PATIENT INFORMATION LEAFLET CEFUROXIME AXETIL TABLETS USP 250mg (PULMOCEF-250)



Keep this leaflet. You may need to read it again.

- If you have any further questions, ask your health care provider.
- 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 becomes serious, or if you notice any side effects not listed in this leaflet, please tell your health care provider

WHAT IS IN THIS LEAFLET

- What PULMOCEF is and what it is used for
- What you need to know before you take PULMOCEF
- How to take PULMOCEF
- Possible Side Effects
- How to store PULMOCEF
- Contents of the pack and other information

WHAT PULMOCEF S IS AND WHAT IT IS USED FOR

Cefuroxime 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 is used to treat infections of:

- The throat
- Sinus
- Middle ear
- The lungs or chest
- The urinary tract
- The skin and soft tissues.

Cefuroxime can also be used: To treat Lyme disease (an infection spread by parasites called ticks).

Your doctor may test the type of bacteria causing your infection and monitor whether the bacteria are sensitive to Cefuroxime during your treatment.

WHAT YOU NEED TO KNOW BEFORE YOU TAKE PULMOCEF

Do not take Cefuroxime:

- If you are allergic to cefuroxime axetil or any cephalosporin antibiotics or any of the other ingredients of Cefuroxime.
- If you have ever had a severe allergic (hypersensitive) reaction to any other type of beta lactam antibiotic (penicillins, monobactams and carbapenems).

If you think this applies to you, don't take Cefuroxime until you have checked with your doctor.

Warnings and precautions

Talk to your doctor or pharmacist before taking Cefuroxime.

Children

Cefuroxime is not recommended for children aged less than 3 months, as the safety and effectiveness are not known in this age group.

You must look out for certain symptoms; such as allergic reactions, fungal infections (such as *candida*) and severe diahorrea (*pseudomembranous colitis*) while you are taking Cefuroxime. This will reduce the risk of any problems. See 'Conditions you need to look out for' in Section 4.

If you need a blood test

Cefuroxime can affect the results of a test for blood sugar levels, or a blood screen called the *Coombs test*. If you need a blood test:

• Tell the person taking the sample that you are taking Cefuroxime.

Other medicines and Cefuroxime

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Medicines used to reduce the amount of acid in your stomach (e.g. *antacids* used to treat heartburn) can affect how Cefuroxime works.

Probenecid

Oral anticoagulants

• Tell your doctor or pharmacist if you are taking any medicine like this.

Contraceptive pills

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

Pregnancy and breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Cefuroxime can make you dizzy and have other side effects that make you less alert.

Don't drive or use machines if you do not feel well.

3. HOW TO TAKE PULMOCEF

Always take this medicine exactly as your doctor or pharmacist has told you to. Check with your doctor or pharmacist if you are not sure.

Take Cefuroxime after food. This will help to make the treatment more effective.

Swallow Cefuroxime tablets whole with some water.

Don't chew, crush or split the tablets — this may make the treatment less effective.

The recommended dose

Adults

The recommended dose of Cefuroxime is 250 mg to 500 mg twice daily depending on the severity and type of infection.

Children

The recommended dose of Cefuroxime is 10 mg/kg (to a maximum of 125 mg) to 15 mg/kg (to a maximum of 250 mg) twice daily depending on:

• The severity and type of infection

Cefuroxime is not recommended for children aged under 3 months, as the safety and effectiveness are not known in this age group.

Depending on the illness or how you or your child responds to treatment, the initial dose may be changed or more than one course of treatment may be needed.

Patients with kidney problems

If you have a kidney problem, your doctor may change your dose.

• Talk to your doctor if this applies to you.

If you take more Cefuroxime than you should

If you take too much Cefuroxime you may have neurological disorders, in particular you may be more likely to have fits (*seizures*).

• Don't delay. Contact your doctor or your nearest hospital emergency department immediately. If possible, show them the Cefuroxime pack.

If you forget to take Cefuroxime: Do not take a double dose to make up for a forgotten dose. Just take your next dose at the usual time. If you stop taking Cefuroxime

Don't stop Cefuroxime without advice

It is important that you take the full course of Cefuroxime. Don't stop unless your doctor advises you to – even if you are feeling better. If you don't complete the full course of treatment, the infection may come back.

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

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

A small number of people taking Cefuroxime get an allergic reaction or potentially serious skin reaction. Symptoms of these reactions include:

- Severe allergic reaction. Signs include raised and itchy rash, swelling, sometimes of the face or mouth causing difficulty in breathing.
- Skin rash, which may blister, and looks like small targets (central dark spot surrounded by a paler area, with a dark ring around the edge).
- A widespread rash with blisters and peeling skin. (These may be signs of *Stevens-Johnson syndrome* or *toxic epidermal necrolysis*).

Other conditions you need to look out for while taking 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 side effect is more likely if you take Cefuroxime for a long time.
- Severe diarrhoea (*Pseudomembranous colitis*). Medicines like Cefuroxime can cause inflammation of the colon (large intestine), causing severe diarrhoea, usually with blood and mucus, stomach pain, fever
- Jarisch-Herxheimer reaction. Some patients may get a high temperature (fever), chills, headache, muscle pain and skin rash while being treated with Cefuroxime for Lyme disease. This is known as the *Jarisch-Herxheimer reaction*. Symptoms usually last a few hours or up to one day.
- Contact a doctor or nurse immediately if you get any of these symptoms.

Common side effects

These may affect up to 1 in 10 people:

- Fungal infections (such as *Candida*)
- Headache
- Dizziness
- Diarrhoea
- Feeling sick
- Stomach pain.

Common side effects that may show up in blood tests:

- An increase in a type of white blood cell (eosinophilia)
- An increase in liver enzymes.

Uncommon side effects

These may affect up to 1 in 100 people:

Being sick

SKIN rashes.

Uncommon side effects that may show up in blood tests:

- A decrease in the number of blood platelets (cells that help blood to clot)
- A decrease in the number of white blood cells
- Positive Coomb's test.

Other side effects

Other side effects have occurred in a very small number of people, but their exact frequency is unknown:

- Severe diarrhoea (pseudomembranous colitis)
- Allergic reactions
- Skin reactions (including severe)
- High temperature (*fever*)
- Yellowing of the whites of the eyes or skin
- Inflammation of the liver (*hepatitis*).

Side effects that may show up in blood tests: red blood cells destroyed too quickly (haemolytic anaemia).

5. HOW TO STORE PULMOCEF

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the pack after EXP. The expiry date refers to the last day of that month.

Store in the original pack in a dry place at or below 30°C

Do not use Cefuroxime if the tablets are chipped or there are other visible signs of deterioration.

Don't throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Pulmocef contains,

Active ingredients: Cefuroxime Axetil

In active ingredients: Microcrystalline cellulose; Cross carmellose sodium; Hydrogenated Castor Oil; Colloidal Silicon Dioxide; Sodium Lauryl Sulphate; Tab Coat TC-1004, Propylene glycol, Talc, Titanium Dioxide USP.

What Pulmocef looks like and contents of the pack

White to off white coloured, oval shaped film coated tablets, engraved with "250" on one side and plain on other side.

ALU/ALU blister pack of 10 Tablets. Such 1 blister is packed in a printed outer carton along with a pack insert. (1x10's)

Manufacturer

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Marketing Authorisation Holder

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