (endocarditis)
- the membranes covering the brain (meningitis)
- the abdomen
- the blood (so called 'bacteraemia')

Furthermore cefotaxime is used to treat the Lyme disease (borreliosis, an infection primarily caused by tick bites, e.g. relapsing fever).

Cefotaxime can also be used before and during surgery in order to prevent possible infections.

**2. What you need to know before you are given Cefotaxime**

**You must not be given Cefotaxime if you:**

- are allergic (hypersensitive) to cefotaxime or to any cephalosporin antibiotics or any of the other ingredients of this medicine (listed in section 6).
- have ever had a severe allergic (hypersensitive) reaction to any other type of beta-lactam antibiotic (penicillins, monobactams and carbapenems).
- have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking cefotaxime or other cephalosporins.

Cefotaxime is sometimes mixed with another medicine called lidocaine. In this case do not have this injection if:

- You are allergic to lidocaine or other local anaesthetics
- Your child is younger than 30 months
- You have heart disease, problems with your heartbeat or severe heart failure.

Do not have this medicine if any of the above applies to you. If you are not sure, talk to your doctor or nurse before you are given Cefotaxime.

**Warnings and precautions**

Talk to your doctor, pharmacist or nurse before you are given Cefotaxime:

- if you have allergic reactions. If you have had any allergic reaction to other antibiotics such as penicillin, you may also be allergic to Cefotaxime. If an allergic reaction occurs, treatment must be stopped.
- if you suffer from severe, persistent diarrhoea during or after treatment with Cefotaxime. In this case contact your doctor immediately. Do not take any antidiarrhoea medicine without consulting your doctor.
- if you have a widespread rash with blisters and peeling skin. (These may be signs of Stevens-Johnson syndrome or toxic epidermal necrolysis). Serious skin reactions including Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS), acute generalized exanthematous pustulosis (AGEP) have been reported in association with cefotaxime treatment.

Stop using cefotaxime and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

- if you have kidney problems.
- if you experience e.g. impairment of consciousness, abnormal movements and cramps after being given this medicine.
- if you are on a low salt diet. Then the sodium content of this product must be taken into account.

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

If you are given this medicine over a longer period, your doctor will take additional care and check your blood for possible changes. Also the overgrowth of bacteria that are unsusceptible to cefotaxime must be examined regularly in this case.

**Other medicines and Cefotaxime**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines you buy without a prescription, and herbal medicines.

This is because Cefotaxime can affect the way some other medicines work. Also some medicines can affect the way Cefotaxime works.

In particular, check with your doctor if you are taking any of the following:

- Aminoglycoside antibiotics - including gentamicin, streptomycin, neomycin, kanamycin, amikacin or tobramycin
- Water tablets (diuretics) such as furosemide, etacrynic acid
- Probenecid – used for gout

**Tests**

If you require any tests (such as blood, urine or diagnostic) while taking this medicine, please make sure your doctor knows that you are taking Cefotaxime.

**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 you are given this medicine.

**Driving and using machines**

You may start to move abnormally, suffer from sudden involuntary muscle contractions, dizziness or feel less alert. If this happens, do not drive or use any tools or machines.

**Cefotaxime contains sodium**

This medicine contains 48 mg of sodium (main component of cooking/table salt) in each 1 g of drug. This is equivalent to 2,4% of the recommended maximum daily dietary intake of sodium for an adult.

Medicinal product is administered after reconstitution, see 'The following information is intended for healthcare professionals only'. To count total sodium content in reconstituted solution sodium in dilutant should be considered. For information about sodium content in dilutant please see Patient Information Leaflet of dilutant.

**3. How Cefotaxime is given**

**Administration**

Cefotaxime is always administered by healthcare personnel. This medicine is first dissolved in sterile water or another suitable solution. The solution may be given as an injection or through a tube (infusion) into a vein, for certain infections it may also be injected into a muscle.

**Dosage**

Adults and adolescents over 12 years.  
You usually receive 2 to 6 g cefotaxime daily. The daily dose should be divided in two single doses every 12 hours. The dosage may be varied according to the severity of your infection and your condition:

- Common infections in presence (or suspicion) of sensitive bacteria: 1 g every 12 hours (i.e. total daily dose of 2 g).
- Infections in presence (or suspicion) of several sensitive or moderately sensitive bacteria: 1 – 2 g every 12 hours (i.e. total daily dose of 2 – 4 g).
- Severe infections or for infections that cannot be localised: 2 – 3 g as a single dose every 6 to 8 hours (i.e. a maximum daily dose of 12 g).

