



Ksivozan 5 mg/ml oral drops, solution

Levocetirizine dihydrochloride

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 side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. What Ksivozan is and what it is used for

The active substance in Ksivozan is levocetirizine dihydrochloride.

Ksivozan is an anti-allergic drug.

For treatment of symptoms in adults and children older than 2 years associated with:

- allergic rhinitis (including persistent allergic rhinitis);
- nettle rash (urticaria).

2. What you need to know before you take Ksivozan

Do not take Ksivozan:

- if you are allergic to levocetirizine dihydrochloride, to other antihistamines, hydroxyzine, piperazine derivatives or any of the other ingredients of this medicine (listed in section 6);
- if you suffer from severe renal impairment (severe kidney failure and creatinine clearance less than 10 ml/min).

Warnings and precautions

Talk to your doctor or pharmacist before taking Ksivozan.

If you are unable to empty your bladder properly due to spinal cord injury or enlarged prostate, or if you suffer from epilepsy or are at risk of seizures, please talk to your doctor.

Children and adolescents

Levocetirizine is not recommended for use in children younger than 2 years.

Other medicines and Ksivozan

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines including non-prescription ones.

Ksivozan with food, drink and alcohol

Caution is required when Ksivozan is taken at the same time as alcohol.

In sensitive patients the concomitant use of Ksivozan with alcohol or other medicines that affect the central nervous

system, may lead to further reduction in alertness and impaired ability to react.

Ksivozan can be taken with or without food.

Pregnancy, breast feeding and fertility

If you are pregnant or breast feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before using this medicine.

Driving and using machines

Some patients taking Ksivozan may experience somnolence/drowsiness, fatigue and asthenia. Be careful when driving and using machines before establishing your response to this medicine. Specific studies conducted in healthy individuals after using levocetirizine at the recommended dose, have not found any impairment of alertness, reactions and the ability to drive.

Ksivozan contains methyl parahydroxybenzoate and propyl parahydroxybenzoate

Methyl parahydroxybenzoate and propyl parahydroxybenzoate can cause allergic reactions (probably delayed type) such as headache, upset stomach and diarrhea.

3. How to take Ksivozan

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

The recommended dose is:

- Adults and children over the age of 6 years: 20 drops once daily
- Children aged 2 to 6 years: 5 drops twice daily.

Use in children and adolescents

Ksivozan is not recommended for use in children younger than 2 years due to an absence of experience with the use in this age group.

Special precautions for use in special populations:

Patients with impaired kidney function should take a lower dose depending on the severity of the kidney disease. In children the dose should be in accordance with the body weight. Your doctor will determine the dose.

Patients with severe impairment of the kidney function should not take Ksivozan.

Patients with impaired liver function only, should take the usually prescribed dose.

Patients with impaired kidney and liver functions may take a lower dose depending on the severity of the kidney disease. In children the dose should depend on their body weight. Your doctor will determine the dose.

No dose adjustment is required for elderly patients with normal kidney function.

How and when should you take Ksivozan?

For oral administration only.

Ksivozan may be taken with or without food.

The drops should be taken through the mouth using a

spoon or can be diluted in water. When diluting the drops it should be considered, particularly if used in children, that the volume of water to which the drops are added, should be adjusted depending on the amount of water which the patient can swallow. The diluted solution should be taken immediately.

When counting the drops, the bottle should be in a vertical position (bottom up). If no drops fall from the bottle or the required quantity is not achieved, the bottle should be placed upright and then turned again upside down, and proceed with the counting of drops.

How long should you take Ksivozan?

Treatment duration depends on the type, duration and development of your symptoms, and shall be determined by your doctor.

If you take more Ksivozan than you should

Significant overdosing may cause sleepiness in adults. In children, initial agitation and restlessness followed by somnolence may occur.

If you think that you have taken more Ksivozan than you should, please tell your doctor, and he will judge what steps should be undertaken.

If you forget to take Ksivozan

If you forget to take Ksivozan or have taken a dose lower than the dose prescribed by your doctor, do not take a double dose to make up for a forgotten one. Take the next dose at the usual time.

If you stop taking Ksivozan

If you stop the treatment earlier than foreseen, this should not cause any side effects except that the symptoms of the disease may reappear. In some cases treatment may have to be initiated again. Upon discontinuation of levocetirizine, in a small number of patients there have been reports of pruritus (itching) even if they did not have it initially.

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

4. Possible side effects

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

Common (1% to 10 %) adverse reactions, mostly mild to moderate, have been reported: dry mouth, headache, tiredness and somnolence/drowsiness.

Uncommon (0,1% to 1 %) adverse reactions: exhaustion and abdominal pain.

Not known: frequency cannot be estimated from the available data.

Other adverse reactions have also been reported, such as: palpitations, accelerated heart rate, fits, tingling of the skin, dizziness, syncope, tremor, dysgeusia, (altered taste), vertigo, movement disorders, vision disturbances, blurred vision, oculogyration (uncontrolled eye rolling), pain or difficulty passing urine, inability to empty the bladder completely, oedema, pruritus (itching), rash, hives (swelling, skin reddening and itching), skin rash, shortness of breath, weight increase, muscle pain, joint pain, aggressive or overexcited behaviour, hallucinations, depression, insomnia, repeated suicidal ideation, nightmares, hepatitis, impaired liver function, vomiting, appetite increased, nausea and diarrhea. Pruritus (itching) upon treatment discontinuation.

With the first appearance of **hypersensitivity reaction**, stop taking Ksivozan and inform your doctor. Symptoms of hypersensitivity reaction include: swelling of the mouth, tongue, face and/or throat, difficulty breathing or swallowing (tightness in the chest or wheezing), nettle rash, sudden drop in the blood pressure leading to collapse or shock which may be fatal.

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 the:

Bulgarian Drug Agency
8, Damian Gruev Str
1303 Sofia
Tel: +359 2 8903417
website: www.bda.bg

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

5. How to store Ksivozan

Keep out of the sight and reach of children.
Store below 25°C.

Store in the original packaging.

Shelf life after first opening: 3 months below 25°C.

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

Do not 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 protect the environment.

6. Contents of the pack and other information

What Ksivozan contains

- The active substance is levocetirizine dihydrochloride. 1 ml (20 drops) of the oral solution contains 5 mg levocetirizine dihydrochloride .
- The other ingredients (excipients) are: sodium acetate trihydrate, acetic acid, propylene glycol, glycerol 85 %, methyl parahydroxybenzoate (E 218), propyl parahydroxybenzoate (E 216), saccharin sodium, purified water.

What Ksivozan looks like and contents of the pack

Transparent, colourless solution.

Dark coloured glass bottle containing 20 ml solution and sealed with a plastic cap with inner dropper.

Each bottle is placed in a carton box with a package insert.

Marketing Authorisation Holder and Manufacturer:

ADIPHARM EAD
130, Simeonovsko shosse blvd.
Sofia 1700, Bulgaria

This leaflet was last revised in:

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