

Package leaflet: Information for the user

Nukast -10

Montelukast Sodium & Levocetirizine
Dihydrochloride Tablets [10 mg + 5 mg]

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 Nukast-10 is and what it is used for
2. What you need to know before you take Nukast-10
3. How to take Nukast-10
4. Possible side effects
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1. What Nukast-10 is and what it is used for

Nukast-10 is a combination of two active substances, Montelukast and Levocetirizine in one tablet. Both of these substances help to control seasonal allergies/allergic rhinitis.

Montelukast is a leukotriene receptor antagonist that blocks substances called leukotrienes. Leukotrienes cause narrowing and swelling of airways in the lungs and also cause allergy symptoms. By blocking leukotrienes, Montelukast helps control asthma and improves seasonal allergy symptoms (also known as hay fever or seasonal allergic rhinitis).

Levocetirizine dihydrochloride is the active ingredient of Levocetirizine 5 mg film-coated tablets.

Levocetirizine is an anti-allergic medication. For the treatment of signs of illness (symptoms) associated with:

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

What are seasonal allergies?

Seasonal allergies (also known as hay fever or seasonal allergic rhinitis) are an allergic response often caused by airborne pollens from trees, grasses and weeds. The symptoms of seasonal

allergies typically may include: stuffy, runny, itchy nose; sneezing; watery, swollen, red, itchy eyes.

2. What you need to know before you take Nukast-10

Do not take Nukast-10

- If you are allergic to montelukast, levocetirizine dihydrochloride, to cetirizine, to hydroxyzine or any of the other ingredients of this medicine (listed in section 6)
- If you have a severe kidney disease requiring dialysis

Warnings and precautions

Talk to your doctor or pharmacist before taking Nukast-10.

- If your asthma or breathing gets worse, tell your doctor immediately.
- Oral Montelukast are not meant to treat acute asthma attacks. If an attack occurs, follow the instructions your doctor has given you. Always have your inhaled rescue medicine for asthma attacks with you.
- It is important that you or your child take all asthma medications prescribed by your doctor. Montelukast should not be substituted for other asthma medications your doctor has prescribed for you.
- Any patient on anti-asthma medicines should be aware that if you develop a combination of symptoms such as a flu-like illness, pins and needles or numbness of arms or legs, worsening of pulmonary symptoms, and/or rash, you should consult your doctor.
- You should not take acetyl-salicylic acid (aspirin) or anti-inflammatory medicines (also known as non-steroidal anti-inflammatory drugs or NSAIDs) if they make your asthma worse.
- If you are likely to be unable to empty your bladder (with conditions such as spinal cord injury or enlarged prostate), please ask your doctor for advice.
- If you suffer from epilepsy or are at risk of convulsions, please ask your doctor for advice as use of Levocetirizine 5mg film-coated tablets may cause seizure aggravation.
- If you are scheduled for allergy testing, ask your doctor if you should stop taking Levocetirizine 5mg film-coated tablets for several days before testing. This medicine may affect your allergy test results.

Patients should be aware that various neuropsychiatric events (for example behaviour and mood-related changes) have been reported in adults, adolescents and children with montelukast (see section 4). If you develop such symptoms while taking Montelukast, you should consult your doctor.

Children and adolescents

Do not give this medicine to children. There are different form (s) of this medicine available for paediatric patients under 18 years of age based on age range.

Other medicines and Nukast-10

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines including those obtained without a prescription.

Some medicines may affect how Montelukast works, or Montelukast may affect how other medicines work.

Tell your doctor if you are taking the following medicines before starting Montelukast:

- Phenobarbital (used for treatment of epilepsy)
- Phenytoin (used for treatment of epilepsy)
- Rifampicin (used to treat tuberculosis and some other infections)
- Gemfibrozil (used for treatment of high lipid levels in plasma)

Taking Nukast-10 with food and drink

Nukast-10 may be taken with or without food.

Caution is advised if Nukast-10 Tablets is taken at the same time as alcohol or other agents acting on the brain. In sensitive patients, the concurrent administration of Levocetirizine and alcohol or other agents acting on the brain may cause additional reductions in alertness and impairment of performance.

Pregnancy and breast feeding

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

- Pregnancy

Your doctor will assess whether you can take Nukast-10 during this time.

- Breast-feeding

It is not known if Nukast-10 appears in breast milk. You should consult your doctor before taking Montelukast if you are breast-feeding or intend to breast feed.

Driving and using machines

Some patients being treated with Nukast-10 (Levocetirizine) may experience somnolence/drowsiness, tiredness and exhaustion. Use caution when driving or operating machinery until you know how this medicine affects you. However, special tests have revealed no impairment of mental alertness, the ability to react or the ability to drive in healthy test persons after taking levocetirizine in the recommended dosage.

2. How to take Nukast -10

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

- You should take only one tablet of Nukast -10 once a day as prescribed by your doctor.
- It should be taken even when you have no symptoms or have an acute asthma attack.

For adults and adolescents 15 years of age and older:

The recommended dose is one Nukast -10 tablet to be taken daily in the evening.

If you are taking Nukast-10, be sure that you do not take any other products that contain the same active ingredient, montelukast or Levocetirizine.

This medicine is for oral use.

You can take Nukast -10 with or without food.

If you take more Nukast-10 than you should

Contact your doctor immediately for advice.

If you take more Nukast-10 tablets than you should somnolence can occur in adults. Children may initially show excitation and restlessness followed by somnolence. If you think you have taken an overdose of Nukast-10, please tell your doctor who will then decide what action should be taken.

