Patient Information Leaflet

CEROXIM SUSPENSION
125 mg/5 ml and 250 mg/5 ml
(Cefuroxime Axetil for Oral Suspension)

What you should know about Cefuroxime Axetil Suspension

Please read this leaflet carefully before you start to take your medicine. It provides a summary of the information about your medicine. Please ask your doctor or pharmacist if you have any questions. This leaflet applies to Ceroxim Suspension 125 mg/5ml and Ceroxim Suspension 250 mg/5ml only.

What is Ceroxim Suspension?

Your medicine is called Ceroxim Suspension (Cefuroxime Axetil for oral Suspension).

Cefuroxime axetil is the active ingredient contained in the suspension and is an antibacterial agent belonging to the group of antibiotics called cephalosporins. Antibacterials help the body fight infections. Cefuroxime axetil works by destroying certain bacteria that cause infection. The suspension also contains sucrose as filler/sweetner, xanthan gum as suspending agent/viscosity building agent, aspartame as sweetner, silicon dioxide as internal dessicant/flow modifier, mono sodium citrate as buffering agent, sodium benzoate as preservative, sodium chloride as taste modifier, mannitol as taste modifier/filler and tutti frutti and peppermint as flavouring agent.

Ceroxim Suspensions 125 mg/5ml and 250 mg/5ml are available in natural, translucent HDPE bottle with a white, opaque, child resistant cap having induction sealing liner. Each bottle contains 50 ml or 100 ml upon constitution and is contained in a cardboard carton.

Ceroxim Suspension is made by Ranbaxy Laboratories Limited, Industrial Area - 3, Dewas 455001, India.

The product licence holder is Ranbaxy Laboratories Limited, Industrial Area - 3, Dewas 455001, India.

What is Ceroxim Suspension used for?

Ceroxim Suspension is used to treat bacterial infections. Some of these infections are respiratory infections such as bronchitis and pneumonia, infections of ear, nose and throat, infections of the urinary tract, skin infections, gonorrhoea and the infection which causes Lyme disease.

It may be prescribed for other infections as determined by your doctor.

Before taking this medicine

Make sure it is safe for you to take Ceroxim Suspension (Cefuroxime Axetil for oral Suspension).
Read the following questions carefully:

*Have you previously had an allergic reaction to antibacterials such as cephalosporins or to any of the suspension ingredients or to any other types of medicine?* (An allergic reaction may include rash, itching, swelling or breathing difficulties)

*Do you think you may be pregnant?*

*Are you breast feeding currently?*

*Do you have any disease of the kidney(s)?*

*Do you have phenylketonuria (as this product contains aspartame, which is a source of phenylalanine)?*

*Are you taking any other medicine, especially probenecid (a medicine for the treatment of gout)?*

If you answer YES to any of the above questions or are not sure, tell your doctor or pharmacist.

Ceroxim Suspension 125mg/5ml and 250mg/5ml (Cefuroxime Axetil for oral Suspension) contain 2.46 and 2.74 g of sucrose per 5 ml, respectively. Cefuroxime Axetil Suspensions may be unsuitable if you suffer from hereditary fructose intolerance, glucose-galactose malabsorption syndrome or sucrose-isomaltase deficiency.

Cefuroxime Axetil Suspensions also contain an inactive ingredient called sodium benzoate, which may cause irritation to the skin, eyes and mucous membranes. It may increase the risk of jaundice in newborn infants.

**When, how and how much of Ceroxim Suspension to take**

Take your medicine as instructed by your doctor. Check the label carefully for how much of the suspension to take and how often to take it. Your pharmacist or doctor can help if you are not sure. If prescribed for a child, make sure the medicine is taken as the label says.

Ceroxim Suspension (Cefuroxime Axetil for oral Suspension) works better if it is taken with food.

Space the doses as evenly as possible through the day. For example, if you have been told to take your medicine 2 times a day, then you may take your doses at about 8.00 AM and 8.00 PM.

The dose of this medicine will be different for different patients, depending on the condition and severity of illness. Your doctor will be able to decide on the dose that's right for you.

