



Package leaflet: Information for the user

Cefotaxime for Injection USP 500 mg

Read all this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or your pharmacist.
- This medicine has been prescribed for you. Do not pass it on 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.

In this leaflet:

1. What Cefotaxime Injection is and what it is used for.
2. Before you are given Cefotaxime Injection.
3. How Cefotaxime Injection is given.
4. Possible side effects.
5. How to store Cefotaxime Injection.
6. Further information.

The name of your medicine is “Cefotaxime for Injection USP 500 mg” (Referred to as **Cefotaxime Injection** throughout this leaflet).

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

Cefotaxime is an antibiotic. It belongs to a group of antibiotics that are called cephalosporins. These types of antibiotics are similar to penicillin.

Cefotaxime kills bacteria and it can be used to treat infections of the:

- Kidneys and bladder
- Blood (Septicaemia)
- Skin and flesh immediately under the skin
- Bones
- Heart valves
- Brain (Meningitis)
- Abdomen (Peritonitis)
- Some sexually transmitted infections (Gonorrhoea)

It can also be used to prevent and treat infections following surgical operations.

2. BEFORE YOU ARE GIVEN CEFOTAXIME INJECTION

You should not be given Cefotaxime Injection if:

- you are allergic (hypersensitive) to Cefotaxime
- you are allergic to any similar antibiotics (known as “cephalosporins”)
- you have ever had a severe allergic reaction when given penicillin or similar antibiotics
- you are allergic to lidocaine

Tell your doctor or nurse if any of the above applies to you.

Before you are given Cefotaxime Injection

You must tell the doctor or nurse if any of the following apply to you:

- you have a history of allergies or asthma
- you are on a low sodium diet
- you have heart or kidney disorder
- you are having any blood or urine tests
- you have a history of gastro-intestinal problems e.g. colitis, which causes diarrhea containing blood)

Taking other medicines

Tell the doctor or nurse if you are taking any of the following medicines:

- the contraceptive pill (in which case you will need to take extra contraceptive precautions such as using a condom)
- any diuretic medicine (“water tablets”) e.g. furosemide
- another antibiotic e.g. chloramphenicol or aminoglycoside antibiotics
- probenecid (for gout)

Please tell your doctor if you are taking, or have recently taken, any other medicines including any that you may have bought without a prescription.

Pregnancy and breast-feeding

If you are pregnant, think you might be pregnant or are breast-feeding, you must tell your doctor before you are given this medicine.

Driving and using machines

If you are given high doses of Cefotaxime, you may feel dizzy/drowsy or fall asleep or experience convulsions (fits) or unusual body movements. If this happens, you should not drive or operate machinery.

3. HOW CEFOTAXIME INJECTION IS GIVEN

Cefotaxime Injection is supplied as a powder so before it can be given it must be diluted and made into a solution. Your doctor or nurse normally does this. They will inject this directly into a vein (intravenous) or muscle (intramuscular). It may also be given by an intravenous infusion (“drip”). Your doctor will decide how much you need and how often the injections should be given.

The usual doses are given below but doctor may prescribe different doses depending on the severity and type of your infection, your weight, your age and how well your kidneys are working. Treatment with Cefotaxime injection is usually continued for 2-3 days after you start to recover from your illness or after your operation.

Adults and children over 12 years old:

The usual dose is 1 g (gram) every 12 hours. In some patients where infections are severe, the doctor may give a higher dose up to 12g every day. For the treatment of gonorrhoea, a single 500 mg dose is usually given. To prevent an infection after surgery, 1-2 g is given before the operation. A second dose may be needed after the operation.

Infants and children up to 12 years old:

The usual daily dose is 50 mg to 100 mg Cefotaxime per kilogram of their body weight. This is usually split into 2 doses each day. Severely ill children may receive up to 200 mg per kg bodyweight daily (to a maximum of 6 g daily), split into 3 separate doses.

Young babies (newborn):

The daily dose should not normally exceed 50 mg Cefotaxime per kg of their bodyweight.

Patients with kidney problems:

Lower doses may be given if you have severe kidney problems. Patients on dialysis machine will be monitored for the correct dose.

If you think you have missed an injection

This is unlikely as you will probably receive this medicine in hospital. If you think you have missed a dose, speak to your doctor or nurse.

If you have been given more of this medicine than you should

This is unlikely to happen but if it does, the doctor will treat any symptoms that follow.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Cefotaxime Injection can cause side effects, although not everybody gets them.

As with other antibiotics, some people find they have an allergy to it. Tell your doctor immediately if any of the following rare symptoms occur:

- Sudden wheeziness and tightness of chest
- Swelling of the eyelids, face, lips or throat
- Skin lumps or “hives” (nettle rash)
- Severe skin rashes with itching
- Serious illness with blistering of the skin, mouth, eyes and genitals
- Loss of consciousness, abnormal movements or convulsions (fits)

Antibiotic treatment can affect the normal bacteria in the gut, causing new infection (colitis). You should tell your doctor immediately, if you develop diarrhea.

The following side effects may occur in some patients treated with Cefotaxime injection. Tell your doctor if any become troublesome:

Very Common side effects (probably affecting more than 1 in 10 people)

- pain at the injection site

Uncommon side effects (probably affecting less than 1 in 100 patients)

- reduction in blood platelets which increases risk of bruising and bleeding
- reduction in number of white blood cells which makes infections more likely
- increase in number of white blood cells
- fever
- increase in liver enzymes and/or bilirubin
- kidney problems

- skin rash, itching, “hives” (nettle rash)
- difficulty in breathing
- convulsions (fits)
- diarrhea
- redness and swelling at injection site

Side effects occurring with unknown frequency

- secondary infections
- serious allergic reactions which may cause difficulty in breathing or dizziness
- serious allergic reaction which causes swelling of the face or throat
- difficulty in breathing or wheezing
- headache
- dizziness
- loss of consciousness, abnormal movements
- feeling sick (nausea)
- being sick (vomiting)
- stomach pains
- diarrhea containing blood
- inflammation of the liver (hepatitis)
- skin and white of the eyes turn yellow (jaundice)
- painful joints
- irregular heart rhythm
- inflammation of the kidneys which may cause dark discolouration of urine, cloudy/bloody urine, or any change in your urine output.

Treatment with high doses of Cefotaxime, particularly in patients with kidney problems, has been known to cause loss of consciousness, abnormal movements and convulsions (“fits”).

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.

5. HOW TO STORE CEFOTAXIME INJECTION

Do not use this medicine after the expiry date which is stated on the vial label and carton after Exp. The expiry date refers to last day of the month.

This medicinal product does not require any special storage conditions.

Store in dry place at temperature below 30°C.

Keep out of the sight and reach of children.

For single use only. Discard any unused solution.

Prepared solution should be used immediately.

Do not use this medicine if you notice any particulate matter and discoloration prior to administration. The solution should only be used if the solution is clear and free from particles.

Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. FURTHER INFORMATION

What Cefotaxime Injection contains:

The active ingredient in this medicinal product is cefotaxime sodium.

Each vial contains:
Sterile Cefotaxime Sodium
Eq. to Cefotaxime500 mg

What Cefotaxime Injection looks like and contents of the pack

Cefotaxime injection is off-white to pale yellow crystalline powder. It is supplied in 10 ml glass vial along with sterile water for injection in a pack.

Marketing Authorization Holder and Manufacturer

Marketing Authorization Holder:

GB Pharma Limited
65, Chatsworth Road, London NW2 4BG,

Manufacturer:

Nectar Lifesciences Limited, Unit -VI
Vill. Bhatolikalan (Adjoining Jharmajri EPIP),
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