

Package leaflet: Information for the user

Cefuroxime Aurobindo 250 mg film-coated tablets Cefuroxime Aurobindo 500 mg film-coated 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. 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).

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

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

Do NOT take Cefuroxime Aurobindo:

- if you are allergic 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 have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after treatment with cefuroxime or any other cephalosporin antibiotics.
- If you think this applies to you, don't take Cefuroxime Aurobindo until you have checked with your doctor.

Warnings and precautions

Talk to your doctor or pharmacist before taking Cefuroxime Aurobindo

Children

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.

Take special care with Cefuroxime Aurobindo:

Serious skin reactions including Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported in association with cefuroxime treatment. Seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described 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, 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 Aurobindo works.

Probenecid

Oral anticoagulants

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

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

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.

Cefuroxime contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'

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 and children weighing 40 kg and over

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

Children weighing less than 40 kg

Children weighing less than 40 kg should preferably be treated with Cefuroxime oral suspension or sachets. 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 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 double dose to make up for a forgotten 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:

- widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome).
- chest pain in the context of allergic reactions, which may be a symptom of allergy triggered cardiac infarction (Kounis syndrome)
- **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 Aurobindo include:

- **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 HPRA Pharmacovigilance Earlsfort Terrace, IRL - Dublin 2, Tel: +353 1 6764971, Fax: +353 1 6762517, Website: www.hpra.ie e-mail: medsafety@hpra.ie

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 medicine does not require any special temperature storage conditions. Store in the original package in order to protect from light.

Do not 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.
Cefuroxime Aurobindo 250 mg film-coated tablet contains 300.72 mg cefuroxime axetil equivalent to 250 mg cefuroxime.
Cefuroxime Aurobindo 500 mg film-coated tablet contains 601.44 mg cefuroxime axetil equivalent to 500 mg cefuroxime.
- The other ingredients are
- *Tablet core:* microcrystalline cellulose (E460), croscarmellose sodium, sodium lauril sulfate, hydrogenated vegetable oil (cotton seed oil, hydrogenated) and colloidal anhydrous silica.
- *Film-coating:* Hypromellose, Titanium dioxide (E171), Macrogol 400

What Cefuroxime Aurobindo looks like and contents of the pack

Film-coated tablet

Cefuroxime Aurobindo 250 mg:

White to off-white, film-coated capsule shaped tablets with 'A33' debossed on one side and plain on the other side. The size is 16.1 mm X 6.6 mm

Cefuroxime Aurobindo 500 mg:

White to off-white, film-coated capsule shaped tablets with 'A34' debossed on one side and plain on the other side. The size is 20.1 mm X 8.6 mm

Cefuroxime Aurobindo Film-coated tablets are available in blister packs and white opaque HDPE bottle packs. HDPE bottle also contains silica gel as desiccant.

Pack sizes:

Blister : 6, 8, 10, 12, 14, 15, 16, 20, 24, 30, 50, 100 & 500 film-coated tablets.

HDPE : 20, 60 & 500 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Aurobindo Pharma (Malta) Limited
Vault 14, Level 2, Valletta Waterfront,
Floriana FRN 1913
Malta

Manufacturer

APL Swift Services (Malta) Limited
HF26, Hal Far Industrial Estate, Hal Far
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