



Package leaflet: Information for the user

Gebexime 750 (Cefuroxime for Injection USP 750 mg)

Read all of this leaflet carefully before you start using 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 or pharmacist or nurse.
- If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Cefuroxime Injection is and what it is used for
2. What you need to know before you are given Cefuroxime Injection
3. How Cefuroxime Injection is given
4. Possible side effects
5. How to store Cefuroxime Injection
6. Contents of the pack and other information

The name of your medicine is Cefuroxime for Injection USP 750 mg but will be referred to as Cefuroxime Injection throughout this leaflet.

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

What Cefuroxime Injection is

Cefuroxime Injection contains Cefuroxime, which is an antibiotic used in adults and children. It works by killing bacteria that cause infections. It belongs to a group of medicines called cephalosporins.

Cefuroxime Injection is used to treat infections:

- the lungs or chest
- the urinary tract
- the abdomen
- the skin and soft tissue

Your doctor may also give it to you before an operation to protect you from infection. Your doctor may test the type of bacteria causing your infection and monitor whether the bacteria are sensitive to Cefuroxime during your treatment.

2. WHAT YOU NEED TO KNOW BEFORE YOU ARE GIVEN CEFUROXIME INJECTION

Your doctor or nurse will make sure it is safe for you to have Cefuroxime Injection.

You must not be given Cefuroxime Injection if you:

- are allergic to Cefuroxime or any other Cephalosporin antibiotic
- have ever had a severe allergic (hypersensitive) reaction to any other type of betalactam antibiotic (penicillin, monobactams, carbapenems).

Tell your doctor before you start on Cefuroxime injection if you think that this applies to you. You must not be given Cefuroxime Injection.

Take special care with Cefuroxime Injection

You must look out for certain symptoms such as allergic reactions, skin rashes, gastrointestinal disorders such as diarrhea and fungal infections while you are being given Cefuroxime Injection. You must tell your doctor or nurse if you develop any of these conditions.

If you have had any allergic reaction to other antibiotics such as Penicillin, you may also be allergic to Cefuroxime Injection.

If you need a blood or urine test

This medicine can affect the results of tests for sugar in your urine or blood, and a blood test known as Coombs Test. If you are having tests it is important to tell the doctor and the person taking the sample(s) that you have been given this medicine.

Other medicines and Cefuroxime Injection

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

Some medicines may affect how Cefuroxime Injection works, or make it more likely that you will have side effects. These medicines include:

- Diuretics (water tablets) e.g. furosemide
- Aminoglycoside-type antibiotics e.g. gentamicin, neomycin
- Probenecid
- Oral anticoagulants (to help prevent blood clots) e.g. warfarin

Tell your doctor if this applies to you. You may need extra monitoring while you are being given Cefuroxime Injection.

Contraceptive pills

Cefuroxime Injection may reduce the effectiveness of the contraceptive pill. If you are taking the contraceptive pill while you are being treated with Cefuroxime Injection, you also need to use a barrier method of contraception (such as a condom). Ask your doctor for advice.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, tell your doctor before you are given this medicine.

Your doctor will consider the benefit of treating you with Cefuroxime Injection against the risk to your baby

Driving and using machines

Cefuroxime Injection is unlikely to affect your ability to drive or operate machinery, but do not drive or use machines if you feel unwell.

3. HOW CEFUROXIME INJECTION IS GIVEN

Your doctor will decide which dose you need. Your doctor or nurse will inject the Cefuroxime Injection into a muscle or into a vein. In some cases, it may be added to a 'drip' (intravenous infusion).

Usual doses

The correct dose of Cefuroxime Injection for you will be decided by your doctor and will depend on the severity and type of your infection, whether you are on any other antibiotics, your weight and age, how well your kidneys are working.

