PACKAGE LEAFLET: INFORMATION FOR THE USER

Cefotaxime 500 mg powder for solution for injection or infusion

Cefotaxime 1 g powder for solution for injection or infusion

Read all of this leaflet carefully before you start to take this medicine.
- Keep this leaflet. You may need to read it again while you are receiving your treatment.
- If you have any further questions, please ask your doctor or nurse.
- 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 pharmacist.

The name of your medicine is cefotaxime 500 mg or 1 g powder for solution for injection or infusion. In the rest of this leaflet it is called cefotaxime for injection.

In this leaflet:

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

Cefotaxime belongs to a group of medicines called cephalosporins which are antibiotics. These medicines work by killing bacteria that cause infections.

Cefotaxime for injection is used for the treatment of a range of serious bacterial infections including infections of the blood stream (septicaemia), bones (osteomyelitis), the heart valves (endocartitis), the membranes covering the brain (meningitis) and the lining of the abdomen (peritonitis), and to prevent and treat infections following surgical operations.

2. BEFORE YOU ARE GIVEN CEFOTAXIME FOR INJECTION

Do not use Cefotaxime for Injection:
- if you are allergic to cefotaxime or any of the other ingredients of this medicine (listed in section 6). Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- if you are allergic to cephalosporins.
- if you have ever developed a severe skin rash or skin peeling and/or mouth sores after taking cefotaxime or other cephalosporins.
- Cefotaxime for Injection is sometimes mixed with 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 having Cefotaxime for Injection.

Warnings and precautions
Talk to your doctor or pharmacist before using Cefotaxime for Injection if:
- you are allergic to antibiotics, particularly an antibiotic called penicillin
- you have kidney problems
- you have ever had severe diarrhoea after taking some antibiotics (‘Pseudomembranous colitis’). If you experience severe diarrhoea, you should contact your doctor straight away as you may need urgent medical attention.

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
Please tell your doctor or nurse if you are taking or have recently taken any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because Cefotaxime for Injection can affect the way some other medicines work. Also some medicines can affect the way Cefotaxime for Injection 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 to prevent 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 for Injection.

Cefotaxime for injection contains sodium
The 500 mg vial contains 24 mg sodium (main component of cooking/table salt) per vial. This is equivalent to 1.2% of the recommended maximum daily dietary intake of sodium for an adult.
The 1 g vial contains 48 mg sodium (main component of cooking/table salt) per vial. This is equivalent to 2.4% of the recommended maximum daily dietary intake of sodium for an adult.

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, nurse or pharmacist for advice before taking 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.

3. HOW CEFOTAXIME FOR INJECTION SHOULD BE GIVEN

Your doctor or nurse will prepare your injection by dissolving the cefotaxime powder in a suitable fluid for injection. The mixture is usually injected intramuscularly (into a muscle) or given intravenously (into a vein) either by injection or infusion (drip).

Cefotaxime which has been dissolved in a solution which contains Lidocaine injection BP, (a local anaesthetic), should not be given intravenously, or to infants under 30 months, or to patients who are allergic to Lidocaine injection BP, or who have heart block (without a pacemaker), or heart failure.

Adults and the Elderly
The usual adult (including the elderly) dose by intramuscular or intravenous injection is 1 g every twelve hours. Lower doses may be given to patients with severe kidney problems.

Children
The usual dose for children aged one month to twelve years is 100-150 mg per kg body weight daily in two to four divided doses.
The usual dose for infants aged one to four weeks is 50 mg per kg body weight in two or four divided doses.

Higher doses may be given, particularly in severe infections.

Your doctor will decide the dose that is best for you. If you do not understand, or are in any doubt, ask your doctor or nurse.

If you think you have been given too much or too little cefotaxime for injection
Your doctor will decide which dose is best for you. If you think too much or too little medicine has been given to you contact your doctor, nurse, pharmacist or nearest hospital.

4. POSSIBLE SIDE EFFECTS

Like all medicines, cefotaxime for 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).

