

Package leaflet: Information for the user

Levocetirizine Dihydrochloride 5mg film-coated 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 or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their sign 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:

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1. What Levocetirizine Dihydrochloride 5 mg film-coated tablets is and what it is used for

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

Levocetirizine Dihydrochloride 5 mg film-coated tablets is an antiallergic medication.

For 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 Dihydrochloride 5 mg film-coated tablets

Do not take Levocetirizine Dihydrochloride 5 mg film-coated tablets :

- 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 impairment of kidney function** (severe renal failure with creatinine clearance below 10 ml/min).

Warnings and precautions

Talk to your doctor or pharmacist before taking Levocetirizine Dihydrochloride 5 mg film-coated tablets.

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 Dihydrochloride 5 mg film-coated tablets may cause seizure aggravation.

If you are scheduled for allergy testing, ask your doctor if you should stop taking Levocetirizine Dihydrochloride 5 mg film-coated tablets for several days before testing. This medicine may affect your allergy test results.

Children

The use of Levocetirizine Dihydrochloride 5 mg film-coated tablets is not recommended in children less than 6 years since the film-coated tablets do not allow for dose adaptation.

Other medicines and Levocetirizine Dihydrochloride 5 mg film-coated tablets

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

Levocetirizine Dihydrochloride 5 mg film-coated tablets with food, drink and alcohol

Caution is advised if Levocetirizine Dihydrochloride is taken at the same time as alcohol or other agents acting on the brain. In sensitive patients, the concurrent administration of Levocetirizine Dihydrochloride 5 mg film-coated tablets and alcohol or other agents acting on the brain may cause additional reductions in alertness and impairment of performance.

Levocetirizine Dihydrochloride can be taken with or without food.

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.

Driving and using machines

Some patients being treated with Levocetirizine Dihydrochloride 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 Dihydrochloride in the recommended dosage.

Levocetirizine Dihydrochloride 5 mg film-coated tablets contains lactose

These tablets contain lactose, if you have been told by your doctor that you have an intolerance to some sugars you should contact your doctor before taking them.

3. How to take Levocetirizine Dihydrochloride 5 mg film-coated tablets

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 tablet 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 severe impairment of kidney function must not take Levocetirizine Dihydrochloride 5 mg film-coated 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

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

How and when should you take Levocetirizine Dihydrochloride 5 mg film-coated tablets?

For oral use only.

The Levocetirizine Dihydrochloride 5 mg film-coated tablets should be swallowed whole with water and may be taken with or without food.

How long should you take Levocetirizine Dihydrochloride 5 mg film-coated tablets?

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 Dihydrochloride 5 mg film-coated tablets than you should

If you take more Levocetirizine Dihydrochloride 5 mg film-coated 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 Levocetirizine Dihydrochloride 5 mg film-coated tablets, please tell your doctor who will then decide what action should be taken.

If you forget to take Levocetirizine Dihydrochloride 5 mg film-coated tablets

If you forget to take Levocetirizine Dihydrochloride, 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 Dihydrochloride 5 mg film-coated tablets

Stopping treatment should have no negative effects. However, rarely pruritus (intense itching) may occur if you stop taking Levocetirizine Dihydrochloride, 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.

Serious side effects

At the first signs of an allergic reaction, stop taking Levocetirizine Dihydrochloride 5 mg film-coated tablets and tell your doctor. Allergic 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.

Not known: frequency cannot be estimated from the available data

recurring thoughts of or preoccupation with suicide and hepatitis (symptoms can include yellow skin or eyes (jaundice), nausea, abdominal pain and tiredness).

Other side effects

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, fainting/loss of consciousness, tremor, dysgeusia (distortion of the sense of taste), sensation of rotation or movement, visual disturbances, blurred vision, painful or difficult urination, inability to completely empty the bladder, swelling in the body, 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, abnormal liver function, increased appetite, nausea, vomiting and diarrhoea have also been reported.

Pruritus (intense itching) upon discontinuation.

Oculogyration (eyes having uncontrolled circular movements), nightmare

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 Dihydrochloride 5 mg film-coated tablets

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 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 Dihydrochloride 5 mg film-coated tablets contains

- The active substance is Levocetirizine Dihydrochloride. Each film-coated tablet contains 5 mg of Levocetirizine Dihydrochloride equivalent to 4.2mg of levocetirizine.
- The other ingredients are Lactose monohydrate, Cellulose microcrystalline (E460), Colloidal anhydrous silica (E551), Magnesium stearate (E572) and Opadry white (Y-1-7000) consisting of Hypromellose (E464), Titanium dioxide (E 171) and Macrogol 400.

What Levocetirizine Dihydrochloride 5 mg film-coated tablets looks like and contents of the pack

Film-coated tablets are White colored oval shaped biconvex film-coated tablet debossed with 'I' and '12' on one side and score line on the other side.

They are supplied in Aluminium – Aluminium blister pack with pack size of 1, 2, 4, 5, 7, 10, 14, 15, 20, 21, 28, 30, 40, 50, 60, 70, 90, 100, 120's per pack

Not all pack sizes may be marketed

Marketing Authorisation Holder and Manufacturer

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