PACKAGE LEAFLET: INFORMATION FOR THE USER

Cefotaxime 500mg powder for solution for injection or infusion
Cefotaxime 1g powder for solution for injection or infusion
Cefotaxime 2g 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 500mg, 1g or 2g powder for solution for injection or infusion. In the rest of this leaflet it is called cefotaxime for injection.

What is 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. What you need to know before you are given cefotaxime for injection

Cefotaxime for injection should not be given if:
- You are allergic to cefotaxime or any other cephalosporin
- You have previously had a severe allergic reaction to penicillin or any other beta-lactam antibiotic
- You have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking cefotaxime or other cephalosporins.

If any of the above applies to you, you should not be given Cefotaxime for Injection.

Take special care with cefotaxime for injection if:
- you have previously had an allergic reaction to penicillin or other antibiotics of this type. Not all people who are allergic to penicillins are also allergic to cephalosporins. Before you are given this medicine your doctor should check whether you have previously had an allergic reaction to such drugs
- you have kidney problems. You will be carefully monitored throughout your treatment
- you are on a low salt diet, your doctor should make sure you are not receiving too much salt by way of cefotaxime injections
- you are being treated for longer than 10 days, your doctor should monitor your blood with blood counts
- you are going to have a blood transfusion, make sure that the doctor who organises your transfusion knows that you are having cefotaxime for injection
- you are diabetic, you may get false positive results with urine glucose tests, such as Clinitest
- you are taking aminoglycosides such as streptomycin and gentamicin. Your kidney function will be carefully monitored.

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.

You should be kept under observation in case you develop another infection, particularly colitis (infection of the lower bowel), while you are being treated with cefotaxime for injection.

Other medicines and cefotaxime
Taking other medicines when cefotaxime for injection is being administered can affect how it or the other medicine works. Make sure that your doctor knows what other medicines you are taking. Do not take any other medicines while you are being treated with cefotaxime for injection unless you have told your doctor or pharmacist and asked their advice. This includes medicines you may have bought yourself without a prescription.

Please check with your doctor if you are taking any of the following (or any other medication):
- Penicillin antibiotics such as mezlocillin and azlocillin
- Aminoglycoside antibiotics such as streptomycin, neomycin or gentamicin
- Furosemide or other strong diuretics, used to get rid of excess water from the body
- Probenecid, used to prevent gout.

If you have any doubts about whether you should be given this medicine, then talk to your doctor.

Important information about some of the ingredients of cefotaxime for injection

Cefotaxime for injection contains 1.045mmol (or 24mg) for the 500mg vial, 2.09mmol (or 48mg) for the 1g vial and 4.18mmol (or 96mg) for the 2g vial of sodium per dose. To be taken into consideration by patients on a controlled sodium diet.

Pregnancy and breast-feeding
You should let your doctor or nurse know if you are pregnant or wish to become pregnant or are breast-feeding before this medicine is administered.

Driving and using machines
Cefotaxime for injection may cause dizziness. If you are affected you should not drive or operate machinery.

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 1g 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 100-150mg per kg body weight daily in two to four divided doses.
The usual dose for infants aged one to four weeks is 50mg 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 many medicines, cefotaxime for injection may cause side effects in some patients, particularly when treatment is first started. You should inform your doctor or nurse immediately if you are unwell.
These include:
- Allergic reactions such as rash, itching, fever and, very rarely, peeling skin, swelling of the face and difficulty breathing. Tell your doctor immediately if you think you are having an allergic reaction to cefotaxime
- Feeling sick, being sick, stomach pain and diarrhoea, particularly when it is first given
- The injection site may be sore
- Other side effects that some patients have had with cefotaxime for injection, particularly if given over long periods, include headaches, dizziness, anaemia or other changes in the blood (which can cause sore throat and mouth ulcers or a tendency to bleed or bruise easily), temporary changes in liver function, inflammation of the liver, kidney problems, jaundice, painful joints and thrush
- Treatment with high doses of cefotaxime, particularly in patients with kidney problems, has been known to cause loss of consciousness, abnormal movements and convulsions
- Occasionally, patients have suffered a blood clot in a vein or irregular heart rhythm after intravenous cefotaxime
- Administration of high doses in patients with kidney problems may cause brain disease
- Antibiotic treatment can affect the normal bacteria in the gut, causing new infection (colitis). You should tell your doctor immediately if you develop diarrhoea, abdominal cramps or pain, nausea, dehydration, fever or bloody, watery diarrhoea. Do not take any anti-diarrhoea medicines, such as loperamide
- Occasionally, if you have had an intravenous injection there may be swelling around the area of infection or inflammation of the vein.

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).

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.

Information for Health Care Professionals

Cefotaxime 500mg powder for solution for injection or infusion
Cefotaxime 1g powder for solution for injection or infusion
Cefotaxime 2g powder for solution for injection or infusion

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

WARNING - Cefotaxime diluted in lidocaine must not be administered:
- intravenously
- to infants under 30 months
- to patients who are allergic to lidocaine
- to patients who have heart block (without a pacemaker), or heart failure

• 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 1g 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 12g daily given in three or four divided doses. For infections caused by sensitive Pseudomonas species daily doses of greater than 6g will usually be required.

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

Neonates:
The recommended dosage is 50mg/kg/day in two to four divided doses.
In severe infections 150-200mg/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 <5ml/ min = serum creatinine approximately 751 miocromol/litre). After an initial loading dose of 1g, daily dose should be halved without change in the frequency or dosing, i.e. 1g twelve hourly becomes 0.5g twelve hourly, 1g eight hourly becomes 0.5g eight hourly, 2g eight hourly become 1g 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 in the section entitled 'Instructions for use/handling'.

• Shelf life and special precautions for storage
Unopened: 2 years. Do not store about 25°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
500mg	2ml	2.3ml	0.3ml
1g	4ml	4.6ml	0.6ml
2g	10ml	11.4ml	1.4ml

*Water for injection

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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°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°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. 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 further information

What cefotaxime for injection contains
Cefotaxime for injection contains the active ingredient cefotaxime as cefotaxime sodium. Each vial contains 500mg, 1g or 2g of cefotaxime. The sodium content per vial is approximately 24mg (1.045mmol), 48mg (2.09mmol) and 96mg (4.18mmol) 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.

X-PIL information
To listen to or request a copy of the leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK only)

Please be ready to give the following information:

Product name Reference number	
Cefotaxime 500mg powder for solution for injection or infusion	PL 29831/0030
Cefotaxime 1g powder for solution for injection or infusion	PL 29831/0030
Cefotaxime 2g powder for solution for injection or infusion	PL 29831/0029

This is a service provided by the Royal National Institute of Blind People.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder: Wockhardt UK Ltd, Ash Road North, Wrexham, LL13 9UF, UK.

Manufacturer: CP Pharmaceuticals Ltd, Ash Road North, Wrexham, LL13 9UF, UK.

This leaflet was last revised in 03/2024

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Dilution Table: Intramuscular Administration

Vial size	Diluent* to be added	Approx available volume	Approx displacement volume
500mg	2ml	2.3ml	0.3ml
1g	4ml	4.6ml	0.6ml
2g	10ml	11.4ml	1.4ml

*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:
1-2g cefotaxime are dissolved in 40-100ml 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.
When using lidocaine as a diluent, intravascular injection must be strictly avoided.

Cefotaxime is compatible with metronidazole infusion (500mg/100ml) 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 03/2024

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

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