

## **PACKAGE LEAFLET: INFORMATION FOR THE USER**

### **CEFUROXIME TEVA 125 MG FILM-COATED TABLETS** **CEFUROXIME TEVA 250 MG FILM-COATED TABLETS** **CEFUROXIME TEVA 500 MG FILM-COATED TABLETS**

Cefuroxime (as cefuroxime axetil)

**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 of the side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

#### **WHAT IS IN THIS LEAFLET:**

- 1. What Cefuroxime Teva is and what it is used for**
- 2. What you need to know before you take Cefuroxime Teva**
- 3. How to take Cefuroxime Teva**
- 4. Possible side effects**
- 5. How to store Cefuroxime Teva**
- 6. Contents of the pack and other information**

#### **1. WHAT CEFUROXIME TEVA IS AND WHAT IT IS USED FOR**

Cefuroxime Teva 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 Teva is used to treat infections of:

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

Cefuroxime Teva can also be used:

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

#### **2. WHAT YOU NEED KNOW BEFORE YOU TAKE CEFUROXIME TEVA**

##### **Don't take Cefuroxime Teva:**

- if you are allergic (hypersensitive) to any cephalosporin antibiotics or any of the ingredients of Cefuroxime Teva.
- 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 Teva** until you have checked with your doctor.

If you are not sure whether any of the above apply to you speak to your doctor or pharmacist before taking this medicine.

### **Warnings and precautions**

**Cefuroxime Teva 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 Teva. 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 Teva 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 Teva.

### **Other medicines and Cefuroxime Teva**

Tell your doctor or pharmacist if you are taking any other medicines, if you've started taking any recently or you start taking new ones. This includes medicines you can obtain without a prescription.

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

- Probenecid
- Oral anticoagulants

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

### **Contraceptive pills**

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

### **Pregnancy and breast-feeding and fertility**

Tell your doctor before you take Cefuroxime Teva:

- 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 Teva against the risk to your baby.

### **Driving and using machines**

Cefuroxime Teva **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 TEVA**

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

Swallow Cefuroxime Teva tablets whole with some water.

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

**The usual dose:**

## Adults

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

## Children

The usual dose of Cefuroxime Teva 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 Teva 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 too much Cefuroxime Teva

If you take too much Cefuroxime Teva 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 Teva pack.

## If you forget to take Cefuroxime Teva

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

## Don't stop Cefuroxime Teva without advice

It is important that you take the full course of Cefuroxime Teva. 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.

## 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 Teva 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 Teva 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 Teva for a long time.
- **severe diarrhoea** (*Pseudomembranous colitis*). Medicines like Cefuroxime Teva 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 Teva 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).

If you get any of the side effects tell your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

## **5. HOW TO STORE CEFUROXIME TEVA**

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

Do not use this medicine after the expiry date that is stated on the blister or outer packaging. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

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 Teva contains:

- The active ingredient is cefuroxime (as cefuroxime axetil).
- The other ingredients in the tablet core are pregelatinised starch, croscarmellose sodium, sodium laurilsulfate, microcrystalline cellulose, anhydrous colloidal silica and hydrogenated vegetable oil.
- The other ingredients in the tablet coating are as follows:

#### *Cefuroxime Teva 125 mg Film-coated Tablets:*

Hypromellose (E464), titanium dioxide (E171), propylene glycol (E1520).

#### *Cefuroxime Teva 250 mg and 500 mg Film-coated Tablets:*

Hypromellose (E464), titanium dioxide (E171), propylene glycol (E1520), Brilliant Blue FCF aluminium lake (E133), Indigo Carmine Aluminium Lake (E132).

### What Cefuroxime Teva looks like and contents of the pack:

Cefuroxime Teva 125mg Film-coated Tablets are white to off-white coloured film-coated tablets engraved with “125” on one side and “P124” on the other side.

Cefuroxime Teva 250 mg Film-coated Tablets are light blue coloured film-coated tablets engraved with “250” on one side and “P125” on the other side.

Cefuroxime Teva 500 mg Film-coated Tablets are light blue coloured film-coated tablets engraved with “500” on one side and “P126” on the other side.

Your medicine is provided in blister packs. Pack sizes are as follows:

- Cefuroxime Teva 125 mg Film-coated Tablets: 10, 12 and 14 tablets.
- Cefuroxime Teva 250 mg Film-coated Tablets: 8, 10, 12, 14, 16, 20 and 24 tablets.
- Cefuroxime Teva 500 mg Film-coated Tablets: 6, 8, 10, 12, 14, 16, 20 and 24 tablets.

Not all pack sizes may be marketed.

### Marketing Authorisation Holder and Manufacturer

*The marketing authorisation holder is:*

Teva Pharma B.V.  
Computerweg 10  
3542 DR Utrecht  
The Netherlands

*The manufacturer is:*

TEVA UK Ltd., Brampton Road, Hampden Park, Eastbourne, East Sussex, BN22 9AG, UK.  
Teva Czech Industries s.r.o., Ostravska 29, c.p. 305, 74770 Opava-Komárov, Czech Republic.  
Teva Operations Poland Sp. z.o.o., Mogilska 80 Str. 31-546 Kraków.  
Merckle GmbH, Ludwig-Merckle-Straße 3, 89143 Blaubeuren, Germany.

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

Ireland	Cefuroxime Teva 125 mg Film-coated tablets Cefuroxime Teva 250 mg Film-coated tablets Cefuroxime Teva 500 mg Film-coated tablets
Italy	Cefuroxima Teva 125 mg compresse rivestite con film Cefuroxima Teva 250 mg compresse rivestite con film Cefuroxima Teva 500 mg compresse rivestite con film
Poland	Cefuroxime Teva, 125mg, tabletki powlekane Cefuroximum 123ratio, 250mg, tabletki powlekane Cefuroximum 123ratio, 500mg, tabletki powlekane
Slovakia	Cefuroxim - Teva 125 mg

	Cefuroxim - Teva 250 mg Cefuroxim - Teva 500 mg
Spain	Cefuroxima Teva 125 mg comprimidos recubiertos con película EFG Cefuroxima Teva 250 mg comprimidos recubiertos con película EFG Cefuroxima Teva 500 mg comprimidos recubiertos con película EFG
United Kingdom	Cefuroxime 125 mg Film-coated Tablets Cefuroxime 250 mg Film-coated Tablets Cefuroxime 500 mg Film-coated Tablets

**This leaflet was last revised: June 2013.**