Package Leaflet: Information for the patient

Cefotaxime 500 mg Powder for Solution for Injection
Cefotaxime 1000 mg Powder for Solution for Injection

Cefotaxime

Read all of this leaflet carefully before you start taking 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, nurse or pharmacist.
- 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, nurse or pharmacist. 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 500 mg Powder for Solution for Injection and Cefotaxime 1000 mg Powder for Solution for Injection contain cefotaxime.

- Cefotaxime belongs to a group of drugs called antibiotics, which are used to treat bacterial infections.
- Cefotaxime is used to treat infections of the following:
  - Chest (respiratory tract)
  - Kidneys, bladder and urethra (the tube that carries urine from the bladder)
  - Skin and soft tissues
  - Abdomen, such as peritonitis
  - Cefotaxime is also used to treat a type of sexually transmitted disease called gonorrhoea.
  - Cefotaxime can also be used to treat other infections, such as meningitis.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE CEFOTAXIME

Do not use Cefotaxime:

- If you are allergic to cefotaxime or any of the other ingredients of this medicine (listed in section 6)
- If you are allergic to certain other antibiotics (e.g. penicillins, cephalosporins)
- If you are allergic to lidocaine and you are to be given cefotaxime as an injection into a muscle

Warnings and precautions
Talk to your doctor or nurse before using this medicine.
- If you are allergic to cefotaxime or any other antibiotic
- Serious skin rashes have been reported with the use of cefotaxime. The rash may progress to widespread blistering and peeling of the skin (See section 4). If you develop a rash or these skin symptoms, contact your doctor immediately.
- If you have a previous history of allergies or asthma

- If you have ever had colitis (inflammation of the bowels)
- If you have kidney problems
- High doses of cefotaxime, especially in patients with kidney problems, may result in encephalopathy (e.g. impairment of consciousness, abnormal movements and convulsions) (See section 4). You should contact your doctor immediately prior to continuing treatment if such reactions occur.
- If you are on a sodium controlled diet
- If your treatment lasts longer than 7 days, your doctor will need to carry out blood tests

Other medicines and Cefotaxime

Tell your doctor or nurse if you are taking, have recently taken or might take any other medicines.

- Antibiotics (e.g. tetracycline, erythromycin, chloramphenicol) or sulfonamides (e.g. co-trimoxazole) as they may affect the action of cefotaxime
- An aminoglycoside antibiotic (e.g. neomycin or streptomycin), as the medicine must be taken separately or a dose adjustment may be required
- Cephalosporins (e.g. cefaclor) as a dose adjustment may be required
- Probenecid as this may lead to higher levels of cefotaxime in the body
- Diuretics "water tablets" (e.g. bumetanide), as your doctor may need to monitor your kidney function or adjust your dose.

Cefotaxime can affect the results of some blood and urine tests. Make sure that the doctor knows you are taking Cefotaxime before you have such tests. Your doctor will arrange regular blood, liver and kidney tests during long term treatment.

Pregnancy, breast-feeding and fertility:

Pregnancy
Your doctor will decide if you should receive Cefotaxime during pregnancy.

Breast-feeding
Your doctor will decide if you should receive Cefotaxime during 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 taking this medicine.

Driving and using machines:

In individual cases, when administered in high doses, cramp, muscle spasms and giddiness have occurred. If affected do not drive or operate machinery.

Important information about some of the ingredients of Cefotaxime:

The sodium content (2.2 mmol/g) should be taken into consideration if you are on a sodium controlled diet.

3. HOW TO TAKE CEFOTAXIME

A doctor or nurse will administer your medicine by injection. Your dose, the duration and the route of administration will depend on the severity and type of infection you have as well as your weight.

The recommended dose is:
Adults and adolescents above 12 years of age:
1000-6000 mg daily, divided into 2 doses at 12 hour intervals. In severe cases the dose may be increased to 12000 mg, divided into 3 or 4 doses and given at 6 or 8 hour intervals.
Infants, toddlers and children (1 month-12 years):

50-100 mg per kilogram of body weight per day (6 to 12 hour intervals).
Pre term new born infants and term new born infants (0-27 days):
50 mg cefotaxime per kilogram of body weight per day (in 2-4 divided doses).

Gonorrhoea
The usual dose is 500 to 1000 mg as a single dose, although 1000 mg is preferable.

Impaired kidney function
Your doctor will decide what dose is best for you.
If you are an adult with a creatinine clearance (a measure of kidney function) of 20 ml/minute or less, your doctor will give you half of the usual dose of Cefotaxime. If your creatinine clearance is 5 ml/minute or less, your doctor will give you 1000 mg of Cefotaxime at first and after that your daily dose will be halved without a change in the frequency of dosing (for example, if you should receive 1000 mg of Cefotaxime 2 times a day, you will receive 500 mg of Cefotaxime 2 times a day).

In patients on haemodialysis, 500 mg - 2000 mg is given by i.v. injection at the end of every dialysis. This dose is repeated every 24 hours.

