

Levocetirizine dihydrochloride**5 mg film-coated tablets**

For adults and children aged 6 years and above

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. Do not pass it on to others. It may harm them, even if their symptoms 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 IS AND WHAT IT IS USED FOR

Levocetirizine dihydrochloride is the active ingredient of this medicine.

Levocetirizine dihydrochloride 5 mg 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 DIHYDROCHLORIDE 5 MG**Do not take Levocetirizine dihydrochloride 5 mg**

- if you are allergic to levocetirizine dihydrochloride or 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.

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 may cause seizure aggravation.

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

Children

The use of Levocetirizine dihydrochloride 5 mg 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

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

Levocetirizine dihydrochloride 5 mg with food, drink and alcohol

Caution is advised if Levocetirizine dihydrochloride 5 mg 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 and alcohol or other agents acting on the brain may cause additional reductions in alertness and impairment of performance.

Levocetirizine dihydrochloride 5 mg 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 dihydrochloride 5 mg may experience 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 dihydrochloride 5 mg contains lactose

These tablets contain 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 DIHYDROCHLORIDE 5 MG

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.

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 5 mg is not recommended for children under 6 years of age.

How and when should you take Levocetirizine dihydrochloride 5 mg

For oral use only.

Levocetirizine dihydrochloride 5 mg tablets should be swallowed whole with water and may be taken with or without food.

How long should you take Levocetirizine dihydrochloride 5 mg?

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 than you should

If you take more Levocetirizine dihydrochloride 5 mg than you should, drowsiness can occur in adults. Children may initially show excitation and restlessness followed by drowsiness.

If you think you have taken an overdose of Levocetirizine dihydrochloride 5 mg, please tell your doctor who will then decide what action should be taken.

If you forget to take Levocetirizine dihydrochloride 5 mg

If you forget to take Levocetirizine dihydrochloride 5 mg, 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

Stopping treatment should have no negative effects. However, rarely pruritus (intense itching) may occur if you stop taking Levocetirizine dihydrochloride 5 mg, 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 recurring thoughts of or preoccupation with suicide, or a hypersensitivity reaction, stop taking Levocetirizine dihydrochloride 5 mg 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: may affect up to 1 in 10 people

Dry mouth, headache, tiredness and 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, 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, swelling, pruritus (itchiness), rash, urticaria (swelling, redness and itchiness of the skin), skin eruption (red patches that recur at the same site of the skin), shortness of breath, weight increase, muscular pain, joint pain, aggressive or agitated behaviour, hallucination, depression, insomnia, nightmare, hepatitis, abnormal liver function, vomiting, increased appetite, nausea and diarrhoea have also been reported. Pruritus (intense itching) upon discontinuation.

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 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

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 first two digits indicate the month and the last four digits indicate the year. The expiry date refers to the last day of that month.

Store in the original package to protect from moisture.

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 to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Levocetirizine dihydrochloride 5 mg contains

- The active substance is levocetirizine. Levocetirizine is present as levocetirizine dihydrochloride (5 mg), corresponding to 4.2 mg of levocetirizine.
- The other ingredients are microcrystalline cellulose, lactose monohydrate (see section 2, 'Levocetirizine dihydrochloride 5 mg contains lactose'), magnesium stearate (core), and hypromellose (E464), titanium dioxide (E171), and macrogol 400 (coating).

What Levocetirizine dihydrochloride 5 mg looks like and contents of the pack

The film-coated tablets are white to off-white, oval, biconvex tablets, debossed with 'L9CZ' on one side and '5' on the other side. They are supplied in blister packs of 6, 7, 10, 14, 15, 18, 20, 21, 28, 30, 40, 50, 56, 60, 70, 90, 100, 112 or 120 tablets per box. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Consilient Health Limited,
5th Floor, Beaux Lane House, Mercer Street Lower, Dublin 2, Ireland

Manufacturer:

Synthon Hispania S.L. Castelló 1, Polígono Las Salinas,
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Manufacturer:

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