The other most frequently occurring symptoms reported with overdose in adults and children included abdominal pain, sleepiness, thirst, headache, vomiting, and hyperactivity.

If you forget to take Nukast-10

Try to take Montelukast as prescribed. However, if you miss a dose, just resume the usual schedule of one tablet once daily.

Do not take a double dose to make up for a forgotten dose.

If you stop taking Nukast-10

Nukast-10 can treat your allergic rhinitis only if you continue to take it. It is important to continue taking Nukast-10 for as long as your doctor prescribes. It will help control your allergic rhinitis/asthma.

Stopping treatment should have no negative effects. However, rarely pruritus (intense itching) may occur if you stop taking Levocetirizine, even if those symptoms were not present before treatment initiation. The symptoms may resolve spontaneously. In some cases, the symptoms may be intense and may require treatment to be restarted. The symptoms should resolve when the treatment is restarted.

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

Special dosage instructions for specific populations:

Renal and hepatic impairment

Patients with impaired kidney function may be given a lower dose according to the severity of their kidney disease and in children the dose will also be chosen on the basis of body weight; the dose will be determined by your doctor.

Patients who have a severe kidney disease requiring dialysis must not take Nukast-10 tablets.

Patients who only have impaired liver function should take the usual prescribed dose.

Patients who have both impaired liver and kidney function may be given a lower dose depending on the severity of the kidney disease, and in children the dose will also be chosen on the basis of body weight; the dose will be determined by your doctor

Elderly patients aged 65 years and above

No adaptation of the dose is necessary in elderly patients, provided their renal function is normal.

Use in Children

Nukast-10 tablets are not recommended for children under 18 years of age.

How long should you take Nukast-10 Tablets

The duration of use depends on the type, duration and course of your complaints and is determined by your physician

4. Possible side effects:

MONTELUKAST:

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

In clinical studies with montelukast 10 mg film-coated tablets, the most commonly reported side effects (may affect up to 1 in 10 people) thought to be related to montelukast were:

- Abdominal pain, Headache

These were usually mild and occurred at a greater frequency in patients treated with montelukast than placebo (a pill containing no medication).

Serious side effects

Talk with your doctor immediately if you notice any of the following side effects, which may be serious, and for which you may need urgent medical treatment.

Uncommon: may affect up to 1 in 100 people

- Allergic reactions including swelling of the face, lips, tongue, and/or throat which may cause difficulty in breathing or swallowing
- Behaviour and mood related changes: agitation including aggressive behaviour or hostility, depression
- Seizure

Rare: may affect up to 1 in 1,000 people

- Increased bleeding tendency, Tremor, Palpitations

Very rare: may affect up to 1 in 10,000 people

- Combination of symptoms such as flu-like illness, pins and needles or numbness of arms and legs, worsening of pulmonary symptoms and/or rash (see Section 2)
- Low blood platelet count
- Behaviour and mood related changes: hallucinations, disorientation, suicidal thoughts and actions
- Swelling (inflammation) of the lungs
- Severe skin reactions (erythema multiforme) that may occur without warning • Inflammation of the liver (hepatitis)

Other side effects while the medicine has been on the market

Very common: may affect more than 1 in 10 people

- Upper respiratory infection

Common: may affect up to 1 in 10 people

- Diarrhoea, nausea, vomiting, Rash, Fever, Elevated liver enzymes

Uncommon: may affect up to 1 in 100 people

- Behaviour and mood related changes: dream abnormalities, including nightmares, trouble sleeping, sleepwalking, irritability, feeling anxious, restlessness
- Dizziness, drowsiness, pins and needles/numbness
- Nosebleed, Dry mouth, indigestion
- Bruising, itching, hives, Joint or muscle pain, muscle cramps
- Bedwetting in children, Weakness/tiredness, feeling unwell, swelling

Rare: may affect up to 1 in 1,000 people

- Behaviour and mood related changes: disturbance in attention, memory impairment, uncontrolled muscle movements

Very rare: may affect up to 1 in 10,000 people

- Tender red lumps under the skin, most commonly on your shins (erythema nodosum)
- behaviour and mood related changes: obsessive-compulsive symptoms, stuttering

LEVOCETIRIZINE

Common: (may affect up to 1 in 10 people)

- dry mouth, headache, tiredness, somnolence/drowsiness

Uncommon: (may affect up to 1 in 100 people)

- exhaustion and abdominal pain

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly: Website: www.zuventus.co.in and click the tab “Safety Reporting” located on the top of the home page.

By reporting side effects, you can help provide more information on the safety of this medicine. You can also report the side effect with the help of your treating physician

5. How to store Nukast -10

Store protected from light and moisture at a temperature not exceeding 30°C.

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

Do not use this medicine after the expiry date which is stated on the blister after EXP. The expiry date refers to the last date 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 Nukast -10 contains:

Qualitative and quantitative composition

Each uncoated bilayered tablet contains:

Montelukast Sodium

Equivalent to Montelukast -10 mg

Levocetirizine Dihydrochloride USP -5 mg

Excipients q.s.

Each strip of Nukast-10 contains 10 Tablets

7. Marketing Authorisation Holder and Manufacturer

Zuventus Healthcare Limited

Zuventus House, Plot Y2, CTS No.: 358/A2,

Near Nahur Railway Station,

Nahur (W), Mumbai, 400078 Maharashtra, India.

8. Date of revision

This leaflet was last revised in 07/2023.