

## Package leaflet: Information for the patient

### Lifurox 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 or nurse.
- 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 or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet:**

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

#### **1. What Lifurox is and what it is used for**

Lifurox 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.

Lifurox is used to treat infections of:

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

Lifurox 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 Lifurox during your treatment.

#### **2. What you need to know before you take Lifurox**

##### **Do not take Lifurox:**

- **if you are allergic** (*hypersensitive*) to any cephalosporin antibiotics or any of the other ingredients of Lifurox (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, do not take Lifurox, until you have checked with your doctor.

### **Warnings and precautions**

Lifurox 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 Lifurox. This will reduce the risk of any problems. See 'Conditions you need to look out for' in Section 4.

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**

Lifurox 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 Lifurox.

### **Other medicines and Lifurox**

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 Lifurox works, probenecid and oral anticoagulants.

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

### **Contraceptive pills**

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

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

Tell your doctor before taking Lifurox:

- If you are pregnant, think you may be pregnant or are planning to have a baby;
- If you are breast-feeding.

Your doctor will weigh the benefits of Lifurox treatment for you against the risk to your baby.

### **Driving and using machines**

Lifurox 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 Lifurox**

Always take this medicine exactly as your doctor has told you to. Check with your doctor or pharmacist if you are not sure.

Take Lifurox after food. This will help to make the treatment more effective. Swallow 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 Lifurox is 250 mg to 500 mg twice daily, depending on the severity and type of infection.

##### **Children**

The recommended dose of Lifurox 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.

**Lifurox 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.

#### **If you take more Lifurox than you should**

If you take too much Lifurox, 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 you forget to take Lifurox**

Do not take a double dose to make up for a forgotten dose. Just take your next dose at the usual time.

#### **If you stop taking Lifurox**

Do not stop Lifurox without advice. It is important that you take the full course of Lifurox. Do not stop unless your doctor advises you to, even if you are feeling better. If you do not complete the full course of treatment, the infection may come back.

### **4. Possible side effects**

Like all medicines, Lifurox can cause side effects, although not everybody gets them.

### **Conditions you need to look out for**

A small number of people taking Lifurox, 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);
- 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).

Other conditions you need to look out for while taking Lifurox, include:

- fungal infections; medicines like Lifurox 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 Lifurox for a long time;
- severe diarrhoea (*Pseudomembranous colitis*). Medicines like Lifurox 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 Lifurox 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. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

Bulgarian Drug Agency.  
8 Damyan Gruev Str. 1303  
Sofia  
Tel.: +35 928903417 website:  
www.bda.bg

By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Lifurox**

Store below 25°C.

Keep this medicine out of the sight and reach of children. Store in the original pack.

Do not use this medicine after the expiry date which is stated on the pack after EXP. The expiry date refers to the last day of that month.

Always return unused tablets to your pharmacist unless your doctor tells you otherwise.

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 Lifurox contains**

- The active substance is cefuroxime, present as cefuroxime axetil. Each tablet contains 500 mg cefuroxime.
- The other ingredients are: microcrystalline cellulose, croscarmellose sodium, sodium lauryl sulphate, silica colloidal anhydrous, calcium stearate, croscarmellose sodium, кросповидон, calcium carbonate, hypromellose, propylene glycol, titanium dioxide. **What Lifurox looks like and contents of the pack**

Lifurox 500 mg are white, biconvex film-coated tablets with a score line on one side and smooth capsules on the other.

The film-coated tablets are packed in aluminum blisters placed in a cardboard box. Each box contains 10 film-coated tablets with a patient leaflet.

**Marketing Authorisation Holder and Manufacturer**

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