

PACKAGE LEAFLET: INFORMATION FOR THE USER

CEFERO 500 (Cefuroxime Axetil Tablets USP 500 mg) film-coated tablets

Read all of 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 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 effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What CEFERO 500 is and what it is used for
2. Before you take CEFERO 500
3. How to take CEFERO 500
4. Possible side effects
5. How to store CEFERO 500
6. Further information

1. What CEFERO 500 is and what it is used for

CEFERO 500 is an antibiotic. It belongs to a group of antibiotics that are called cephalosporins. These types of antibiotics are similar to penicillin. CEFERO 500 kills bacteria and it can be used against various sorts of infections.

Like all antibiotics CEFERO 500 is only effective against some types of bacteria. So, it is only suitable for treating some types of infection.

CEFERO 500 can be used to treat:

- ear, sinus and throat infections
- chest infections such as bronchitis
- infections of the bladder
- infections in the skin and the layers just under the skin (such as furuncles, impetigo-an infection on the surface of the skin)
- early Lyme disease (from a tick bite) and to prevent late complications in adults and children above the age of 12.

2. Before You Take CEFERO 500

CEFERO 500

- if you are hypersensitive (allergic) to the active substance cefuroxime or to any of the other ingredients of CEFERO 500.
- if you are hypersensitive to other type of cephalosporins antibiotic.
- if you have ever had a severe allergic reaction to any sort of penicillin antibiotic. Not all people who are allergic to penicillins are also allergic to cephalosporins.

However, you should not take this medicine if you have ever had a severe allergic reaction to any penicillin. This is because you might also be allergic to this medicine.

Take special care with CEFERO 500

Please inform your doctor if:

- you have ever had an allergic reaction to penicillins.
- you have severe and persistent diarrhea while using or after using CEFERO 500 you should not use any medicines for diarrhea that inhibit peristalsis;
- you are vomiting or have diarrhoea.
- you get fever and feel ill a short time after using CEFERO 500 for the treatment of Lyme disease (this is a sign of a disease called Jarisch Herxheimer disease)
- you are also using medicines that decrease stomach acidity. (see: "Using other medicines");

Some children have experienced mild to moderate hearing loss during treatment with cefuroxime sodium

Having a course of CEFERO 500 can temporarily increase the chance that you can get infections caused by other sorts of germs. For example, thrush may occur.

Taking other medicines

Please inform your doctor or pharmacist if you are taking, or have recently taken any other medicines, including medicines obtained without prescription.

Please tell your doctor if you are taking:

- medicines that decrease stomach acidity (medicines for heartburn);
- certain other medicines for the prevention or control of infections (antibiotics), such as tetracyclines, macrolides, chloramphenicol, aminoglycosids;
- probenecid (a medicine for gout and other ailments).
- water tablets or injections (diuretics)
- certain medicines against fungal infections (Amphotericin)

CEFERO 500 may interfere with certain tests, such as tests for determining the amount of glucose (sugar) in the blood or urine and tests for determining some substances in the blood (Coombs test).

Under antibiotic treatment, disorders of the intestinal flora may occur. This may reduce the absorption of oestrogen. Take this into account, if you take oral contraceptives (the "pill"). Therefore, due to possibly reduced efficacy of contraception, additional contraceptive measures should be used.

Taking CEFERO 500 with food and drink

Take CEFERO 500 tablets after meals.

Pregnancy and breast-feeding

Ask your doctor or pharmacists for advice before taking any medicine.

Pregnancy

Please inform your doctor if you are pregnant or think you might be pregnant, your doctor will decide if you should discontinue the treatment or change you to another medicinal product

Breast-feeding

Please inform your doctor if you are breast-feeding. You should not breast-feed while on treatment with CEFERO 500.

Driving and using machines

CEFERO 500 may cause dizziness, you should be cautious when driving a vehicle or operating machinery.

3. How To Take CEFERO 500

Always take CEFERO 500 tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

For an individual dosage, CEFERO 500 250 mg and 500 mg film-coated tablets are available. General dosage recommendations for CEFERO 500 depend on the sensitivity of the respective pathogen (germ) and the site of infection.

CEFERO 500 should be taken with some fluid shortly after a meal to ensure ideal absorption. The film-coated tablets should be taken in intervals of 12 hours.

Due to the bitter taste, CEFERO 500 should not be broken, crushed, or chewed.

Dosage for adults and children (over 12 years of age):

The usual treatment duration is 5-10 days. Some infections may require longer treatment in order to prevent late complications.

For ear, sinus and throat infections:

1 tablet of CEFERO 500 twice a day for 5-10 days.

For chest infections such as bronchitis and pneumonia:

1 tablet of CEFERO 500 twice a day for 5-10 days.

For bladder infections:

1 tablet of CEFERO 500 twice a day for 5-10 days.

For skin infections and infections in the layers just under the skin:

1 tablet of CEFERO 500 twice a day for 5-10 days.

For the treatment of early Lyme disease (an infection spread by infected ticks):

1 tablet of CEFERO 500 twice a day for 20 days.

Dosage for children (5-12 years):

For the conditions listed above:

125 - 250 mg twice a day for 5-10 days.

For acute otitis media (infection of the middle ear space, behind the eardrum):

1 tablet of CEFERO 500 twice a day for 5-10 days.

Children between 5 and 12 years should not receive more than a daily dose of 500 mg cefuroxime. For younger children, administration of a suspension is more suitable.

