

## 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 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

**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.

#### **Contraceptive pills**

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

#### **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.

### **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 recommended dose of Cefuroxime Aurobindo 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 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.

For doses not realisable/practicable with this medicinal product other strengths of this medicinal product or other pharmaceutical forms and products are available.

## **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:

- **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:** 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:** 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 HPRC Pharmacovigilance Earlsfort Terrace, IRL - Dublin 2, Tel: +353 1 6764971, Fax: +353 1 6762517, Website: [www.hpra.ie](http://www.hpra.ie) e-mail: [medsafety@hpra.ie](mailto: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 bottle packs

#### 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  
Birzebbugia, BBG 3000  
Malta

**This leaflet was last revised in**

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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**

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- 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).
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#### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Cefuroxime Aurobindo

**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.

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

#### **Other medicines and Cefuroxime Aurobindo**

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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:

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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.

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

### **Children**

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For doses not realisable/practicable with this medicinal product other strengths of this medicinal product or other pharmaceutical forms and products are available.

### **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:

- **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:** 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:** 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 HPRAs Pharmacovigilance Earlsfort Terrace, IRL - Dublin 2, Tel: +353 1 6764971, Fax: +353 1 6762517, Website: [www.hpra.ie](http://www.hpra.ie) e-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie)

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- *Tablet core:* microcrystalline cellulose (E460), croscarmellose sodium, sodium lauril sulfate, hydrogenated vegetable oil (cotton seed oil, hydrogenated) and colloidal anhydrous silica.
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### **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  
Birzebbugia, BBG 3000  
Malta

| **This leaflet was last revised in ~~06/2022~~**