

LEVOCETIRIZINE 5 mg film-coated tablets

For adults and children aged 6 years and above
Levocetirizine dihydrochloride

Package leaflet: Information for the patient

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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Levocetirizine 5 mg Film-coated Tablet is and what it is used for
2. What you need to know before you take Levocetirizine 5 mg Film-coated Tablets
3. How to take Levocetirizine 5 mg Film-coated Tablets
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1 What Levocetirizine 5 mg Film-coated Tablet is and what it is used for

Levocetirizine dihydrochloride is the active ingredient of Levocetirizine 5 mg Film-coated Tablets.

Levocetirizine 5 mg Film-coated Tablets is an antiallergic medication.

Levocetirizine 5 mg Film-coated Tablets is used for the treatment of signs of illness (symptoms) associated with:

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

Antihistamines such as Levocetirizine 5 mg Film-coated Tablets relieve the unpleasant symptoms and discomfort associated with the above conditions, such as sneezing, irritated, runny and blocked up nose, itchy, red and watering eyes and skin rashes.

2 What you need to know before you take Levocetirizine 5 mg Film-coated Tablets

Do not take Levocetirizine 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 kidney disease requiring dialysis**

Warnings and precautions

Talk to your doctor or pharmacist before taking Levocetirizine 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 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 5 mg Film-coated Tablets for several days before testing. This medicine may affect your allergy test results.

Children

The use of Levocetirizine 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 5 mg Film-coated Tablets

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

Taking Levocetirizine 5 mg Film-coated Tablets with food, drink and alcohol

Caution is advised if Levocetirizine 5 mg Film-coated Tablets is taken at the same time as alcohol or other agents acting on the brain. In sensitive patients, the concurrent administration of Levocetirizine 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 5 mg Film-coated Tablets 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 5 mg Film-coated Tablets 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 5 mg Film-coated Tablets contains lactose

Levocetirizine 5 mg Film-coated Tablets 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.

3 How to take Levocetirizine 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.

Adults and children aged 6 years and above

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 a severe kidney disease requiring dialysis must not take Levocetirizine 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 5 mg Film-coated Tablets is not recommended for children under 6 years of age.

How and when should you take

Levocetirizine 5 mg Film-coated Tablets

For oral use only.

The tablet should be swallowed whole with water and may be taken with or without food.

How long should you take Levocetirizine 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 5 mg Film-coated Tablets than you should

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

If you forget to take Levocetirizine 5 mg Film-coated Tablets

If you forget to take Levocetirizine 5 mg Film-coated Tablets, 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 5 mg Film-coated Tablets

Stopping treatment with Levocetirizine 5 mg Film-coated Tablets should have no negative effects. However, rarely pruritus (intense itching) may occur if you stop taking Levocetirizine 5 mg Film-coated Tablets, 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.

At the first signs of a **hypersensitivity reaction**, stop taking Levocetirizine 5 mg Film-coated Tablets 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.

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

- dry mouth
- headache
- tiredness
- somnolence/drowsiness

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

- exhaustion
- abdominal pain

Frequency not known (cannot be estimated from the available data):

- increased appetite
- aggressive or agitated behaviour, hallucination, depression, insomnia, recurring thoughts of or preoccupation with suicide, nightmare
- 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)
- palpitations, increased heart rate
- shortness of breath
- nausea, vomiting, diarrhoea
- hepatitis, abnormal liver function test
- painful or difficult urination, inability to completely empty the bladder
- skin eruption, pruritus (itchiness), rash, urticaria (swelling, redness and itchiness of the skin)
- pruritus (intense itching) upon discontinuation
- muscular pain, joint pain
- oedema
- weight increase

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 Yellow Card Scheme at: 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 5 mg Film-coated Tablets

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

This medicinal product does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the carton and blister. 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 Levocetirizine 5 mg Film-coated Tablets contains:

- The active substance is levocetirizine dihydrochloride. Each film-coated tablet contains 5 mg levocetirizine dihydrochloride.
- The other ingredients are: microcrystalline cellulose, lactose monohydrate, colloidal anhydrous silica, magnesium stearate, hypromellose, titanium dioxide (E171) and macrogol 400.

What Levocetirizine 5 mg Film-coated Tablets looks like and contents of the pack

The film-coated tablets are white to off white and oval; one side of the tablet is debossed with "LC5". The other side of the tablet is plain.

Levocetirizine 5 mg Film-coated Tablets is available in blister packs of 7, 10, 14, 15, 20, 21, 28, 30, 40, 50, 60, 90 and 100 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation holder: Teva UK Limited, Ridings Point, Whistler Drive, Castleford, WF10 5HX, United Kingdom.

Company Responsible for Manufacture: TEVA Pharmaceutical Works Private Limited Company, Pallagi Street 13, Debrecen, H-4042, Hungary.

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