

Package leaflet: Information for the patient

Lifurox 750 mg powder for solution for

injection/infusion

(Cefuroxe)

Read all of this leaflet carefully before you start using 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 nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

1. What Lifurox is and what it is used for
2. What you need to know before you are given Lifurox
3. How Lifurox is given
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 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 lungs or chest;
- the urinary tract;
- the skin and soft tissue;
- the abdomen.

Lifurox is used also:

- **to prevent infections during surgery.**

2. What you need to know before you are given Lifurox

You must not be given Lifurox:

- if you are allergic (*hypersensitive*) 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 have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after treatment with cefuroxime or any other cephalosporin antibiotics.

Tell your doctor before you start on Lifurox if you think that this applies to you. You must not be given Lifurox.

Take special care with Lifurox

You must look out for certain symptoms such as allergic reactions and gastrointestinal disorders such as diarrhoea while you are being given Lifurox. This will reduce the risk of possible problems. See (“Conditions you need to look out for”) in section 4. If you have had any allergic

reaction to other antibiotics such as penicillin, you may also be allergic to Lifurox. 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 or urine test

Lifurox can affect the results of urine or blood tests for sugar and a blood test known as the *Coombs* test. If you are having tests:

Tell the person taking the sample that you have been given Lifurox.

Other medicines and Lifurox

Tell your doctor 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. Some medicines may affect how Lifurox works, or make it more likely that you'll have side effects. These include:

- **aminoglycoside-type antibiotics;**
- **water tablets** (diuretics), such as furosemide;
- **probenecid (used to treat gout);**
- **oral anticoagulants.**

Tell your doctor, if this applies to you. You may need extra check-ups to monitor your renal function while you are taking Lifurox.

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.

Lifurox with food and drink

Lifurox can be used with food and drinks.

Pregnancy, breast-feeding and fertility

If you are pregnant, think you might be pregnant or are planning to become pregnant, talk to your doctor before use this medicine.

Your doctor will consider the benefit of treating you with Lifurox against the risk to your baby.

If you are being given this medicine while breast-feeding, you should discuss this with your doctor, as cefuroxime is excreted in breast milk in small amounts. It is recommended to stop breast-feeding.

Driving and using machines

Do not drive and use machines, if you do not feel well.

Important information about some of the ingredients of Lifurox

Lifurox contains sodium. You need to take this into account if you are on a controlled sodium diet.

<u>Lifurox - strength</u>	<u>Amount of sodium per vial</u>
750 mg	42 mg

3. How Lifurox is given

Lifurox is usually be given by a doctor or nurse.

Your doctor or nurse will prepare your injection by dissolving Lifurox with a suitable liquid for injection. The mixture is usually injected intramuscularly or administered intravenously by injection or infusion.

Recommended dose

The correct dose of Lifurox for you will be decided by your doctor and depends on: the severity and type of infection, whether you are on any other antibiotics; your weight and age; how well your kidneys are working.

Use in children and adolescents**Newborn babies (0 - 3 weeks)**

For every 1 kg the baby weighs, they'll be given 30 to 100 mg Lifurox per day divided in two or three doses.

Babies (over 3 weeks) and children

For every 1 kg the baby or child weighs, they'll be given 30 to 100 mg Lifurox per day divided in three or four doses.

Adults and adolescents

750 mg to 1.5 g of Lifurox two, three or four times daily. Maximum dose: 6 g daily.

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.

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*).
- **fungal infections.** On rare occasions, 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.
- 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*).

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**):

- injection site pain, swelling and redness along a vein.

Tell your doctor, if any of these are troubling you.

Common side effects that may show up in blood tests:

- increases in substances (*enzymes*) produced by the liver;
- changes in your white blood cell count (*neutropenia* or *eosinophilia*);
- low levels of red blood cells (*anaemia*).

Uncommon side effects (These may affect **up to 1 in 100 people**):

- skin rash, itchy, bumpy rash (*hives*);
- diarrhoea, nausea, stomach pain.

Tell your doctor, if you get any of these.

Uncommon side effects that may show up in blood tests:

- low levels of white blood cells (*leucopenia*);
- increase in bilirubin (a substance produced by the liver);
- 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:

- fungal infections;
- high temperature (*fever*);
- allergic reactions;
- inflammation of the colon, causing diarrhoea, usually with blood and mucus, stomach pain;
- inflammation in the kidney and blood vessels;
- red blood cells destroyed too quickly (*haemolytic anaemia*);
- *erythema multiformae* - 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).

