

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986**

The medicine is dispensed with a physician's prescription only

**CefuAvenir Tablets 250 mg**

Each tablet contains cefuroxime (as axetil) 250 mg

**CefuAvenir Tablets 500 mg**

Each tablet contains cefuroxime (as axetil) 500 mg

The list of additional ingredients is detailed in section 6

**Read the entire leaflet carefully before using this medicine.**

This leaflet contains concise information about the medicine. If you have further questions, contact the physician or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar to yours.

**1. What is this medicine intended for?**

CefuAvenir Tablets is an antibiotic used to treat adults and children.

It works by destroying bacteria that cause infections. It belongs to a group of medicines called cephalosporins (second-generation).

CefuAvenir Tablets is used to treat infections of:

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

CefuAvenir can also be used:

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

Your physician may test the type of bacteria causing your infection and check whether the bacteria are sensitive to CefuAvenir Tablets during your treatment.

**Therapeutic group:**

Second-generation cephalosporin antibiotic.

**2. Before using this medicine**

**Do not use this medicine if:**

- **You are sensitive (allergic) to cefuroxime axetil or to any cephalosporin antibiotics** or any of the additional ingredients in this medicine (as listed in section 6).
  - You have ever had a severe allergic (hypersensitivity) reaction to any other type of beta-lactam antibiotic (penicillins, monobactams and carbapenems).
- If you think this applies to you, do not take CefuAvenir Tablets before checking it with your physician.

## Special warnings regarding use of this medicine

### Children

**CefuAvenir Tablets is not recommended for children aged under 3 months**, as the safety and effectiveness are not known in this age group.

You must pay attention to certain symptoms, such as allergic reactions, fungal infections (such as candida) and severe diarrhea (pseudomembranous colitis) while you are taking CefuAvenir Tablets. This will reduce the risk of any problems. See 'Conditions you must pay attention to' in section 4.

### If you need a blood test

CefuAvenir Tablets may affect the results of a test for blood sugar levels, or a blood test called Coombs test. If you need a blood test, **tell the person taking the sample** that you are taking CefuAvenir Tablets.

### Other medicines and CefuAvenir Tablets

**If you are taking, have recently taken, or if you might take other medicines, including non-prescription medicines and nutritional supplements, tell the physician or pharmacist.**

Especially if you are taking:

- Medicines used **to reduce the amount of acid in your stomach** (e.g., antacids used to treat **heartburn**) - can affect how CefuAvenir Tablets works.
- Probenecid.
- Oral anticoagulants.

### Using this medicine and food

**Take CefuAvenir Tablets after food.** This will help to make the treatment more effective.

### Contraceptive pills

CefuAvenir Tablets may reduce the effectiveness of contraceptive pills. If you are taking contraceptive pills while you are being treated with CefuAvenir Tablets, you also need to use **a barrier method of contraception** (such as condoms). Ask your physician for advice.

### Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you might be pregnant or are planning to become pregnant, consult your physician or pharmacist before taking this medicine.

### Driving and using machines

CefuAvenir Tablets **can make you dizzy** and has other side effects that make you less alert.

→ **Do not drive or operate dangerous machines while using the medicine** if you do not feel well. Children should be warned against riding bicycles or playing near the road, and the like.

Important information about some of this medicine's ingredients:

- CefuAvenir Tablets contain:

Sodium benzoate:

3.58 mg sodium in each 250 mg tablet

7.159 mg sodium in each 500 mg tablet.

- This medicine contains less than 23 mg sodium per tablet and is, therefore, considered sodium-free.

### **3. How to use this medicine?**

Always use this medicine according to your physician's instructions.

Check with the physician or pharmacist if you are not sure about the dosage or about how to take this medicine.

Only your physician will determine the dosage and how you should take this medicine. The recommended dosage is usually:

#### **Adults**

The recommended dosage of CefuAvenir Tablets is usually 250 mg to 500 mg twice daily, depending on the severity and type of infection.

#### **Children**

The recommended dosage of CefuAvenir Tablets is usually 10 mg/kg (up to a maximum of 125 mg) to 15 mg/kg (up to a maximum of 250 mg) twice daily, depending on the severity and type of infection.

The usual treatment duration is 7 days (may vary in the range of 5-10 days).

#### **Do not exceed the recommended dose.**

Depending on the illness or how you or your child respond to treatment, the initial dose may be changed or more than one course of treatment may be needed.

CefuAvenir Tablets should be swallowed whole with a little water, **after food**.

**Do not chew, crush or split the tablets** - it may make the treatment less effective.

For little children who do not swallow tablets, a suspension should be used.

#### **Patients with kidney problems**

If you have a kidney problem, your physician may change your dose.

→ **Contact your physician** if this applies to you.

#### **If you have accidentally taken a higher dosage**

If you take too much CefuAvenir Tablets, you may suffer from neurological disorders, and in particular, you may be **more likely to develop fits** (seizures).

→ If you have taken an overdose or if a child has accidentally swallowed some medicine, immediately contact a physician or go to a hospital emergency room and bring the medicine package with you.

#### **If you have forgotten to take the medicine**

**Do not take a double dose to make up for a forgotten dose.** Take your next dose at the usual time and consult a physician.