Newborns (0 – 28 days), infants and children up to 12 years of age  
The dosage is dependent on the severity of the infection. The usual dosage for newborns, infants and children is 50 to 100 to 150 mg cefotaxime per kg body weight per day, divided into 2 to 4 single doses (i.e. every 12 to 6 hours).

For very severe or life-threatening infections up to 200 mg cefotaxime per kg body weight per day, divided into 2 to 4 single doses, may be required. The doctor will take the differences in maturation of the kidneys and their function into account, especially in newborns from 0 – 7 days.

Premature infants

The recommended dosage is 50 mg per kg body weight per day divided into 2 to 4 doses (every 12 to 6 hours). This maximum dose should not be exceeded due to the not yet fully matured kidneys.

Elderly

Provided that your kidney and liver function is normal, no dosage adjustment is required.

People with kidney and/or liver problems

If you have problems with your kidneys and/ or liver, you may be given a lower dose. You may need to have blood tests to check that you are getting the dose you need. Your doctor will decide on the dose.

**Other special recommendations**

*Gonorrhoea*

You will receive a single injection of 500 mg – 1 g Cefotaxime as an injection into a muscle or a vein for treatment of gonorrhoea.

*Bacterial meningitis*

Adults receive a daily dose of 9 to 12 g cefotaxime divided into equal doses every 6 to 8 hours.



**The following information is intended for healthcare professionals only:**

Cefotaxime 1 g powder for solution for injection/infusion  
Cefotaxime 2 g powder for solution for injection/infusion  
cefotaxime

**Method of administration**

Cefotaxime solutions should never be administered intravenously with lidocaine.

After being properly diluted, the medicine is administered intravenously in a 3–5 minute injection or intramuscularly – deep into the upper outer quadrant of the gluteus maximum or the lateral part of a thigh. The medicine can be given by intravenous infusion over a period of 20–60 minutes.

After the solvent is added to the vial contents, the vial should be shaken until the powder dissolves; the solution should be clear after 1–2 minutes. The solution of the reconstituted product should be inspected visually for clearness and particulate matter prior to administration. If it is cloudy or it contains particulate matter, the solution is not suitable for use. The solution after reconstitution may be colorless to yellow.

**Preparation of solution for injection and infusion**

Antibiotic content per vial	Solvent volume		
	Intramuscular injection	Intravenous injection	Intravenous infusion
1 g	4 ml	10 ml	40-100 ml
2 g	-	10 ml	40-100 ml

**Intramuscular injection**

The contents of 1 g vial should be dissolved in 4 ml of water for injection, 0.9% sodium chloride solution or 1% lidocaine solution. The medicine must not be administered intravenously with lidocaine solution.

**Children** receive 150 to 200 mg per kg body weight divided into equal doses every 6 to 8 hours.

**Newborns:** 0-7 days old babies receive 50 mg per kg body weight every 12 hours, 7 – 28 days old infants every 8 hours.

*Prevention of infections (perioperative prophylaxis)*

You may be given between 1 g and 2 g cefotaxime before an operation for the prevention of possible infections. If the operation lasts longer than 90 minutes, you may be given an additional dose preventively.

*Infections inside the abdomen*

You should be given a combination of cefotaxime and an antibiotic acting against 'anaerobic' bacteria.

**Treatment duration**

Your treatment duration depends on the severity of your infection as well as on your recovery from your illness. You will usually continue to be given the medicine for at least 2 to 3 days after you have started to recover from your illness. Treatment over at least 10 days is necessary in infections caused by the bacterium *Streptococcus pyogenes*.

**If you are given more Cefotaxime than you should**

Tell your doctor or nurse if you think that you have been given too much Cefotaxime.

**If a dose of Cefotaxime has been forgotten**

Please contact your doctor immediately. A double dose must not be given to make up for a forgotten dose. A forgotten dose should be given only if the time until the next regular dose is long enough.

