

PACKAGE LEAFLET: INFORMATION FOR THE USER

Levocetirizine Glenmark 5mg Film-coated tablets

Levocetirizine dihydrochloride
For adults and children aged 6 years and above

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.

What is in this leaflet:

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

Levocetirizine dihydrochloride is the active ingredient of Levocetirizine Glenmark 5mg film-coated tablets

Levocetirizine Glenmark 5mg Film-coated tablets is an antiallergic medication. For the treatment 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 Glenmark 5mg Film-coated Tablets

Do not take Levocetirizine Glenmark 5mg Film-coated Tablets:

- if you are allergic to levocetirizine dihydrochloride, to cetirizine, to hydroxuzine 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 Glenmark 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 Glenmark 5mg film-coated tablets may cause seizure aggravation.

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

Children

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

Other medicines and Levocetirizine Glenmark 5mg Film-coated Tablets

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

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 Glenmark 5mg film-coated tablets and alcohol or other agents acting on the brain may cause additional reductions in alertness and impairment of performance.

Levocetirizine Glenmark 5mg film-coated 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 Levocetirizine Glenmark 5mg 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 Glenmark 5mg 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 Glenmark 5mg 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 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 Levocetirizine 5 mg Film-coated tablets.

Patient 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 Glenmark 5mg 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 tablets should be swallowed whole with a drink of water. It 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 Glenmark 5mg Film-coated tablets than you should

A substantial overdose (you take more than you should) may cause somnolence in adults. Children may initially show excitation and restlessness and followed by drowsiness.

If you think you have taken an overdose of Levocetirizine Glenmark 5mg Film-coated tablets please tell your doctor immediately who will then decide what action should be taken.

If you forget to take Levocetirizine Glenmark 5mg Film-coated tablets

If you forget to take Levocetirizine Glenmark 5mg Film-coated tablets or if you take a dose lower than that prescribed by your doctor, do not take a double dose to compensate; just wait for the time to take the next dose, and take a normal dose as prescribed by your doctor.

If you stop taking Levocetirizine Glenmark 5mg Film-coated tablets

Stopping treatment should have no negative effects, however, symptoms may return but they should not be any worse than they were prior to treatment with Levocetirizine 5 mg Film-coated tablets..

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.

Hypersensitivity reactions (symptoms may include: swelling of the mouth, tongue, face and/or throat breathing or swallowing difficulties together with hives (angioedema), sudden fall in blood pressure leading to collapse or shock, which may be fatal.) At the first signs of a hypersensitivity reaction, stop taking Levocetirizine 5 mg Film-coated tablets and see your doctor immediately.

Common side effects (occur in less than 10 users in 100)

- dry mouth
- headache
- tiredness
- somnolence/drowsiness
- sleep disorders

Uncommon side effects) (occur in less than 10 users in 1000)

- exhaustion
- abdominal pain
- constipation

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Not known side effects (cannot be estimated from the available data)

- Increased heart rate
- palpitations
- convulsions or fits
- pins and needles
- dizziness
- syncope
- tremor
- dysgeusia (distortion of the sense of taste)
- sensation of ratiion or movemnt
- visual disturbances (such as blurred vision)
- oculogyration (eyes having uncontrolled circular movements)
- painful or difficult urination
- inability to completely empty the bladder
- oedema (water retention causing swelling)
- pruritus (itchiness)
- rash
- urticaria (swelling, or outbreak, redness and itchiness of the skin)
- skin eruption
- shortness of breath
- weight increase
- muscular pain
- joint pain
- aggressive or agitated behaviour
- hallucination

- depression
- insomnia
- depression
- recurring thoughts of orpreoccupation with suicide
- hepatitis (the skin or whites of the eyes may become yellow)
- abnormal liver function test
- nausea
- vomiting
- increased appetite
- diarrhoea

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 report side effects directly via

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 Glenmark 5mg 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 and blister 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 Glenmark 5mg Film-coated tablets contain

- 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 (E464), titanium dioxide (E171), and macrogol 400.

What Levocetirizine Glenmark 5mg Film-coated tablets look like and contents of the pack

The 5mg film-coated tablets are white, oval, with a G breakline G on one side and the other side is plain. The tablet can be divided into equal doses.

The tablets are packed in either Aluminium/Aluminium blisters or PVC / PVdC – Aluminium blisters

Pack Sizes

10, 20, 21, 28, 30, 50, 90 and 100 tablets*

*Not all pack sizes may be marketed.

Marketing Authorisation Holder

Glenmark Pharmaceuticals Europe Limited, Laxmi House, 2 B Draycott Avenue, Kenton, Middlesex HA3 0BU, United Kingdom

Manufacturers

Glenmark Pharmaceuticals s.r.o, Fibíchova 143, 566 17 Vysoké Mýto, Czech Republic

Tillomed Laboratories Ltd. 3 Howard Road, Eaton Socon, St.Neots, Cambridgeshire, PE19 8ET, United Kingdom

Glenmark Pharmaceuticals Europe Limited: Building 2, Croxley Green Business Park, Croxley Green, Hertfordshire, WD18 8YA, United Kingdom

This medicinal product is authorised in the Member States of the EEA under the following names:

Portugal	Levocetirizina Glenmark 5mg Comprimido revestido por película
Denmark	Levocetirizin Glenmark 5mg Filmovertrukket tablets
Finland	Levocetirizin Glenmark 5mg tabletti, kalvopäällysteinen
Greece	LEVOCETIRIZINE/GLENMARK
Ireland	Levocetirizine Glenmark 5mg Film-coated tablets
Poland	Cetilevo

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