Package Leaflet: Information for the patient

Cefotaxime 500 mg Powder for Solution for Injection
Cefotaxime 1 g Powder for Solution for Injection
Cefotaxime 2 g Powder for Solution for Injection or Infusion

Cefotaxime

Read all of this leaflet carefully before you receive this medicine.

- 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. 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 gets serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. WHAT CEFOTAXIME IS AND WHAT IT IS USED FOR

Cefotaxime 500 mg Powder for Solution for Injection, Cefotaxime 1 g Powder for Solution for Injection and Cefotaxime 2 g Powder for Solution for Injection or Infusion 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. BEFORE YOU RECEIVE 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)

Warnings and precautions
Talk to your doctor or nurse before using this medicine if:
- You are allergic to cefotaxime or any other antibiotic
- You are allergic to lidocaine and you are to be given Cefotaxime as an injection into a muscle
- Have a previous history of allergies or asthma
- You have ever had colitis (inflammation of the bowels)
- You have kidney problems
- You are on a sodium controlled diet

If your treatment lasts longer than 7 days, your doctor will need to carry out blood tests

Check with your doctor or nurse if you are taking any of the following:
- 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 and Breast-feeding:
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 RECEIVE CEFOTAXIME

A doctor or nurse will administer your medicine usually by injection or as an infusion (with a drip). 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 usual dose is as follows:
Adults and adolescents above 12 years of age:
1-6 g daily, divided into 2 doses at 12 hour intervals. In severe cases the dose may be increased to 12 g, 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 0.5 to 1 g as a single dose, although 1 g is preferable.

Impaired kidney function
Your doctor will decide what dose is best for you.
If you are an adult with a creatinin 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 creatinin clearance is 5 ml/minute or less, your doctor will give you 1 g 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 1 g of Cefotaxime 2 times a day, you will receive 0.5 g of Cefotaxime 2 times a day).

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:

- twitching (spasm) of muscles
- muscle cramps (painful muscle contractions).

4. POSSIBLE SIDE EFFECTS

Like all medicines, Cefotaxime can have side effects.

A few people (*may affect up to 1 in 1,000 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 - Johnsons 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:

Common (may affect up to 1 in 10 people)

- Pain where the injection was given (with or without the hardening of the skin)
- Pain or a burning feeling along the vein where Cefotaxime has been given.
- Loss of appetite, nausea
- Sickness
- Stomach ache
- Diarrhoea.

Rare (may affect up to 1 in 1,000 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
  - changes in certain liver function test results (SGOT, SGPT, GGT, 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)
- Epileptic fits (especially if you have kidney problems)
- Inflammation of the large bowel (colon). The signs include diarrhoea, usually with blood and mucus, stomach pain and fever.

Very rare (may affect up to 1 in 10,000 people)

- Irregular heart beat
- Kidney problems including inflammation

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet.

5. HOW TO STORE CEFOTAXIME

Keep Cefotaxime out of the reach and sight 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 Cefotaxime after the expiry date shown on the outer packaging. The expiry date refers to the last day of that month.
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. FURTHER INFORMATION

What Cefotaxime contains:

- The active ingredient is cefotaxime (as cefotaxime sodium). Each vial contains 500 mg, 1 g or 2 g 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, 1 or 2 g 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
Computerweg 10
P.O. Box 43028
3540 AA Utrecht
The Netherlands

Manufacturer

Pharmachemie B.V.	or	Laboratorio Reig Jofré, S.A.
Swensweg 5		C/ Jarama 111 Polígono Industrial
P.O. Box 552		Toledo
2003 RN Haarlem		45007 Toledo
The Netherlands		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
	Cefotaxime TEVA 2000 mg poeder voor oplossing voor injectie
Germany	Cefotaxim-GRY® 500 mg Pulver zur Herstellung einer Injektionslösung
	Cefotaxim-GRY® 1000 mg Pulver zur Herstellung einer Injektionslösung
	Cefotaxim-GRY® 2000 mg Pulver zur Herstellung einer Injektionslösung
Ireland	Cefotaxime 500 mg Powder for Solution for Injection
	Cefotaxime 1 g Powder for Solution for Injection
	Cefotaxime 2 g Powder for Solution for Injection or Infusion
Italy	Cefotaxime Teva Italia 500 mg
	Cefotaxime Teva Italia 1000 mg
	Cefotaxime Teva Italia 2000 mg
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
	Cefotaxim 2000 PCH, poeder voor oplossing voor i.v. infusie 2000 mg
Sweden	Cefotaxim Teva

This leaflet was last revised in 10/2013.