**Adults:**

Most infections will respond to 250 mg twice daily, in mild to moderate lower respiratory tract infections e.g. bronchitis 250 mg twice daily should be given. For more severe lower respiratory
tract infections, or if pneumonia is suspected then 500 mg twice daily should be given. For urinary tract infections a dose of 125 mg twice daily is usually adequate; in pyelonephritis (a kidney infection) the recommended dose is 250 mg twice daily. A single dose of 1 gram is recommended for the treatment of uncomplicated gonorrhoea. In the treatment of Lyme disease in adults and children over the age of 12 years, the recommended dose is 500 mg twice daily for 20 days.

An injectable form of Cefuroxime Axetil is also available called Cefuroxime Sodium. Cefuroxime Sodium can be injected into a muscle (intramuscular injection) or injected into your vein (intravenous injection). It is normally given in hospital or under the close supervision of a healthcare professional.

To treat pneumonia in adults, the usual dose of Cefuroxime Sodium is 1.5 g, twice daily for 2 to 3 days, followed by Cefuroxime Axetil 500 mg twice daily for 7 days.

To treat sudden worsening of chronic bronchitis in adults, the usual dose of Cefuroxime Sodium is 750mg twice daily for 2 to 3 days, followed by Cefuroxime Axetil 500mg twice daily for 5-7 days.

The duration of your treatment with Cefuroxime Sodium or Cefuroxime Axetil will depend on how severe your infection is and how well you are responding to the treatment.

**Children:**
The usual dose is 125 mg twice daily or 10 mg/kg twice daily to a maximum of 250 mg daily. For otitis media (infection of the middle ear), in children less than 2 years of age the usual dosage is 125 mg twice daily or 10 mg/kg twice daily to a maximum of 250 mg daily and in children over 2 years of age, 250 mg twice daily or 15 mg/kg twice daily to a maximum of 500 mg daily. There is no experience in children under 3 months of age.

You must take this medicine for as long as your doctor has told you to. This will usually be a period of 7 days. The duration may be longer if your infection is severe or persistent. It is important not to stop taking it when you feel better as the infection may then return.

If you miss a dose, take one as soon as you can. However, if it is almost time for the next dose, skip the missed dose and continue with your regular dosing schedule. If you miss several doses, tell your doctor.

Do not take more medicine than your doctor tells you to. **If you ever take too much, go to the nearest hospital casualty department, taking the medicine with you, or tell your doctor immediately.**

**While taking your medicine**

While taking Ceroxim Suspension (Cefuroxime Axetil for oral Suspension), do not take any other medicine (including over the counter medicines), without first talking to your doctor.

This medicine may cause some changes to the body’s normal blood levels of cells and chemicals.
If you are told you need a blood test, tell your doctor you are taking this medicine first as it may affect the results.

Along with its needed effects, a medicine may cause some unwanted effects. Cefuroxime Axetil for oral Suspension can occasionally cause allergic reactions. Stop the medicine and consult your doctor immediately if you develop skin rash, itchiness, fever, swelling of eyelids, face or lips, skin lumps or hives, sudden wheeziness and tightness of chest or any other unusual problems. Some patients may have nausea, diarrhoea or headache; usually these symptoms are mild, if such symptoms are severe or troublesome, consult your doctor. If you experience any of the following side-effects tell your doctor as soon as possible: feeling sick or being sick, jaundice (yellow colour of skin or whites of eyes), an unexpected change in the appearance of your urine.

If you notice any unwanted effects not mentioned in this leaflet or if you are unsure about the effects of this product, please inform your doctor or pharmacist.

**Storing your medicine**

On the label you will find the letters 'exp' (or expiry date) followed by some numbers. These numbers are the date when the medicine is no longer fit for use. Do not use this medicine after this date.

Keep the suspension in the original pack at a temperature below 25°C, protected from moisture.

**KEEP YOUR MEDICINE OUT OF REACH OF CHILDREN**

If your doctor tells you to stop your treatment, return any unused suspension to the pharmacist.

**REMEMBER: This medicine is for you. Only a doctor can prescribe it. Never give it to others. It may harm them, even if their symptoms are the same as yours.**