There is no experience in the use of cefuroxim axetil in children below 3 months of age.

Dosage in elderly patients and patients with impaired renal function:

If a total daily dose of 1000 mg cefuroxime is not exceeded, dose adjustment is not required.

Patients on haemodialysis

Additional doses may be needed at the end of each dialysis.

If you take more CEFERO 500 than you should

If you have taken more of this medicine than you should, talk to your doctor straight away or go to the nearest hospital accident and emergency department.

Overdose of CEFERO 500 can lead to convulsion.

If you forget to take CEFERO 500

If you forget to take a dose of this medicine at the right time, take it as soon as you remember. Do not take a double dose to make up for a forgotten dose.

If you stop taking this medicine

It is important that you take this medicine until you finish the prescribed course. You should not stop the medicine just because you feel better. If you stop too soon, the infection may start up again. If you still feel unwell at the end of the prescribed course of treatment, or feels worse during treatment, tell your doctor.

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

4. Possible Side Effects

Like all medicines, CEFERO 500 can cause side effects, although not everybody gets them. If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

If you notice any of the following serious side effects, stop taking CEFERO 500 and contact a doctor immediately:

- Sudden wheezing, swelling of your lips, face or body, rash, fainting or difficulties swallowing (severe allergic reaction). This effect is very rare, affecting less than 1 in 10,000 users.
- Yellow skin, dark urine and tiredness which can be symptoms of liver problems. This effect is very rare, affecting less than 1 in 10,000 users.
- Reddening of the skin with blisters or peeling and may be associated with a high fever and joint pains. There may also be severe blisters and bleeding in the lips, eyes, mouth, nose and genitals. This could be erythema multiforme, Stevens-Johnson syndrome or toxic epidermal necrolysis. This effect is very rare, affecting less than 1 in 10,000 users.

Common (affecting less than 1 in 10 people):

- increase in some type of white blood cells (eosinophilia)
- headache, dizziness
- stomach problems, diarrhoea, nausea and vomiting.
- kidney and urinary problems: if you have been told that your kidneys do not work very well, changes in kidney function may occur (higher levels of creatinine and urea in the blood).
- skin rash with or without severe itching and wheal formation
- fever and feeling generally being unwell a short time after taking CEFERO 500 for the treatment of Lyme disease (Jarisch-Herxheimer reaction)
- temporary increase of some liver enzymes, which is measured by blood tests

Uncommon (affecting less than 1 in 100 people):

- decrease in white blood cells (leucopenia) or some types of white blood cells (neutropenia) or platelets in your blood
- acute kidney inflammation

Rare (affecting less than 1 in 1000 people):

- decreased haemoglobin concentration in the blood. Haemoglobin is in the red-blood cells and transports oxygen and carbon dioxide in the bloodstream
- pseudomembranous colitis, infection of the colon, The illness is characterized by diarrhoea, fever, and abdominal pain.
- as with other antibiotics prolonged use may lead to secondary super infections caused by insusceptible organisms, e.g. *Candida*, *Enterococci* and *Clostridium difficile*
- a fever associated with an allergic reaction which disappears on discontinuation
- serum sickness, hypersensitive reaction characterized by fever, swelling, skin rash, and enlargement of the lymph nodes.

Very rare (affecting less than 1 in 10 000 people):

- haemolytic anaemia (reduction in red blood cells) symptoms such as nosebleeds, bleeding gums, shortness of breath, fatigue, rapid heartbeat, pale skin color or yellow skin color (jaundice), chills, and dark-colored urine.
- restlessness, nervousness, confusion, hallucinations
- allergic reactions including sudden wheezing, swelling of lips, face or body, rash, fainting or difficulties swallowing
- reddening of the skin with blisters or peeling and sometimes with a high fever and joint pains. There may also be severe blisters and bleeding in the lips, eyes, mouth, nose and genitals (erythema multiforme, Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN))
- hepatitis with symptoms such as yellow discoloration of skin or eyes (jaundice), fever, liver enlargement, and abdominal pain, obstructive jaundice

Investigations

Certain tests for determining some substances in your blood might show different results while you take CEFERO 500 (Coombs test).

5. How To Store CEFERO 500

Keep out of the reach and sight of children.

Do not store above 30°C, protect from moisture.

Do not use CEFERO 500 after the expiry date which is stated on the package after EXP. The expiry date refers to the last day of that month.

Do not use CEFERO 500 if you notice any visible signs of deterioration.

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 CEFERO 500 contains

- The active substance is: 500 mg cefuroxime as cefuroxime axetil.

- *6.1 List of excipients:*

Core: Citric Acid Monohydrate, Sodium Lauryl Sulphate, Magnesium Stearate, Purified Talc, Mannitol, Sodium Carbonate, Crospovidone, Croscarmellose Sodium, Colloidal Anhydrous Silica, Microcrystalline Cellulose,

Coating: Propylene Glycol, Titanium Dioxide, Hypromellose 15 cps & Erythrosine Lake.

What CEFERO 500 looks like and contents of the pack

Pink coloured, caplet shaped film coated tablet having breakline on one side and plain on other side

Pack sizes:

1x10 Tablets in Alu-Alu Blister pack.

Marketing Authorization Holder and Manufacturer

ZIM LABORATORIES LIMITED

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Nagpur 441501, Maharashtra State,
India.

This leaflet was last approved in December 2013.