Package leaflet: Information for the user

Cefotaxime 500mg, 1g Powder for solution for injection or infusion

Read all of this leaflet carefully before you start taking this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or your pharmacist.
- This medicine 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 of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or your pharmacist.

In this leaflet:

The name of your medicine is "Cefotaxime powder for solution for injection or infusion" (referred to as **Cefotaxime Injection** throughout this leaflet).

1. WHAT CEFOTAXIME INJECTION IS AND WHAT IT IS USED FOR

Cefotaxime is an antibiotic. It belongs to a group of antibiotics that are called cephalosporins. These types of antibiotic are similar to penicillin.

Cefotaxime kills bacteria and it can be used to treat infections of the:
- Kidneys and bladder
- Blood (septicaemia)
- Skin and flesh immediately under the skin
- Bones
- Heart valves
- Brain (meningitis)
- Abdomen (peritonitis)
- Some sexually transmitted infections (gonorrhoea)

It can also be used to prevent and treat infections following surgical operations.

2. BEFORE YOU ARE GIVEN CEFOTAXIME INJECTION

You should not be given Cefotaxime injection if:
- you are allergic (hypersensitive) to cefotaxime
- you are allergic to any similar antibiotics (known as "cephalosporins")
- you have ever had a serious allergic reaction when given penicillin or similar antibiotics
- you are allergic to lidocaine
- you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking cefotaxime or other cephalosporins.

Tell your doctor or nurse if any of the above apply to you.

Before you are given Cefotaxime injection
You must tell the doctor or nurse if any of the following apply to you:
- you have a history of allergies or asthma
- you are on a low sodium diet
- you have a heart or kidney disorder

- you are having any blood or urine tests
- you have a history of gastro-intestinal problems e.g. colitis, which causes diarrhoea containing blood.

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.

Taking other medicines
Tell the doctor or nurse if you are taking any of the following medicines:
- the contraceptive pill (in which case you will need to take extra contraceptive precautions such as using a condom)
- any diuretic medicine ("water tablets") e.g. furosemide
- another antibiotic e.g. chloramphenicol or aminoglycoside antibiotics
- probenecid (for gout)

Please tell your doctor if you are taking, or have recently taken, any other medicines including any that you may have bought without a prescription.

Pregnancy and breast-feeding
If you are pregnant, think you might be pregnant or are breastfeeding, you must tell your doctor before you are given this medicine.

Driving and using machines
If you are given high doses of cefotaxime, you may feel dizzy/drowsy or fall asleep or experience convulsions (fits) or unusual body movements. If this happens, you should not drive or operate machinery.

Important information about some of the ingredients of Cefotaxime injection
Cefotaxime Injection contains approximately 50mg (2.2 mmol) of sodium per 1g dose. This should be taken into consideration by patients on a controlled sodium diet. Tell your doctor or nurse if you are on a low sodium diet.

3. HOW CEFOTAXIME INJECTION IS GIVEN

Cefotaxime Injection is supplied as a powder so before it can be given it must be diluted and made into a solution. Your doctor or nurse normally does this. They will inject this directly into a vein (intravenous) or muscle (intramuscular). It may also be given by an intravenous infusion ("drip").

Your doctor will decide how much you need and how often the injections should be given.
The usual doses are given below but doctors may prescribe different doses depending on the severity and type of your infection, your weight, your age and how well your kidneys are working.

Treatment with Cefotaxime injection is usually continued for 2-3 days after you start to recover from your illness or after your operation.

Adults and children over 12 years old:
The usual dose is 1 g every twelve hours. In some patients where infections are severe, the doctor may give a higher dose up to 12g every day.
For the treatment of gonorrhoea, a single 500mg dose is usually given.
To prevent an infection after surgery, 1 -2 g is given before the operation. A second dose may be needed after the operation.

Infants and children up to 12 years old:

The usual daily dose is 50 mg to 100 mg Cefotaxime per kilogram of their bodyweight. This is usually split into 2 doses each day. Severely ill children may receive up to 200 mg per kg bodyweight daily (to a maximum of 6 g daily), split into 3 separate doses.

Young babies (newborn):
The daily dose should not normally exceed 50 mg Cefotaxime per kg of their bodyweight.

Patients with kidney problems:
Lower doses may be given if you have severe kidney problems. Patients on dialysis machines will be monitored for the correct dose.

If you think you have missed an injection
This is unlikely as you will probably receive this medicine in hospital. If you think you have missed a dose, speak to your doctor or nurse.

If you have been given more of this medicine than you should
This is unlikely to happen but if it does, the doctor will treat any symptoms that follow.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Cefotaxime Injection 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:
- 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).

As with other antibiotics, some people find they have an allergy to it. Tell your doctor immediately if any of the following rare symptoms occur:
- Sudden wheeziness and tightness of chest
- Swelling of eyelids, face, lips or throat
- Skin lumps or “hives” (nettle rash)
- Severe skin rashes with itching
- Serious illness with blistering of the skin, mouth, eyes and genitals
- Loss of consciousness, abnormal movements or convulsions (fits)

Antibiotic treatment can affect the normal bacteria in the gut, causing new infection (colitis). You should tell your doctor **immediately** if you develop diarrhoea.