Elderly
No dosage adjustments are needed in patients with normal renal function

If you take more Cefotaxime than you should:

As a doctor or nurse will be giving you your medicine, it is unlikely that you will receive an overdose. However, if you have any concerns you should let your doctor or nurse know immediately.
With accidental overdose, you can feel:

- impairment of consciousness, abnormal movements and convulsions (encephalopathy)
- twitching (spasm)of muscles
- muscle cramps (painful muscle contractions).

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

A few people (may affect up to 1 in 1000 people) may develop a severe allergic reaction. This is a rare but very serious side effect. If you experience any of the following side effects tell your doctor or nurse straight away:
- Swelling of the face, hands, feet, lips, tongue or throat
- Difficulty swallowing or breathing.

A few people (may affect up to 1 in 10 000 people) may develop a life-threatening skin disease (Stevens-Johnson syndrome). This is a very rare but very serious side effect. If you experience any of the following side effects tell your doctor or nurse straight away:
- skin peeling
- sores on the mucous membranes
- skin rash.

The following side effects have been reported at the approximate frequencies shown:

Very common (may affect more than 1 in 10 people)
- For intramuscular injections: pain where the injection was given (with or without the hardening of the skin).

Common (may affect up to 1 in 10 people*)*
- Pain or a burning feeling along the vein where Cefotaxime has been given.
- Loss of appetite, nausea
- Sickness
- Stomach ache
- Diarrhoea.

Uncommon (may affect up to 1 in 100 people)
- Low numbers of all types of white blood cells. The signs include increased number of infections, for example in your mouth, gums, throat and lungs.
- Low numbers of platelets in your blood. The signs include bruising easily and nose bleeds
- Increase in eosinophils
- Increased joint or muscle pain, headaches, chills, fever (usually low grade), drop in blood pressure, hives and rash (Jarisch-Herxheimer reaction).
- Epileptic fits (especially if you have kidney problems)
- Changes in certain liver function test results (ALAT, ASAT**,** gamma GT, AP, LDH)
- Changes in certain kidney function test results (creatinin, urea)
- Skin reactions. These include a nettle rash which may cover a lot of your body and itching
- Fever (a high temperature)

Rare (may affect up to 1 in 1000 people*)*
- Some side effects are only seen when a blood test is taken. These include:
  decreases in the number of certain types of blood cells e.g. low red blood cell count due to destruction (haemolytic anaemia) causing unusual tiredness or weakness, low number of specific white blood cells, leading to increased susceptibility to infections.
- Inflammation of the large bowel (colon). The signs include diarrhoea, usually with blood and mucus, stomach pain and fever.
- Allergic skin reactions, itching and drug-fevers

Very rare (may affect up to 1 in 10 000 people)
- Irregular heart beat
- Kidney problems including inflammation

Not known (frequency cannot be estimated from the available data)
- Superinfections
- Swollen face, tongue or pharynx, difficulty in swallowing, hives and difficulties in breathing (angioedema)
- Headache, dizziness, encephalopathy (e.g. impairment of consciousness, abnormal movements)
- Vomiting
- Inflammation of the liver (hepatitis, sometimes with jaundice)
- For intramuscular injection, containing anaesthetic lidocaine, systemic reactions to lidocaine are possible

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 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.

Do not store above 25°C. The vial should be kept in the outer carton in order to protect from light.

Do not use this medicine after the expiry date which is stated on the carton 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 to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Cefotaxime contains

- The active substance is cefotaxime (as cefotaxime sodium). Each vial contains 500 mg or 1000 mg of cefotaxime as the sodium salt.

What Cefotaxime looks like and contents of the pack

- Transparent type II glass vial with bromobutyl rubber stopper and aluminium seal with a flip off cap, containing cefotaxime sodium, equivalent to 500 mg or 1000 mg cefotaxime.
  The vials are packed in a carton box containing 1, 5 or 10 vials.
  Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Teva Pharma B.V., Swensweg 5, 2031GA Haarlem, The Netherlands.
Manufacturer
Pharmachemie B.V., Swensweg 5, P.O. Box 552, 2003 RN Haarlem, The Netherlands
or
Laboratorio Reig Jofré, S.A., C/ Jarama 111 Polígono Industrial, Toledo, 45007 Toledo, Spain

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

Belgium	Cefotaxime TEVA 500 mg poeder voor oplossing voor injectie
	Cefotaxime TEVA 1000 mg poeder voor oplossing voor injectie
Ireland	Cefotaxime 500 mg Powder for Solution for Injection
	Cefotaxime 1000 mg Powder for Solution for Injection
The Netherlands	Cefotaxim 500 PCH, poeder voor oplossing voor i.v./i.m. injectie 500 mg
	Cefotaxim 1000 PCH, poeder voor oplossing voor i.v./i.m. injectie 1000 mg
Sweden	Cefotaxim Teva

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