Adults and adolescents are usually given 750 mg of Cefuroxime two, three or four times daily. The maximum dose is 6 g per day. If you have kidney trouble, you may be given a lower dose. Your doctor may give you 1.5 g of Cefuroxime Injection before surgery to protect you from infection. You may receive further doses of 750 mg of Cefuroxime Injection after the operation.

Babies (over 3 weeks) and children will usually be given 30 to 100 mg for each kilogram of their body weight each day. This will be divided into three or four doses.

Newborn babies (0-3 weeks) will usually be given 30 to 100 mg for each kilogram of their body weight each day. This will be divided into two or three doses.

If you are given more Cefuroxime Injection than you expect

It is most unlikely that you will be given too much medicine by the nurse or doctor. Your doctor and nurse will be monitoring your progress, and checking the medicine that you are given. However, always ask if you are not sure why you are getting a dose of medicine.

If you think you have missed a dose of Cefuroxime injection

Your doctor or nurse have instructions when to give you your medicine. It is unlikely that you will not be given the medicine as it has been prescribed. However, if you think you may have missed a dose, talk to your doctor or nurse. It is important that the course of treatment your doctor has prescribed is given. You may start to feel better but it is important not to stop this medicine until the doctor advises, otherwise your condition may get worse again.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. POSSIBLE SIDE EFFECTS

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

Conditions you need to look out for

Some people given Cefuroxime may get an allergic reaction or potentially serious skin reaction.

Tell a doctor or nurse immediately if you get any of the following symptoms:

- Severe allergic reactions - signs include feeling lightheaded or faint, sudden wheezing, chest tightness or breathing difficulties, a fast heartbeat, feeling sick, clammy skin, confusion and anxiety, swelling particularly of the face or mouth, a raised and itchy rash.
- Skin rash, which may blister, and looks like small targets (central dark spots surrounded by a paler area, with a dark ring around the edge).
- Widespread rash with blisters and peeling skin

Other symptoms you need to be aware of while being given Cefuroxime include:

- Fungal infections – medicines like Cefuroxime can cause an overgrowth of yeast (*Candida*) in the body which can lead to fungal infections such as thrush; this is more likely if you take Cefuroxime for a long time.
- Severe diarrhoea (*Pseudomembranous colitis*) - medicines like Cefuroxime can cause inflammation the colon (large intestine), causing severe diarrhoea, usually with blood and mucus, stomach pain, fever.

Tell your doctor or nurse if you get any of these symptoms.

Other side effects:

Common (may affect up to 1 in 10 people):

- pain at the site of injection, swelling and redness along a vein

Common side effects that may show up in blood tests:

- increase in the levels of enzymes produced by the liver
- changes in the white blood cell count
- decrease in blood haemoglobin concentration

Uncommon (may affect up to 1 in 100 people):

- diarrhoea, nausea, stomach pain
- skin rash, itchy, bumpy rash (hives)

Uncommon side effects that may show up in blood tests:

- low levels of white blood cells
- increase in bilirubin (a substance produced by the liver)
- positive Coombs test

Not known (frequency cannot be estimated from the available data):

The following side effects have occurred but their exact frequency is unknown:

- high temperature (fever)
- inflammation in the kidney and blood vessels
- easy bruising

Side effects that may show up in blood tests:

- decrease in the very tiny blood cells called platelets (cells that help blood to clot), resulting in bruising and prolonged bleeding
- low levels of red blood cells
- increase in blood levels of urea nitrogen and serum creatinine

5. HOW TO STORE CEFUROXIME 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 below 30°C. Protect from light and moisture.

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. CONTENTS OF THE PACK AND OTHER INFORMATION

What Cefuroxime Injection contains:

The active ingredient in this medicinal product is cefuroxime sodium.

Each Vial Contains:

Sterile Cefuroxime Sodium USP
equivalent to Cefuroxime...750 mg

What Cefuroxime looks like and contents of the pack

Cefuroxime for injection is white or faintly yellow 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),
P.O. Barotiwala, Teh. Baddi,
Distt. Solan (H.P.) 174103, INDIA

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