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. If you 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 this leaflet:
1. What cefotaxime for injection is and what it is used for
2. Before you are given cefotaxime for injection
3. How cefotaxime for injection should be given
4. Possible side effects
5. How to store cefotaxime for injection
6. Further information

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 (septicemia), bones (osteomyelitis), the heart valves (endocarditis), 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

Cefotaxime for injection should not be given if:
- You are allergic to cefotaxime or any other cephalosporin.
- You have previously had an allergic reaction to penicillin or any other beta-lactam antibiotic.
- 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 had kidney problems. This will be carefully monitored throughout your treatment.
- You are on a low salt diet, your doctor may make sure you are not receiving too much salt by way of cefotaxime.
- You are having any surgery. Your doctor should monitor your blood level during and after surgery.
- You are going to have a blood transfusion, make sure that the doctor who organises your transfusion knows that you are taking cefotaxime for injection.
- You are diabetic, you may get a false positive results with urine glucose tests, such as Clinistix.
- You develop a severe skin rash such as Stevens-Johnson syndrome.

You must stop treatment immediately and contact your doctor.
- You are taking amiodarone such as streptomyxin and gentamicin. Your kidney function will be carefully monitored.
- 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.

Taking other medicines
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 for the treatment you are having 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):
- Penicillins such as mecillinam and azlocillin.
- Aminoglycoside antibiotics such as streptomycin, neomycin or gentamicin.
- Fusidic acid 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 tell your doctor or nurse know if you are pregnant or wish to become pregnant or are breast-feeding before taking 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 infection (into the skin) or intravenously (into a vein) or intraperitoneally (into the peritoneum). The usual adult (including the elderly) dose 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 or 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.

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.

Dosage and Administration Information Only
Information for Health Care Professionals
Cefotaxime 500mg powder for solution for injection or infusion
Cefotaxime 2g powder for solution for injection or infusion
Cefotaxime 1g powder for solution for injection or infusion

Reading the product characteristics for further information.

Dosage and Administration Information Only

- Please refer to the Summary of Product Characteristics for further information.
- Please read the leaflet that came with your medicine before you take it.
- Please talk to your doctor or pharmacist if you have any questions about your medicine.
- This medicine is for injection only. Do not take it by mouth.
- This medicine must not be mixed with other medicines except those listed in this leaflet.
- Do not use this medicine if you have any other allergies.
- Do not use this medicine if you are allergic to cefotaxime or any other cephalosporin.
- Take special care with cefotaxime for injection if:
- You have had kidney problems. This will be carefully monitored throughout your treatment.
- You are on a low salt diet, your doctor may make sure you are not receiving too much salt by way of cefotaxime.
- You are having any surgery. Your doctor should monitor your blood level during and after surgery.
- You are going to have a blood transfusion, make sure that the doctor who organises your transfusion knows that you are taking cefotaxime for injection.
- You are diabetic, you may get a false positive results with urine glucose tests, such as Clinistix.
- You develop a severe skin rash such as Stevens-Johnson syndrome.

You must stop treatment immediately and contact your doctor.
- You are taking amiodarone such as streptomyxin and gentamicin. Your kidney function will be carefully monitored.
- 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.

Taking other medicines
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 for the treatment you are having 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):
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Pregnancy and breast-feeding
You should tell your doctor or nurse know if you are pregnant or wish to become pregnant or are breast-feeding before taking 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.
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 may 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 throat.
- 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 of cefotaxime in patients with kidney problems may cause brain disease.
- Antibiotic treatment can affect other bacteria in the normal bacteria in the gut, causing new infection (colitis). You should tell your doctor immediately if you develop pain, nausea, dehydration, fever or bloody, watery diarrhoea. Do not take any antibiotic diarrhoea medicines, such as loperamide.

5. HOW TO STORE CEFOXIME 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. MORE 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 (1.046mmol), 48mg (2.093mmol) and 96mg (4.188mmol) 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-PIE 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:

<table>
<thead>
<tr>
<th>Product name</th>
<th>Reference number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cefotaxime 500mg powder for solution for injection or infusion</td>
<td>PL 29831/0030</td>
</tr>
<tr>
<td>Cefotaxime 1g powder for solution for injection or infusion</td>
<td>PL 29831/0030</td>
</tr>
<tr>
<td>Cefotaxime 2g powder for solution for injection or infusion</td>
<td>PL 29831/0029</td>
</tr>
</tbody>
</table>

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

Marketing Authorisation Holder: RECOVERY Ltd, Ash Road North, Wrexham, LL13 9UF, UK.

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

This leaflet was last revised in 03/2017.

- Shelf life and special precautions for storage
  Unopened 2 years. Do not store above 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 reconstituted solutions, 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.

Dilution Table: Intravenous Administration

<table>
<thead>
<tr>
<th>Concentration</th>
<th>Silumet to be added</th>
<th>Approx available volume</th>
<th>Approx displacement volume</th>
</tr>
</thead>
<tbody>
<tr>
<td>500mg 2ml</td>
<td>2ml</td>
<td>2.3ml</td>
<td>0.3ml</td>
</tr>
<tr>
<td>1g 4ml</td>
<td>4ml</td>
<td>4.6ml</td>
<td>0.6ml</td>
</tr>
<tr>
<td>2g 10ml</td>
<td>10ml</td>
<td>11.4ml</td>
<td>1.4ml</td>
</tr>
</tbody>
</table>

* Water for injection

Dilution Table: Intramuscular Administration

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<td>11.4ml</td>
<td>1.4ml</td>
</tr>
</tbody>
</table>

* Water for injection or 1% Lidocaine