

## PACKAGE LEAFLET: INFORMATION FOR THE USER

### Cefuroxime Actavis 250 mg film-coated tablets Cefuroxime Actavis 500 mg film-coated tablets

#### Cefuroxime

#### **Read all of this leaflet carefully before you start taking this medicine.**

- 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. 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 gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

#### **In this leaflet:**

1. What Cefuroxime Actavis is and what it is used for
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## **1. WHAT CEFUROXIME ACTAVIS IS AND WHAT IT IS USED FOR**

Cefuroxime Actavis is an antibiotic. It belongs to a group of antibiotics that are called cephalosporins. These types of antibiotics are similar to penicillin. Cefuroxime Actavis kills bacteria and it can be used against various sorts of infections.

Like all antibiotics Cefuroxime Actavis is only effective against some types of bacteria. So, it is only suitable for treating some types of infection.

Cefuroxime Actavis can be used to treat:

- ear, sinus and throat infections
- chest infections such as bronchitis
- infections of the bladder
- infections in the skin and the layers just under the skin (such as furuncles, impetigo-an infection on the surface of the skin)
- early Lyme disease (from a tick bite) and to prevent late complications in adults and children above the age of 12.

## **2. BEFORE YOU TAKE CEFUROXIME ACTAVIS**

#### **Do not take Cefuroxime Actavis**

- if you are hypersensitive (allergic) to the active substance cefuroxime or to any of the other ingredients of Cefuroxime Actavis.
- if you are hypersensitive to other type of cephalosporins antibiotic.
- if you have ever had a severe allergic reaction to any sort of penicillin antibiotic.

Not all people who are allergic to penicillins are also allergic to cephalosporins.

However, you should not take this medicine if you have ever had a severe allergic reaction to any penicillin. This is because you might also be allergic to this medicine.

### **Take special care with Cefuroxime Actavis**

Please inform your doctor if:

- you have ever had an allergic reaction to penicillins.
- you have severe and persistent diarrhea while using or after using Cefuroxime Actavis you should not use any medicines for diarrhea that inhibit peristalsis;
- you are vomiting or have diarrhoea.
- you get fever and feel ill a short time after using Cefuroxime Actavis for the treatment of Lyme disease (this is a sign of a disease called Jarisch Herxheimer disease)
- you are also using medicines that decrease stomach acidity. (see: "Using other medicines");

Some children have experienced mild to moderate hearing loss during treatment with cefuroxime sodium

Having a course of Cefuroxime Actavis can temporarily increase the chance that you can get infections caused by other sorts of germs. For example, thrush may occur.

### **Taking other medicines**

Please inform your doctor or pharmacist if you are taking, or have recently taken any other medicines, including medicines obtained without prescription.

Please tell your doctor if you are taking:

- medicines that decrease stomach acidity (medicines for heartburn);
- certain other medicines for the prevention or control of infections (antibiotics), such as tetracyclines, macrolides, chloramphenicol, aminoglycosids;
- probenecid (a medicine for gout and other ailments).
- water tablets or injections (diuretics)
- certain medicines against fungal infections (Amphotericin)

Cefuroxime Actavis may interfere with certain tests, such as tests for determining the amount of glucose (sugar) in the blood or urine and tests for determining some substances in the blood (Coombs test).

Under antibiotic treatment, disorders of the intestinal flora may occur. This may reduce the absorption of oestrogen. Take this into account, if you take oral contraceptives (the "pill"). Therefore, due to possibly reduced efficacy of contraception, additional contraceptive measures should be used.

### **Taking Cefuroxime Actavis with food and drink**

Take Cefuroxime Actavis tablets after meals.

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

Ask your doctor or pharmacists for advice before taking any medicine.

#### *Pregnancy*

Please inform your doctor if you are pregnant or think you might be pregnant, you doctor will decide if you should discontinue the treatment or change you to another medicinal product

#### *Breast-feeding*

Please inform your doctor if you are breast-feeding. You should not breast-feed while on treatment with Cefuroxime Actavis

### **Driving and using machines**

Cefuroxime Actavis may cause dizziness, you should be cautious when driving a vehicle or operating machinery.