Tell your doctor straight away if you notice any of the following serious side effects – you may need urgent medical treatment if:
- You have an allergic reaction. The signs may include: rash, itching, fever, difficulty in breathing or wheezing, chills, swelling. (Not known: frequency cannot be estimated from the available data).
- You have sudden involuntary muscle contractions or begin to lose consciousness. This is called “encephalopathy”. (Not known: frequency cannot be estimated from the available data).
- Irregular heartbeat (palpitations). (Not known: frequency cannot be estimated from the available data).
- Severe watery diarrhoea, possibly with blood and mucus (‘Pseudomembranous colitis’). (Not known: frequency cannot be estimated from the available data).
- You notice changes in the way your kidneys are working. (Uncommon: may affect up to 1 in 100 people).

Tell your doctor or nurse if any of the following side effects get serious or lasts longer than a few days:

Very common: may affect up to 1 in 10 people
- Intramuscular injection may be painful

Uncommon: may affect up to 1 in 100 people
- You bruise more easily and get more infections than usual. This could be because of a blood disorder.
- Reactions at the site of injection including reddening of the skin, pain or swelling.
- Diarrhoea.
- Fits.
- Skin rash, itching, hives.
- Fever.

Not known: Frequency cannot be estimated from the available data
- Feeling or being sick (vomiting), stomach pain.
- Dizziness or headache.
- Liver problems such as jaundice or hepatitis that may cause your eyes or skin to go yellow and your urine to become darker.
- Difficulty breathing, wheezing, tightness in the chest (something called “bronchospasm”).
- Blood in your urine. This could be due to a kidney problem (called “interstitial nephritis”).
- Infection.

Other side effects include:

Uncommon: may affect up to 1 in 100 people
- Blood and kidney problems or changes in the way your kidney works. These would show up in the results of blood tests.
- A Jarisch-Herxheimer reaction that may cause skin rash, itching, fever, blood and liver problems, difficulty in breathing and joint discomfort.

Not known: Frequency cannot be estimated from the available data
- Thrush.

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 national reporting system listed below.

Ireland
HPRA Pharmacovigilance
Website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE CEFOTAXIME FOR INJECTION

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

- This medicine should not be used after the expiry date (EXP) shown on the vial and carton. The expiry date refers to the last day of that month.
- The vials should not be stored above 25^{o}C.
- Keep the vial in the outer carton in order to protect from light.
- Chemical and physical in-use stability has been demonstrated for 24 hours at 2-8^{o}C. From a microbiological point of view, once opened, 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^{o}C, unless reconstitution has taken place in controlled and validated aseptic conditions. For single use only. Once reconstituted, any unused portion of solution should be discarded.
- Do not use cefotaxime for injection if the solution contains particles or is cloudy

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What cefotaxime for injection contains
Cefotaxime for injection contains the active ingredient cefotaxime as cefotaxime sodium. Each vial contains 500 mg or 1 g of cefotaxime. The sodium content per vial is approximately 24 mg (1.045 mmol) and 48 mg (2.09 mmol) respectively.

What cefotaxime for injection looks like and contents of the pack
Cefotaxime for injection is an off white to pale yellow powder, which must be made into a solution before injection. It is available in packs of 1, 10, 25 and 50 vials.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Pinewood Laboratories Ltd., Ballymacarbry, Clonmel, Co. Tipperary, Ireland.

Manufacturer
Labesfal - Laboratorios Almiro, S.A, Zona Industrial do Lagedo, Santiago de Besteiros, 3465-157, Portugal.

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Information for Health Care Professionals

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Dosage and Administration Information Only
Please refer to the Summary of Product Characteristics for further information

- **Posology and method of administration**

Cefotaxime may be administered intravenously, by bolus injection or by infusion, or by intramuscular injection. 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.

Adults:
The recommended dosage for mild to moderate infections is 1 g 12 hourly. However, dosage may be varied according to the severity of the infection, sensitivity of causative organisms and condition of the patient. Therapy may be initiated before the results of the sensitivity tests are known.

In severe infections dosage may be increased up to 12 g daily given in three or four divided doses. For infections caused by sensitive Pseudomonas species daily doses of greater than 6 g will usually be required.

Children:
The usual dosage range is 100-150 mg/kg/day may be required. However, in very severe infection doses of up to 200 mg/kg/day may be required.

