

Package leaflet: Information for the user
Levocetirizine Dihydrochloride 5 mg 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 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 Film-coated Tablets. Here after it will be referred to as Levocetirizine tablets throughout the leaflet.

What is in this leaflet:

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

1. What Levocetirizine Tablets are and what they are used for

The name of your medicine is Levocetirizine 5 mg Film-coated Tablets and the active substance is Levocetirizine dihydrochloride. Levocetirizine Tablets 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 Tablets

Do not take Levocetirizine 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 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 may cause seizure aggravation.

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

Children

The use of this medicine is not recommended in children less than 6 years since the film coated tablets do not allow for dose adaptation.

Other medicines and Levocetirizine Tablets

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

Levocetirizine Tablets with food, drink and alcohol

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

Levocetirizine Tablets 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 this medicine 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 Tablets contain Lactose

If you have been told by your doctor that you have intolerance to some sugars you should contact your doctor before taking them.

3. How to take Levocetirizine Tablets

Always take this medicine exactly as your doctor or pharmacist have 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: 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 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 Tablets are not recommended for children under 6 years of age.

How and when should you take Levocetirizine Tablets

For oral use only.

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

How long should you take Levocetirizine 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 Tablets than you should

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

If you forget to take Levocetirizine Tablets

If you forget to take this medicine, 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 Tablets

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

Stop taking this medicine and tell your doctor immediately if you experience:

- Allergic reactions, 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
- Recurring thoughts of or preoccupation with suicide.

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, syncope, 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, 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, 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 to:

HPRA Pharmacovigilance

Earlsfort Terrace

IRL - Dublin 2

Tel: +353 1 6764971

Fax: +353 1 6762517

Website: www.hpra.ie

E-mail: medsafety@hpra.ie

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

5. How to store Levocetirizine Tablets

- Keep this medicine out of the sight and reach of children.
- This medicinal product does not require any special conditions.
- Do not use this medicine after the Expiry Date which is stated on the carton or blister (Exp). The expiry date refers to the last day of that month.
- Do not throw away any medicines via waste water 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 Tablets contain

- Each film-coated tablet contains 5 mg Levocetirizine dihydrochloride as the active ingredient.
- The other ingredients are: Cellulose Microcrystalline, Lactose Monohydrate, Colloidal Anhydrous Silica, Magnesium Stearate, Hypromellose (E464), Talc, Titanium Dioxide (E171) and Macrogol-400.

What Levocetirizine Tablets look like and contents of the pack

- Levocetirizine 5mg Film-coated Tablets are white to off white, oval, biconvex film-coated tablets with 'BL' debossed on one side and '5' debossed on other side.
- These tablets are available in blister packs of 14, 28, 30, 56, 60, 84 and 100 tablets.
- Not all pack sizes may be marketed.

Marketing Authorisation Holder

Name and address: Brillpharma (Ireland) Limited

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E-mail: info@brillpharma.co.uk

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Name and address:

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369 Burnt Oak Broadway,

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axcount Generika GmbH
Max-Planck-Straße 36 d,
61381 Friedrichsdorf, Germany

This medicinal product is authorized in the member states of the EEA under the following names:

United Kingdom: Levocetirizine dihydrochloride 5 mg Film-Coated Tablets

This leaflet was last revised in September 2020

To request a copy of this leaflet in Braille, large print or audio format, please contact the marketing authorisation holder at the address (or e-mail) above.