Package leaflet: Information for the patient

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 this medicine is Levocetirizine dihydrochloride 5mg film-coated tablets, which will be referred to as Levocetirizine tablets

What is in this leaflet

1. What Levocetirizine tablet is and what it is 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 tablet is and what it is used for

This medicine contains levocetirizine dihydrochloride as the active ingredient

It is an antiallergic medication.

This medicine is used for the treatment of signs of illness (symptoms) associated with:
- allergic rhinitis (including persistent allergic rhinitis);
- nettle rash (urticaria).

This medicine is not suitable for children below 6 years of age.

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 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 tablets for several days before testing. This medicine may affect your allergy test results.

Children
The use of Levocetirizine 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 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 Levocetirizine tablet 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.

This medicine 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 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 this medicine in the recommended dosage.

Levocetirizine tablets contains lactose
This medicine contains lactose monohydrate and anhydrous lactose. If you have been told by your doctor that you have an intolerance to some sugars you should contact your doctor before taking this medicine.

3. How to take Levocetirizine tablets

<u>For prescription</u>

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

Use in children
Levocetirizine tablet is not recommended for children under 6 years of age

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 this medicine.

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.

How and when should you take Levocetirizine tablets?
For oral use only.
Levocetirizine 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 doctor**.**

If you take more Levocetirizine tablets than you should:
If you take more of this medicine than you should, somnolence can occur in adults. Children may initially show excitement and restlessness followed by somnolence.

If you think you have taken an overdose of Levocetirizine tablets, 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 Levocetirizine tablets, 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.

At the first signs of a hypersensitivity reaction, stop taking this medicine and **tell your doctor immediately.** 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.

The following side effects have been reported:

Common (may affect up to 1 in 10 people),

- dry mouth,
- headache,
- tiredness
- somnolence/drowsiness.

Uncommon (may affect up to 1 in 100 people)
- exhaustion
- abdominal pain.

Not known: frequency cannot be estimated from the available data.

Other side effects
- 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,
- nightmare
- hepatitis,
- abnormal liver function,
- nausea,
- diarrhoea,
- vomiting,
- increased appetite,
- recurring thoughts of or preoccupation with suicide.
- 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 at 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 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 and blister after Exp. The expiry date refers to the last day of that month.

This medicinal product does not require any special temperature storage conditions.

Store in the original package in order 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 protect the environment.

6. Contents of the pack and other information

What Levocetirizine tablet contains

- The active substance is levocetirizine dihydrochloride. Each film-coated tablet contains 5 mg levocetirizine dihydrochloride.
- The other ingredients are anhydrous lactose, lactose monohydrate, microcrystalline cellulose, crospovidone (Type A), magnesium stearate, hypromellose (E464), titanium dioxide (E171) and macrogol 6000.

What Levocetirizine tablets looks like and contents of the pack

The film-coated tablets are white, oval shaped, biconvex, film coated tablets debossed with ‘C5’ on one side and plain on other side.

They are supplied in blister packs of 7, 10, 14, 20, 28, 30, 50, 56, 84, and 100 tablets in an outer carton.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Ennogen IP Ltd
Unit G4, Riverside Industrial Estate,
Riverside Way,
Dartford, DA1 5BS,
UK

Manufacturer
Cipla (EU) Ltd, 20 Balderton Street, London W1K 6TL, United Kingdom

S&D Pharma CZ, spol. s r.o, Theodor 28, Pchery (Pharmos a.s. facility), 27308, Czech Republic

Cipla Europe NV, Uitbreidingstraat 80, 2600 Antwerp, Belgium

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