Tell your doctor, if you get any of these.

Side effects that may show up in blood tests:

- decrease in number of blood platelets (cells that help blood to clot - *thrombocytopenia*);
- increase in levels of urea nitrogen and serum creatinine in the blood.

If you get any side effects

Tell your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

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 national reporting system of Bulgarian Drug Agency.

Contacts:

Bulgarian Drug
Agency, Bulgaria
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

Lifurox powder for solution for injection/infusion used only on prescription, the expiry date and

storage instructions are information about your doctor, nurse or pharmacist. Your doctor, pharmacist or nurse will prepare your medicine.

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

Store below 25°C.

Store in the original package in order to protect from light.

After adding water for injections, the solution is stored at 2 ° to 8 °C in a refrigerator for 24 hours.

During storage, the color of the prepared solution and suspension may become more intense.

Do not use Lifurox powder for solution for injection after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Do not use this medicine, if you notice a change in the color of the solution other than that described, darkening or sludge formation.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Lifurox contains

Lifurox 750 mg powder for solution for injection/infusion:

- The active substance is cefuroxime sodium. Each vial contains 789 mg cefuroxime sodium, as 750 mg cefuroxime.
- The product does not contain excipients.

What Lifurox looks like and contents of the pack

Lifurox 750 mg powder for solution for injection/infusion is available in vials of 15 ml, 1, 10 and 100 vials in a carton box.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Tchaikapharma High Quality Medicines

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The following information is intended for medical or healthcare professionals only:

Instructions for reconstitution

Intramuscular injection:

The 750 mg vial of Lifurox is diluted with 3 ml of sterile water for injections and shaken to give an opaque matte suspension. Intramuscular injection is performed deep intramuscularly after pre-aspiration to avoid penetration into a vessel.

Intravenous administration:

The 750 mg Lifurox vial is reconstituted least with 6 ml of sterile water for injections and shaken to give a full dissolution..

The suspension is white to pale yellow in color and the solution is pale yellow to dark yellow in color, which is a property of the active substance and is not related to the efficacy or safety of the product.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Dilution should be performed under aseptic conditions. The solution should be inspected visually for particulate matter and discoloration prior to administration. The solution should only be used if it is clear and free of particles.

Compatibility

Cefuroxime is compatible with the most commonly used infusion and electrolyte solutions.

Cefuroxime sodium is compatible with the following infusion fluids:

- Sodium Chloride Injection 0.9% w/v;
- 5% Dextrose Injection;
- 0.18% w/v Sodium Chloride plus 4% Dextrose Injection;
- 5% Dextrose and 0.9% Sodium Chloride Injection;
- 5% Dextrose and 0.45% Sodium Chloride Injection;
- 5% Dextrose and 0.225% Sodium Chloride Injection;
- 10% Dextrose Injection;
- 10% Invert Sugar in Water for Injection;
- Ringer's Injection;
- Lactated Ringer's Injection;
- M/6 Sodium Lactate Injection;
- Compound Sodium Lactate Injection (Hartmann's Solution).

The stability of cefuroxime sodium in Sodium Chloride Injection 0.9% w/v and in 5% Dextrose Injection is not affected by the presence of hydrocortisone sodium phosphate. Cefuroxime sodium has also been found compatible for 24 h at room temperature when admixed in i.v. infusion with:

- Heparin (10 and 50 units/ml) in 0.9% Sodium Chloride Injection;
- Potassium Chloride (10 and 40 mEqL) in 0.9% Sodium Chloride Injection.

It is desirable to use the solutions immediately after preparation. If this is not possible, the reconstituted solution and suspension may be stored for up to 24 hours at 2 ° to 8 ° C (in a refrigerator).

Incompatibilities

Due to the pH of 2.74 volume units, sodium bicarbonate solution may cause discoloration of the solutions, therefore it is not recommended for dilution of cefuroxime. If patients need to receive sodium bicarbonate as an intravenous infusion, cefuroxime may be administered via a separate venous route.

Cefuroxime solution should not be mixed with aminoglycosides due to possible interactions.