## **3. HOW TO TAKE CEFUROXIME ACTAVIS**

Always take Cefuroxime Actavis tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

For an individual dosage, Cefuroxime Actavis 250 mg and 500 mg film-coated tablets are available. General dosage recommendations for Cefuroxime Actavis depend on the sensitivity of the respective pathogen (germ) and the site of infection.

Cefuroxime Actavis should be taken with some fluid shortly after a meal to ensure ideal absorption. The film-coated tablets should be taken in intervals of 12 hours. Due to the bitter taste, Cefuroxime Actavis should not be broken, crushed, or chewed.

### ***Dosage for adults and children (over 12 years of age):***

The usual treatment duration is 5-10 days. Some infections may require longer treatment in order to prevent late complications.

#### ***For ear, sinus and throat infections:***

1 tablet of Cefuroxime Actavis 250 mg or 500 mg twice a day for 5-10 days.

#### ***For chest infections such as bronchitis and pneumonia:***

1 tablet of Cefuroxime Actavis 500 mg twice a day for 5-10 days.

#### ***For bladder infections:***

1 tablet of Cefuroxime Actavis 250 mg twice a day for 5-10 days.

#### ***For skin infections and infections in the layers just under the skin:***

1 tablet of Cefuroxime Actavis 250 mg or 500 mg twice a day for 5-10 days.

#### ***For the treatment of early Lyme disease (an infection spread by infected ticks):***

1 tablet of Cefuroxime Actavis 500 mg twice a day for 20 days.

### ***Dosage for children (5-12 years):***

#### ***For the conditions listed above:***

125 - 250 mg twice a day for 5-10 days.

#### ***For acute otitis media (infection of the middle ear space, behind the eardrum):***

1 tablet of Cefuroxime Actavis 250 mg twice a day for 5-10 days.

Children between 5 and 12 years should not receive more than a daily dose of 500 mg cefuroxime.

For younger children, administration of a suspension is more suitable.

There is no experience in the use of cefuroxim axetil in children below 3 months of age.

### ***Dosage in elderly patients and patients with impaired renal function:***

If a total daily dose of 1000 mg cefuroxime is not exceeded, dose adjustment is not required.

#### ***Patients on haemodialysis***

Additional doses may be needed at the end of each dialysis.

#### **If you take more Cefuroxime Actavis than you should**

If you have taken more of this medicine than you should, talk to your doctor straight away or go to the nearest hospital accident and emergency department.

Overdose of Cefuroxime Actavis can lead to convulsion.

#### **If you forget to take Cefuroxime Actavis**

If you forget to take a dose of this medicine at the right time, take it as soon as you remember. Do not take a double dose to make up for a forgotten dose.

#### **If you stop taking this medicine**

It is important that you take this medicine until you finish the prescribed course. You should not stop the medicine just because you feel better. If you stop too soon, the infection may start up again. If you still feel unwell at the end of the prescribed course of treatment, or feel worse during treatment, tell your doctor.

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

## **4. POSSIBLE SIDE EFFECTS**

Like all medicines, Cefuroxime Actavis can cause side effects, although not everybody gets them. If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

#### **If you notice any of the following serious side effects, stop taking Cefuroxime Actavis and contact a doctor immediately:**

- Sudden wheezing, swelling of your lips, face or body, rash, fainting or difficulties swallowing (severe allergic reaction). This effect is very rare, affecting less than 1 in 10,000 users.
- Yellow skin, dark urine and tiredness which can be symptoms of liver problems. This effect is very rare, affecting less than 1 in 10,000 users.
- Reddening of the skin with blisters or peeling and may be associated with a high fever and joint pains. There may also be severe blisters and bleeding in the lips, eyes, mouth, nose and genitals. This could be erythema multiforme, Stevens-Johnson syndrome or toxic epidermal necrolysis. This effect is very rare, affecting less than 1 in 10,000 users.