**If you stop using Cefotaxime**

Low dosage, irregular administration or stopping treatment too early can compromise the outcome of the treatment or lead to a relapse, whose treatment is more difficult. Please follow the instructions of your doctor. If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

**4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**Stop taking cefotaxime and tell your doctor immediately if you notice any of the following symptoms:**

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

- Increased tendency to bleed or bruise more easily caused by a fall in the number of blood platelets (thrombocytopenia), fever, sore throat or mouth ulcers due to infections caused by a low level of white blood cells (leucopenia) or high level of a specific type of white blood cells (eosinophilia)

**Not known: frequency cannot be estimated from the available data**

- Inflammation of the bowels, called colitis (or antibiotic-associated colitis), causing severe long-lasting watery or bloody diarrhoea with stomach cramps and fever
- Serious blood problems, including changes in the numbers of some white blood cells (which may cause frequent infections, fever, severe chills, sore throat, or mouth ulcers)
- Damage to red blood cells (causing tiredness, being short of breath or looking pale)
- Severe allergic reactions with symptoms such as swelling of the lips, tongue, face and neck, sudden difficulty in breathing, speaking and swallowing;
- Headache, dizziness, convulsions (fits) (these may be symptoms of a brain disorder called encephalopathy)
- Changes in heart beat (rhythm or rate), after a very quick injection into a vein
- Yellow skin and eyes, loss of appetite, light-coloured urine caused by inflammation of the liver
- Skin rash, which may blister, and looks like small targets (central dark spot surrounded by a paler area, with a dark ring around the edge)
- Reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome, toxic epidermal necrolysis).
- Widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome).
- A red, scaly widespread rash with bumps under the skin and blisters accompanied by fever. The symptoms usually appear at the initiation of treatment (acute generalised exanthematous pustulosis).
- Increased or reduced urine output, or traces of blood in your urine, sometimes with swollen limbs and / or flank pain caused by kidney problems
- For intramuscular injection: combination with lidocaine can cause systemic reactions

**Other possible side effects:**

**Very common: may affect more than 1 in 10 people**

- Intramuscular injection may be painful

**Uncommon: may affect up to 1 in 100 people**

- People being treated for infections with bacteria called spirochetes often show symptoms like fever and shivering which are described as 'Herxheimer reaction' and indicate the effectiveness of the therapy.
- Changes in the results of blood tests that check how the liver and kidneys are working
- Fever

- Allergic reactions such as skin rash (nettle rash), itchy skin
- Painful swelling and inflammation where the injection is given into a vein
- Soft stools or diarrhoea
- Convulsions

**Not known: frequency cannot be estimated from the available data**

- Feeling sick (nausea) and being sick (vomiting)
- Pain in your stomach (abdomen)
- Your doctor may want to perform tests during your treatment to measure any changes.

**Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme, Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

**5. How to store Cefotaxime**

Keep this medicine out of the sight and reach of children.

This medicine does not require any special temperature storage conditions.

Keep the vials in the outer carton in order to protect from light.

After reconstitution:

The prepared solution can be stored in a refrigerator, i.e. at 2°C to 8°C for 24 hours or at a temperature below 25°C:

- for 6 hours for solutions prepared for intramuscular injection and intravenous injection,
- for 12 hours for solutions prepared for intravenous infusion.

The reconstituted product does not require protection from light.

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.

Do not use this medicine after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

**6. Contents of the pack and other information**

**What Cefotaxime contains**

- The active substance is cefotaxime. Each vial contains 1 or 2 g of cefotaxime as cefotaxime sodium.
- This medicine does not contain excipients.

**What Cefotaxime looks like and contents of the pack**

The medicine is a white or slightly yellow powder.  
A package contains 10 vials.

**Marketing Authorisation Holder**

hameln pharma ltd  
Nexus, Gloucester Business Park  
Gloucester, GL3 4AG  
United Kingdom

**Manufacturer**

hameln rds s.r.o.  
Horna 36  
900 01 Modra, Slovakia

**This leaflet was last revised in March 2025.**

118/09/25

**Intravenous injection** (from 3 to 5 minutes)

The contents of a vial should be dissolved in 10 ml of water for injection, 0.9% sodium chloride solution or 5% glucose solution.

**Intravenous infusion** (from 20 to 60 minutes)

In order to prepare solutions of cefotaxime for intravenous infusion, the powder is dissolved in water for injection (in the same way as for intravenous injections). The solution thus obtained should be further diluted with one of the following solutions:

- 0.9% sodium chloride solution,
- 5% glucose solution,
- 5% glucose solution with 0.9% sodium chloride solution 1:1,
- 5% glucose solution with 0.9% sodium chloride solution 2:1,
- Ringer's solution,
- lactated Ringer's solution.

**Incompatibilities**

Aminoglycosides are incompatible with cephalosporins in parenteral mixtures.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.