



Package leaflet: Information for the user

Cefuroxime Aurobindo 125 mg tablets Cefuroxime Aurobindo 250 mg tablets Cefuroxime Aurobindo 500 mg tablets Cefuroxime

Read all of this leaflet carefully before you start taking 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.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- 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 Aurobindo is and what it is used for
2. What you need to know before you take Cefuroxime Aurobindo
3. How to take Cefuroxime Aurobindo
4. Possible side effects
5. How to store Cefuroxime Aurobindo
6. Contents of the pack and other further information

1. What Cefuroxime Aurobindo is and what it is used for

Cefuroxime Aurobindo 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 Aurobindo is used to treat infections of:

- the throat
- sinus
- middle ear
- the lungs or chest
- the urinary tract
- the skin and soft tissues.

Cefuroxime Aurobindo can also be used:

- to treat Lyme disease (an infection spread by parasites called ticks).

2. What you need to know before you take Cefuroxime Aurobindo

Do NOT take Cefuroxime Aurobindo:

- if you are allergic (hypersensitive) to any cephalosporin antibiotics or any of the other ingredients of this medicine (listed in section 6).
 - if you have ever had a severe allergic (hypersensitive) reaction to any other type of betalactam antibiotic (penicillins, monobactams and carbapenems).
- If you think this applies to you, don't take Cefuroxime Aurobindo until you have checked with your doctor.

Warnings and precautions

Cefuroxime Aurobindo is not recommended for children aged under 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 diarrhoea (pseudomembranous colitis) while you are taking Cefuroxime Aurobindo. 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 Aurobindo 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 Aurobindo.

Other medicines and Cefuroxime Aurobindo

Tell your doctor or pharmacist if you are taking 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 Aurobindo works.

Probenecid

Oral anticoagulants

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

Pregnancy and breast-feeding and fertility

Tell your doctor before you take Cefuroxime Aurobindo:

- if you are pregnant, think you might be pregnant or are planning to become pregnant
- if you are breastfeeding.

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

Driving and using machines

Cefuroxime Aurobindo **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 Cefuroxime Aurobindo

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

Swallow Cefuroxime Aurobindo 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 usual dose of Cefuroxime Aurobindo is 250 mg to 500 mg twice daily depending on the severity and type of infection.

Children

The usual dose of Cefuroxime Aurobindo 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 Aurobindo 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 Aurobindo than you should

If you take too much Cefuroxime Aurobindo 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 Aurobindo pack

If you forget to take Cefuroxime Aurobindo

Don't take an extra dose to make up for a missed dose. Just take your next dose at the usual time.

If you stop taking Cefuroxime Aurobindo

It is important that you take the full course of Cefuroxime Aurobindo. 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 Aurobindo 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).
- **fungal infections**. Medicines like Cefuroxime Aurobindo 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 Aurobindo for a long time.
- **severe diarrhoea (*Pseudomembranous colitis*)**. Medicines like Cefuroxime Aurobindo 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 Aurobindo 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*).

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V*. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Cefuroxime Aurobindo

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 carton and blister after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special temperature storage conditions.

Store in the original package in order to protect from light.

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 Cefuroxime Aurobindo contains

- The active substance is Cefuroxime.

Each tablet contains 150.36 mg cefuroxime axetil equivalent to 125 mg cefuroxime.

Each tablet contains 300.72 mg cefuroxime axetil equivalent to 250 mg cefuroxime.

Each tablet contains 601.44 mg cefuroxime axetil equivalent to 500 mg cefuroxime.

- The other ingredients are microcrystalline cellulose, croscarmellose sodium, sodium lauril sulfate, cottonseed oil, hydrogenated and colloidal anhydrous silica.

What Cefuroxime Aurobindo looks like and contents of the pack

Tablet

Cefuroxime Aurobindo 125 mg:

White to off-white, capsule shaped tablets with 'A32' debossed on one side and plain on the other side.

The size is 12.5 mm X 5.0 mm.

Cefuroxime Aurobindo 250 mg:

White to off-white, capsule shaped tablets with 'A33' debossed on one side and plain on the other side. The size is 16.0 mm X 6.5 mm

Cefuroxime Aurobindo 500 mg:

White to off-white, capsule shaped tablets with 'A34' debossed on one side and plain on the other side. The size is 20.0 mm X 8.5 mm

Polyamide/Aluminium/PVC/Aluminium blister.

Pack sizes: 6, 8, 10, 12, 14, 15, 16, 20, 24, 50, 100 or 500 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Milpharm Limited
Ares, Odyssey Business Park
West End Road
South Ruislip HA4 6QD
United Kingdom

Manufacturer

APL Swift Services (Malta) Limited
HF 26, Hal Far Industrial Estate, Hal Far
Birzebbugia, BBG 3000
Malta

This medicinal product is authorised in the Member States of the EEA under the following names:

Germany:	Cefuroxim Aurobindo 125mg, 250 mg, 500 mg Tabletten
Ireland:	Cefuroxime Aurobindo 125mg, 250 mg, 500 mg tablets
Italy:	Cefuroxima Aurobindo 250 mg, 500 mg compresse
Poland:	Cefuroxim Aurobindo
Portugal:	Cefuroxima Aurobindo
Romania:	Cefuroxime Aurobindo 125mg, 250 mg, 500 mg comprimate
Spain:	Cefuroxima Aurobindo 125mg, 250 mg, 500 mg comprimidos

This leaflet was last approved in 01/2017.