Package leaflet: Information for the patient

Cefotaxime 500 mg powder for solution for injection/infusion
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
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).

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 anti-diarrhoea 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*).
- 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, streptomicin, 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
500 mg vial: This medicine contains 24 mg sodium (main component of cooking/table salt) in each vial. This is equivalent to 1.2 % of the recommended maximum daily dietary intake of sodium for an adult.
1 g vial: This medicine contains 48 mg sodium (main component of cooking/table salt) in each vial. This is equivalent to 2.4 % of the recommended maximum daily dietary intake of sodium for an adult.
2 g vial: This medicine contains 96 mg sodium (main component of cooking/table salt) in each vial. This is equivalent to 4.8 % of the recommended maximum daily dietary intake of sodium for an adult.

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.
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.

The following information is intended for healthcare professionals only:

Methods of administration

Intravenous injection
In case of intravenous administration, reconstitute Cefotaxime with Water for Injections as given in the below Table. Shake well until dissolved. The reconstitution time is less than 1 minute.

Intravenous administration	Volume of diluent	Nature of diluent
Cefotaxime 500 mg Cefotaxime 1 g Cefotaxime 2 g	2 mL 4 mL 10 mL	Water for Injections

Intramuscular injection
In case of intramuscular administration, reconstitute Cefotaxime with Water for Injections or 1% Lidocaine solution as per Table below. To prevent pain from the injection, a 1% Lidocaine solution may be used alternatively (only for adults). Solutions in lidocaine must not be administered intravenously. The product information of the chosen lidocaine containing solution must be regarded. When using Lidocaine solution as diluent, intravascular injection must be strictly avoided. The 1% Lidocaine solution is only to be used for intramuscular injection of the Cefotaxime 500 mg and Cefotaxime 1 g.

Intramuscular administration	Volume of diluent	Nature of diluent
Cefotaxime 500 mg Cefotaxime 1 g	2 mL 4 mL	Water for Injections or 1 % Lidocaine solution

Reconstituted solution:
When dissolved in Water for Injections or 1 % Lidocaine, a clear, slight yellow to yellow solution is formed.

Intravenous infusion
1 g of cefotaxime should be dissolved in 40 – 50 mL of one of the infusion fluids listed below.
2 g cefotaxime should be dissolved in 100 mL of one of the infusion fluids listed below.

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.
You must contact your doctor immediately if you notice any of the following:
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)
- A widespread rash with blisters and peeling skin. (These may be signs of Stevens-Johnson syndrome or toxic epidermal necrolysis)
- Increased or reduced urinie 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
For UK: Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.
For IE: HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2, Tel: +353 1 6764971; Fax: +353 1 6762517, Website: www.hpra.ie; E-mail: medsafety@hpra.ie.
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:
Chemical and physical in-use stability has been demonstrated for 12 hours at 2 °C – 8 °C after reconstitution with Water for injections and for 6 hours at 2 °C – 8 °C after reconstitution with 1 % Lidocaine.
From a microbiological point of view, unless the method of reconstitution precludes the risk of microbial contamination, the product should be used immediately.
If not used immediately, in-use storage times and conditions are the responsibility of user.
After reconstitution and dilution:
Chemical and physical in-use stability for the diluted medicinal product has been demonstrated between 0.25 mg/mL and 50 mg/mL when stored in polypropylene bags for 24 hours at 2 °C – 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 normally not be longer than 24 hours at 2 – 8 °C, unless reconstitution/dilution has taken place in controlled and validated aseptic conditions.
Do not use this medicine after the expiry date which is stated on the carton and vial label after EXP. 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.
- 500 mg vial: Each vial contains cefotaxime sodium equivalent to 500 mg cefotaxime.
- 1 g vial: Each vial contains cefotaxime sodium equivalent to 1 g cefotaxime.
- 2 g vial: Each vial contains cefotaxime sodium equivalent to 2 g cefotaxime.

What Cefotaxime looks like and contents of the pack
White to slightly yellow powder in a glass vial. Glass vials closed with bromobutyl rubber closures and sealed with aluminium caps with a yellow (for 500 mg), red (for 1 g), grey (for 2 g – 20 mL vial) or dark blue for 2 g – 50 mL vial) flip-top plastic cover.
The medicine is supplied in pack sizes of 1, 5, 10, 25 or 50 vials. Not all pack sizes may be marketed.

Marketing Authorisation Holder: Noridem Enterprises Limited, Evagorou & Makariou, Mitsi Building 3, Office 115, 1065 Nicosia, Cyprus.
Manufacturer: DEMO S.A., PHARMACEUTICAL INDUSTRY, 21st km National Road Athens-Lamia, 14568 Krioneri, Attiki, Greece.

This medicinal product is authorised in the Member States of the EEA under the following names:

Ireland:	Cefotaxime 500 mg, 1 g, & 2 g powder for solution for injection/infusion
France:	CEFOTAXIME NORIDEM 0,5 g, 1 g & 2 g poudre pour solution injectable/pour perfusion
Belgium:	Cefotaxime Noridem 500 mg, 1000 mg & 2000 mg poudre pour solution injectable / pour perfusion - poeder voor oplossing voor injectie / infusie - Pulver zur Herstellung einer Injektions-/ Infusionslösung
Luxemburg:	CEFOTAXIME NORIDEM 0,5 g, 1 g & 2 g poudre pour solution injectable/pour perfusion
United Kingdom:	Cefotaxime 500 mg, 1 g, & 2 g powder for solution for injection/infusion
Greece:	OXIMEZIN 0,5 g, 1 g & 2 g Κόνις για ενέσιμο διάλυμα / διάλυμα προς έγχυση
Cyprus:	OXIMEZIN 0,5 g, 1 g & 2 g Κόνις για ενέσιμο διάλυμα / διάλυμα προς έγχυση

This leaflet was last revised in 04/2020.

Compatibility with infusion fluids
Whilst it is preferable to use immediately the prepared solutions for both intravenous and intramuscular injection, Cefotaxime is compatible with several commonly used intravenous infusion fluids stored in polypropylene bags and will retain satisfactory potency for up to 24 hours refrigerated (2 °C – 8 °C) in the following:
- Water for Injections
- Sodium Chloride Injection
- 5% Dextrose Injection
- Dextrose and Sodium Chloride Injection
- Compound Sodium Lactate Injection (Ringer-lactate Injection)

Cefotaxime is also compatible with metronidazole infusion (500 mg/100 mL) and both will maintain potency when refrigerated (2 °C – 8 °C) for up to 24 hours.

The product should be inspected visually for particles. Only clear solution free from particles or precipitates should be used.

For single use only.

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.