The following side effects may occur in some patients treated with Cefotaxime injection. Tell your doctor if any become troublesome:

Very common side effects (probably affecting more than 1 in 10 people)
- pain at the injection site

Uncommon side effects (probably affecting less than 1 in 100 patients)
- reduction in blood platelets which increases risk of bruising or bleeding
- reduction in number of white blood cells which makes infections more likely
- increase in number of white blood cells
- fever
- increase in liver enzymes and/or bilirubin
- kidney problems

- skin rash, itching, ‘hives’ (nettle rash)
- difficulty breathing
- convulsions (fits)
- diarrhoea
- redness and swelling at injection site

Side effects occurring with unknown frequency
- secondary infections
- serious allergic reactions which may cause difficulty in breathing or dizziness
- serious allergic reaction which causes swelling of the face or throat
- difficulty in breathing or wheezing
- headache
- dizziness
- loss of consciousness, abnormal movements
- feeling sick (nausea)
- being sick (vomiting)
- stomach pains
- diarrhoea containing blood
- inflammation of the liver (hepatitis)
- skin and whites of the eyes turn yellow (jaundice)
- painful joints
- irregular heart rhythm
- inflammation of the kidneys which may cause dark discolouration of urine, cloudy/bloody urine, or any change in your urine output.

Treatment with high doses of Cefotaxime, particularly in patients with kidney problems, has been known to cause loss of consciousness, abnormal movements and convulsions (“fits”).

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 the Yellow Card Scheme, Website: 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 INJECTION

Keep out of the reach and sight of children.
Do not use Cefotaxime injection after the expiry date which is printed on the label and carton.
Do not store above 25°C. Keep the vial in the outer carton.
Your doctor, pharmacist or nurse will know how to store Cefotaxime injection properly.

6. FURTHER INFORMATION

What Cefotaxime injection contains:
Each vial contains 500mg or 1g Cefotaxime (as Cefotaxime sodium).
There are no other ingredients.

What Cefotaxime injection looks like and contents of the pack:
Cefotaxime injection is a white to slightly yellow powder in a glass vial.
Each carton contains 1, 10, 25 or 50 vials. Not all pack sizes may be marketed.

Marketing Authorisation Holder:
Istituto Biochimico Italiano G. Lorenzini S.p.A.,
Via Fossignano 2,
04011 Aprilia (LT), Italy

Manufacturers:
Anfarm Hellas S.A.,
Shimatari Viotias,
320 09 Greece

ACS DOBFAR S.p.A,
Nucleo Industriale S. Atto,
San Nicolò a Tordino, 64100 Teramo – Italy

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INFORMATION FOR THE HEALTHCARE PROFESSIONAL

The following information is intended for medical or healthcare professionals only.

Storage precautions:
Unopened vial: Do not store above 25°C. Keep container in the outer carton.
Following reconstitution: 2°C - 8°C.

Instructions for use and handling
Following reconstitution: Cefotaxime sodium is compatible with the following diluents:
Water for Injections
Sodium Chloride 0.9%
Dextrose 5 and 10%
Ringer's Solution
Ringer-Lactate Solution
Lidocaine 1% (only freshly prepared solutions should be used)

Chemical and physical in-use stability has been demonstrated for 24 hours at 2°C-8°C. However, 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 should not exceed 24 hours at 2°C-8°C. After 24 hours any unused solution should be discarded.

Preparation and administration of Cefotaxime Injection

Cefotaxime (as Cefotaxime sodium) per vial	Diluent to be added	Final concentration of solution
500mg	2ml	500mg/ 2.2ml
1g	4ml	1g/4.4ml

Intravenous Injection
Cefotaxime 500mg is dissolved in at least 2 ml water for injections, Cefotaxime 1 g in at least 4 ml and subsequently injected directly into the vein over 3 to 5 minutes or after clamping of the infusion tube into the distal end of the tube. During post-marketing surveillance, potentially life-threatening arrhythmia has been reported in a very few patients who received rapid intravenous administration of cefotaxime through a central venous catheter.

Intravenous Infusion
For brief infusion 2g of Cefotaxime is dissolved in 100 ml of isotonic sodium chloride or glucose solution and subsequently IV infused over 50 to 60 minutes. Another compatible infusion solution can also be used for the solution.

Intramuscular Injection
For intramuscular injection. Cefotaxime 500mg is dissolved in 2 ml and Cefotaxime 1 g in 4 ml water for injections respectively. Afterwards the injection should take place deep into the gluteal muscle. Pain with the IM injection can be avoided by dissolving Cefotaxime 500mg in 2ml or Cefotaxime 1 g in 4 ml 1% lidocaine solution. An intravascular injection is to be avoided in this case, since with intravascular administration lidocaine may lead to unrest, tachycardia, disturbances of cardiac conduction as well as vomiting and cramp. Cefotaxime reconstituted with lidocaine should not be administered in children under 30 months.

