

Package leaflet: Information for the patient

Levocetirizine dihydrochloride 5 mg Orodispersible Tablets

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, 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.

The name of your medicine is Levocetirizine dihydrochloride 5 mg orodispersible tablets. It will be called Levocetirizine for ease from here on.

What is in this leaflet

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

1. What Levocetirizine is and what it is used for

Levocetirizine dihydrochloride is the active ingredient of Levocetirizine. Levocetirizine is an antiallergic medication.

For the treatment of signs of illness (symptoms) associated with:

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

2. What you need to know before you take Levocetirizine

Do not take Levocetirizine

- if you are allergic to 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 Levocetirizine.

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 may cause seizure aggravation.

If you are scheduled for allergy testing, ask your doctor if you should stop taking Levocetirizine for several days before testing. This medicine may affect your allergy test results.

Children

The use of Levocetirizine is not recommended in children less than 6 years since the orodispersible tablets do not allow for dose adaptation.

Other medicines and Levocetirizine

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Levocetirizine with food, drink and alcohol

Caution is advised if Levocetirizine 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.

Levocetirizine 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 or pharmacist for advice before taking this medicine.

Driving and using machines

Some patients being treated with 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.

Levocetirizine contains lactose, aspartame (E951) and sorbitol (E420)

Levocetirizine contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Levocetirizine contains 5 mg of aspartame in each tablet. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

Levocetirizine contains 3.95 mg of sorbitol.

3. How to take Levocetirizine

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

The recommended dose for adults and children aged 6 years and over is one Levocetirizine daily.

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 Levocetirizine.

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

Levocetirizine is not recommended for children under 6 years of age.

How and when should you take Levocetirizine?

For oral use only.

Levocetirizine should be placed on the tongue. It will disintegrate quickly and then you can swallow as normal with or without water. It may be taken with or without food. It is recommended to take the daily dose in one single intake.

How long should you take Levocetirizine?

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

If you take more Levocetirizine than you should

If you take more Levocetirizine 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 Levocetirizine, please tell your doctor who will then decide what action should be taken.

If you forget to take Levocetirizine

If you forget to take Levocetirizine, or if you take a dose lower than that prescribed by your doctor, do not take a double dose to make up for a forgotten dose. Take your next dose at your normal time.

If you stop taking Levocetirizine

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.

4. Possible side effects

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

Common: may affect up to 1 in 10 people

Dry mouth, headache, tiredness and somnolence/drowsiness

Uncommon: may affect up to 1 in 100 people

Exhaustion and abdominal pain

Not known: frequency cannot be estimated from the available data

Other side effects such as palpitations, increased heart rate, fits, pins and needles, dizziness, syncope, tremor, dysgeusia (distortion of the sense of taste), sensation of rotation or movement, visual disturbances, blurred vision, oculogyration (eyes having uncontrolled circular movements), painful or difficult urination, inability to completely empty the bladder, oedema, pruritus (itchiness), rash, urticaria (swelling, redness and itchiness of the skin), skin eruption, shortness of breath, weight increase, muscular pain, joint pain, aggressive or agitated behaviour, hallucination, depression, insomnia, recurring

thoughts of or preoccupation with suicide, nightmare, hepatitis, abnormal liver function, vomiting, increased appetite, nausea and diarrhoea have also been reported. Pruritus (intense itching) upon discontinuation.

At the first signs of a hypersensitivity reaction, stop taking Levocetirizine and tell your doctor. Hypersensitivity reaction symptoms may include: swelling of the mouth, tongue, face and/or throat, breathing or swallowing difficulties (chest tightness or wheezing), hives, sudden fall in 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:

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

5. How to store Levocetirizine

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 label and carton after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

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 Levocetirizine contains

- The active substance is levocetirizine dihydrochloride.
- Each Levocetirizine 5 mg orodispersible tablet contains 5 mg of levocetirizine dihydrochloride.
- The other ingredients are:

- Polacrillin Potassium, Lactose Monohydrate, Aspartame (E951), Silica, Colloidal Anhydrous (E 551), Flavor-Black Currant, Magnesium Stearate (E 572) and Pharmaburst B2 consist: Mannitol (E 421), Polyplasdone, Sorbitol (E 420), Syloid.

What Levocetirizine looks like and contents of the pack

- Levocetirizine orodispersible tablets are round, white to off-white, flat, and bevelled edged tablets plain on both the sides.

Levocetirizine is available in blister pack of:

1, 2, 4, 5, 7, 10, 14, 15, 20, 21, 28, 30, 40, 50, 60, 70, 90, 100 tablets.

Not all pack sizes may be marketed

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation

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The Manufacturer

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And

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The leaflet was last revised in June 2025.