Adhere to the treatment as recommended by the physician.

#### **Do not stop taking CefuAvenir Tablets without getting advice.**

**It is important that you complete the full course of treatment with CefuAvenir Tablets.** Do not stop taking the medicine unless your physician advises you to stop. Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the physician, because if you do not complete the full course of treatment, the infection may come back.

**Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.**

**If you have further questions regarding the use of the medicine, consult the physician or pharmacist.**

#### **4. Side effects**

As with any medicine, using CefuAvenir Tablets may cause side effects in some of the users. Do not be alarmed by reading the list of side effects. You may not suffer from any of them.

##### **Conditions you must pay attention to**

A small number of people taking CefuAvenir Tablets may develop an allergic reaction or a 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 **difficulties in breathing**.
- **skin rash**, which may **blister**, and looks like **small targets** (central dark spot surrounded by a pale area, with a dark ring around the edges).
- **a widespread rash with blisters and peeling skin** these may be signs of Stevens-Johnson syndrome or toxic epidermal necrolysis.

##### **Other conditions you must pay attention to while taking CefuAvenir Tablets include:**

- **fungal infections.** Medicines like CefuAvenir Tablets can cause an overgrowth of yeast (candida) in the body, which may lead to fungal infections (such as oral thrush). This side effect is more likely if you take CefuAvenir Tablets for a long time.
- **severe diarrhea, pseudomembranous colitis.** Medicines like CefuAvenir Tablets may cause inflammation of the colon, causing severe diarrhea, usually with blood and mucus, abdominal pain, fever.
- **Jarisch-Herxheimer reaction.** Some patients may develop high fever, chills, headache, muscle pain and skin rash while being treated with CefuAvenir Tablets for Lyme disease. This is known as the Jarisch-Herxheimer reaction. Symptoms usually last a few hours or up to one day.

→ **Contact a physician immediately if any of these symptoms appear.**

##### **Additional side effects**

###### **Common side effects**

These may affect **up to 1 in 10** people:

- fungal infections (such as candida)
- headache
- dizziness
- diarrhea
- nausea
- abdominal pain.

Common side effects that may show up in blood tests:

- an increase in a type of white blood cells (eosinophilia)
- an increase in liver enzymes.

###### **Uncommon side effects**

These may affect **up to 1 in 100** people:

- vomiting
- skin rashes

Uncommon side effects that may show up in blood tests:

- a decrease in the number of platelets (cells that help blood to clot)
- a decrease in the number of white blood cells
- positive Coombs test.

### **Other side effects**

Other side effects have occurred in a very small number of people, but their exact frequency is unknown:

- severe diarrhea, pseudomembranous colitis
- allergic reactions
- skin reactions (including severe)
- high 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 (hemolytic anemia).

**If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect that has not been mentioned in the leaflet, consult the physician.**

Side effects can be reported to the Ministry of Health by clicking on the link 'Reporting Side Effects of Drug Treatment' found on the Ministry of Health homepage ([www.health.gov.il](http://www.health.gov.il)) that directs to the online form for reporting side effects, or by entering the link:

<https://sideeffects.health.gov.il/>

### **5. How to store the medicine?**

Prevent poisoning! Keep this and all other medicines in a closed place, out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the physician.

Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month. Store below 25°C.

Do not use the medicine if the tablets are chipped or if you notice other visible signs of deterioration of the medicine.

Do not discard medicines in wastewater or household waste. Consult the pharmacist regarding how to throw away medicines you no longer use. These measures will help protect the environment.

### **6. Additional information**

**In addition to the active ingredient, the medicine also contains:**

Tablet's core: Crospovidone, Microcrystalline cellulose, Croscarmellose sodium, Sodium lauryl sulfate, Talc, Citric acid anhydrous, Sodium hydrogen carbonate, Silica colloidal anhydrous.

Film coating: Hypromellose, Titanium dioxide, Propylene glycol, Sodium benzoate, Purified water.

**What the medicine looks like and the contents of the pack:**

CefuAvenir Tablets 250 mg are white to off-white, film-coated, capsule-shaped, biconvex in both sides tablets, engraved with 'A 05' on one side and plain on the other. The tablets are supplied in an aluminum foil blister pack and packed in a carton box containing 6 or 10 tablets.

CefuAvenir Tablets 500 mg are white to off-white, film-coated, capsule-shaped, biconvex in both sides tablets, engraved with 'A 07' on one side and plain on the

other. The tablets are supplied in an aluminum foil blister pack and packed in a carton box containing 6 or 10 tablets.

Not all pack sizes may be marketed.

**Registration numbers of the medicine in the National Drug Registry of the Ministry of Health:**

CefuAvenir 250 mg - 174-07-36745-99

CefuAvenir 500 mg - 174-08-36746-99

**Manufacturer's name and address:** Nectar Lifesciences Ltd., S.C.O. 38-39, Sector 9-D, Madhya Marg. Chandigarh (UT), Punjab, 160009 – India  
Neutral Code: HP/06/346

**License holder's name and address:** BioAvenir Ltd., 1 David Hamelech St., Herzliya Pituach

**Revised in August 2023**