#### *Common (affecting less than 1 in 10 people):*

- increase in some type of white blood cells (eosinophilia)
- headache, dizziness
- stomach problems, diarrhoea, nausea and vomiting.
- kidney and urinary problems: if you have been told that your kidneys do not work very well, changes in kidney function may occur (higher levels of creatinine and urea in the blood).
- skin rash with or without severe itching and wheal formation
- fever and feeling generally being unwell a short time after taking Cefuroxime Actavis for the treatment of Lyme disease (Jarisch-Herxheimer reaction)
- temporary increase of some liver enzymes, which is measured by blood tests

#### *Uncommon (affecting less than 1 in 100 people):*

- decrease in white blood cells (leucopenia) or some types of white blood cells (neutropenia) or platelets in your blood
- acute kidney inflammation

*Rare (affecting less than 1 in 1000 people):*

- decreased haemoglobin concentration in the blood. Haemoglobin is in the red-blood cells and transports oxygen and carbon dioxide in the bloodstream
- pseudomembranous colitis, infection of the colon, The illness is characterized by diarrhoea, fever, and abdominal pain.
- as with other antibiotics prolonged use may lead to secondary super infections caused by insusceptible organisms, e.g. *Candida*, *Enterococci* and *Clostridium difficile*
- a fever associated with an allergic reaction which disappears on discontinuation
- serum sickness, hypersensitive reaction characterized by fever, swelling, skin rash, and enlargement of the lymph nodes.

*Very rare (affecting less than 1 in 10 000 people):*

- haemolytic anaemia (reduction in red blood cells) symptoms such as nosebleeds, bleeding gums, shortness of breath, fatigue, rapid heartbeat, pale skin color or yellow skin color (jaundice), chills, and dark-colored urine.
- restlessness, nervousness, confusion, hallucinations
- allergic reactions including sudden wheezing, swelling of lips, face or body, rash, fainting or difficulties swallowing
- reddening of the skin with blisters or peeling and sometimes with a high fever and joint pains. There may also be severe blisters and bleeding in the lips, eyes, mouth, nose and genitals (erythema multiforme, Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN))
- hepatitis with symptoms such as yellow discoloration of skin or eyes (jaundice), fever, liver enlargement, and abdominal pain, obstructive jaundice

### **Investigations**

Certain tests for determining some substances in your blood might show different results while you take Cefuroxime Actavis (Coombs test).

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

Keep out of the reach and sight of children.

This medicinal product does not require any special storage conditions

Do not use Cefuroxime Actavis after the expiry date which is stated on the package after EXP. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## **6. FURTHER INFORMATION**

### **What Cefuroxime Actavis contains**

- The active substance is: 250 mg or 500 mg cefuroxime as cefuroxime axetil.

- Other ingredients are:  
*Core:* pregelatinised starch, croscarmellose sodium, sodium lauril sulfate, microcrystalline cellulose, silica colloidal anhydrous, hydrogenated vegetable oil.  
*Coating:* Opadry blue: hydroxypropyl methylcellulose (E 464), titanium dioxide (E 171), propylene glycol, brilliant blue aluminium coating (E133), indigo carmine aluminium coating (E132).

### **What Cefuroxime Actavis looks like and contents of the pack**

250 mg: Light blue coloured film coated, capsule shaped tablets marked “250” on one side and “P125” on the other side.

500 mg: Light blue coloured film coated, capsule shaped tablets marked “500” on one side and “P126” on the other side.

#### *Pack sizes:*

Blisters: 10, 12, 14, 16, 20 and 50 film-coated tablets.

Tablet containers: 20 and 60 film-coated tablets.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer**

#### *Marketing Authorisation Holder*

Actavis Group PTC ehf.  
Reykjavíkurvegur 76-78  
IS-220 Hafnarfjörður  
Iceland

#### *Manufacturer:*

Orchid Europe Limited  
Building 3, Chiswick Park  
566 Chiswick High Road  
Chiswick  
London, W4 5YA  
UNITED KINGDOM

Actavis Group PTC ehf.  
Reykjavíkurvegur 76-78  
IS-220 Hafnarfjörður  
Iceland

**This leaflet was last revised in October 2013.**