It is recommended that no more than 4 ml be injected unilaterally. If the daily dose exceeds 2 g Cefotaxime or if Cefotaxime is injected more frequently than twice per day, the IV route is recommended.

<u>Combination Therapy</u>

Combination therapy of Cefotaxime with aminoglycosides is indicated without availability of an antibiogram in the case of severe, life-threatening infections. Kidney function must be watched in such combination usage. Cefotaxime and aminoglycosides should not be mixed in the same syringe or infusion fluid.

In cases of infections with Pseudomonas aeruginosa combination with other antibiotics effective against Pseudomonas can also be indicated.

For infection prophylaxis (peri-operative prophylaxis in surgical procedures such as colorectal, gastrointestinal, prostatic, urogenital, obstetric and gynaecological surgery) in patients with weakened defence mechanisms, combination can also be indicated with other suitable antibiotics.

Posology
Cefotaxime sodium may be administered intravenously, by bolus injection or infusion, or intramuscularly. The dosage, route and frequency of administration should be determined by the severity of infection, the sensitivity of causative organisms and condition of the patient. Therapy may be initiated before the results of sensitivity tests are known.
The clinician should consult published protocols for information on dosage regimens in specific conditions such as gonorrhoea, Pseudomonas infections and CNS infections.

Dosage and type of administration depend on the severity of the infection, the sensitivity of the bacterium and the condition of the patient.

The duration of the treatment depends on the course of the disease. As a general rule Cefotaxime is administered for a further 3 to 4 days after improvement/regression of the symptoms.

Adults and children over 12 years in general receive 1 g Cefotaxime every 12 hours. In severe cases, the daily dose can be increased up to 12 g. Daily doses up to 6 g can be divided into at least two individual administrations at 12 hourly intervals. Higher daily doses must be divided into at least 3 to 4 individual administrations at 8 or 6 hour intervals respectively.

The following table may serve as a guide to dosages:

Type of Infection	**Single Dose Cefotaxime**	**Dose Interval**	**Daily Dose Cefotaxime**
Typical infections, in which sensitivity is demonstrated and bacterium is proven or suspected	1 g	12 h	2 g
Infections, in which various bacteria with high to medium sensitivity are demonstrated or suspected	2 g	12 h	4 g
Unclear bacterial illness which cannot be localised and where the patient is critically ill	2-3 g	8 h up to 6 h up to 6 h	6 g up to 8 g up to 12 g

For the treatment of gonorrhoea in adults, 1 vial of Cefotaxime 500mg administered as a single administration.

In most cases due to less sensitive infective bacteria, an increase may be necessary, i.e. 1 g Cefotaxime. Examination for syphilis needs to be carried out before commencing therapy.

Perioperative Infection Prophylaxis
For peri-operative infection prophylaxis the administration of a single dose of 1 to 2 g Cefotaxime 30 to 60 minutes prior to the operation is recommended. Another antibiotic to cover anaerobic organisms is necessary. A repeat dose is required if the duration of the operation exceeds 90 minutes.

Special Dose Recommendations
Lyme borrelisosis: A daily dose of 6 g Cefotaxime (14 to 21 days duration). The daily dose was generally administered divided into 3parts (2 g Cefotaxime 3 times daily).

Infants and children up to 12 years receive 50 to 100 mg Cefotaxime according to the severity of the infection (up to 150 mg) per kilogram of body weight per day, divided into equal doses, administered at 12 (up to 6) hour intervals. In individual cases - particularly in life threatening situations - it may be necessary to increase the daily dose to 200 mg Cefotaxime per kilogram of body weight.

In neonates and infants doses of 50 mg Cefotaxime per kilogram of body weight per day should not be exceeded in view of not fully matured kidney clearance.

In case of life-threatening situations it may be necessary to increase the daily dose.
In those situations the following table is recommended.

Age Daily Dose of Cefotaxime

Age	**Daily Dose of Cefotaxime**
0 - 7 days	50 mg/kg every 12 hours IV
7 days - 1 month	50 mg/kg every 8 hours IV
> 1 month	75 mg/kg every 8 hours IV

It is not necessary to differentiate between premature and normal gestational age infants.

Dosage in the Case of Impaired Renal Function
With patients with a creatinine clearance of 20ml/minute or less, the maintenance dose is reduced to half the normal dose. With patients with a creatinine clearance of 5ml/minute or less, a reduction of the maintenance dose to 1 g Cefotaxime (divided into two individual administrations at 12 hour intervals), seems to be appropriate. The stated recommendations are based on experience with adults.

Since Cefotaxime is to a large extent eliminated by haemodialysis, an additional dose should be administered to patients who are dialysed, after the dialysis procedure.

Elderly Patients
No dosage adjustments are needed in patients with normal function.

Other Advice
Electrolyte content of the injection solutions: Since Cefotaxime is available as the sodium salt, the sodium content per dose should be taken into account within the framework of the overall therapy and with special balance checks.

Basis for calculation: 1 g Cefotaxime (equivalent to 1.04 g Cefotaxime sodium) should be calculated as 48 mg sodium equivalent to 2.1 mmol sodium.