Neonates:
The recommended dosage is 50 mg/kg/day in two to four divided doses. In severe infections 150-200 mg/kg/day, in divided doses, have been given.

Dosage in renal impairment: Because of extra-renal elimination, it is only necessary to reduce the dosage of cefotaxime in severe renal failure (G=FR <5 ml/ min = serum creatinine approximately 751 micromol/litre). After an initial loading dose of 1 g, daily dose should be halved without change in the frequency or dosing, i.e. 1 g twelve hourly becomes 0.5 g twelve hourly, 1 g eight hourly becomes 0.5 g eight hourly etc. As in all other patients, dosage may require further adjustment according to the course of the infection and the general condition of the patient.

Dosage in hepatic impairment: No dosage adjustment is required.

Intravenous and Intramuscular Administration: Reconstitute cefotaxime with Water for Injections PhEur as discussed below in the section entitled 'Instructions for use/handling'. Shake well until dissolved and then withdraw the entire contents of the vial into the syringe.

Intravenous administration (Injection or Infusion): Cefotaxime may be administered by intravenous infusion using the fluids stated below in the section entitled 'Instructions for use/handling'. The prepared infusion may be administered over 20-60 minutes.

For intermittent I.V. injections, the solution must be injected over a period of 3 to 5 minutes. During post-marketing surveillance, potentially life-threatening arrhythmia has been reported in very few patients who received rapid intravenous administration of cefotaxime through a central venous catheter.

Cefotaxime and aminoglycosides should not be mixed in the same syringe or perfusion fluid.

- **Incompatibilities**

Cefotaxime sodium should not be mixed with alkaline solutions such as sodium bicarbonate injection or solutions containing aminophylline.

Cefotaxime should not be admixed with aminoglycosides. If they are used concurrently they should be administered in separate sites.

Cefotaxime should not be mixed with other medicinal products except those listed below in the section entitled 'Instructions for use/handling'.

- **Shelf life and special precautions for storage**

Unopened: 2 years. Do not store above 25^{o}C. Keep the vials in the outer carton.

For the reconstituted solution, chemical and physical in-use stability has been demonstrated for 24 hours at 2-8°C. From a microbiological point of view, once opened, 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 has taken place in controlled and validated aseptic conditions.

- **Instructions for use/handling**

For single use only. Discard any unused contents.

When dissolved in Water for injections PhEur, cefotaxime forms a straw-coloured solution suitable for intravenous and intramuscular injection. Variations in the intensity of colour of the freshly prepared solutions do not indicate a change in potency or safety.

Dilution Table: Intravenous Administration

Vial size	Diluent* to be added	Approx available volume	Approx displacement volume
500 mg	2 ml	2.3 ml	0.3 ml
1 g	4 ml	4.6 ml	0.6 ml

***Water for injection

Dilution Table: Intramuscular Administration

Vial size	Diluent* to be added	Approx available volume	Approx displacement volume
500 mg	2 ml	2.3 ml	0.3 ml
1 g	4 ml	4.6 ml	0.6 ml

***Water for injection or 1% lidocaine

Reconstituted solution: Whilst it is preferable to use only freshly prepared solutions for both intravenous and intramuscular injection, cefotaxime is compatible with several commonly used intravenous infusion fluids and will retain satisfactory potency for up to 24 hours refrigerated in the following:

Water for Injection Ph Eur
Sodium Chloride Intravenous Infusion BP
5% Glucose Intravenous Infusion BP
Sodium Chloride and Glucose Intravenous Infusion BP
Compound Sodium Lactate Intravenous Infusion BP (Ringer-lactate solution for injection)

Intravenous Infusion:
1 g cefotaxime is dissolved in 40 ml of infusion fluid.
After 24 hours any unused solution should be discarded.

Cefotaxime is compatible with 1% lidocaine; however freshly prepared solutions should be used.

Cefotaxime is compatible with metronidazole infusion (500 mg/100 ml) and both will maintain potency when refrigerated (2°-8°C) for up to 24 hours. Some increase in colour of prepared solutions may occur on storage. However, provided the recommended storage conditions are observed, this does not indicate change in potency or safety.

This leaflet was last revised in 05/2024.

The information in this leaflet applies only to Cefotaxime Powder for solution for injection or infusion.