

Package leaflet: Information for the user

LEVOCETIRIZINE TEVA 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, pharmacist or nurse. 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 Teva 5 mg Film-coated Tablet is and what it is used for

Levocetirizine Teva 5 mg Film-coated Tablets belong to a group of medicines called antihistamines. They relieve the unpleasant symptoms and discomfort associated with the below conditions, such as sneezing, irritated runny or blocked up nose, itchy, red and watering eyes and skin rashes.

Your doctor has prescribed Levocetirizine Teva 5 mg Film-coated Tablets to treat hay fever (seasonal allergic rhinitis), year round allergies such as dust or pet allergies (perennial allergic rhinitis) and urticaria (swelling, redness and itchiness of the skin).

2. What you need to know before you take Levocetirizine Teva 5 MG Film coated Tablets

Do not take Levocetirizine Teva 5 mg Film-coated Tablets

- if you are allergic to Levocetirizine dihydrochloride or any of the other ingredients of this medicine (listed in section 6).
- if you have severe kidney problems (severe renal failure with creatinine clearance below 10 ml/min).

Warnings and precautions

Talk to your doctor or pharmacist before taking Levocetirizine Teva 5 mg Film-coated Tablets.
Tell your doctor or pharmacist if you have trouble or a condition that may increase your risk of trouble urinating (e.g enlarged prostate, spinal cord lesion)

Children and adolescents

- Levocetirizine Teva 5 mg Film-coated Tablets are not recommended for use in children under 6 years of age.

Other medicines and Levocetirizine Teva 5 mg Film-coated Tablets

Levocetirizine Teva 5 mg Film-coated Tablets may be used together with other medicines you may be taking.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including those medicines obtained without a prescription.

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

Levocetirizine Teva 5 mg Film-coated Tablets may be taken with or without food.

Caution should be taken if Levocetirizine Teva 5 mg Film-coated Tablets are taken at the same time as alcohol or other centrally acting agents, although the racemate ceterizine has been shown not to increase the effect of alcohol..

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.

Breast feeding: When taking Levocetirizine Teva 5 mg Film-coated Tablets, levocetirizine may be present in breast-milk..

Driving and using machines

Levocetirizine Teva 5 mg Film-coated Tablets are not expected to affect your ability to drive a car or operate machinery. *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 Teva 5mg Film coated Tablets contains lactose

Levocetirizine Teva 5 mg Film-coated Tablets contains lactose. If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Levocetirizine Teva 5 mg Film-coated Tablets

Always take this medicine exactly as your doctor or pharmacist has told you, even when you have no symptoms. Check with your doctor or pharmacist if you are not sure.

The recommended dose is:

The recommended dose for adults is one 5 mg tablet daily.

Use in children and adolescents

The recommended dose for children aged between 6 and 12 years upwards is one 5 mg tablet daily. Levocetirizine Teva 5 mg Film-coated Tablets is not recommended for children under 6 years of age.

Older people

The elderly, at present there are no data to suggest that the dose needs to be reduced in elderly subjects provided that their kidney function is normal.

Kidney problems

In patients with kidney problems it may be necessary to reduce the dose of levocetirizine to one tablet every two or three days. Your doctor will decide how often you should take levocetirizine depending on how well your kidneys are working.

Liver problems

In patients with liver problems it is not necessary to adjust the dose of levocetirizine you are taking.

Kidney and liver problems

In patients with kidney and liver problems it may be necessary to reduce the dose of levocetirizine to one tablet every two or three days. Your doctor will decide how often you should take levocetirizine depending on how well your kidneys are working.

Your doctor will tell you how long to take levocetirizine

The tablets should be swallowed whole with liquid and can be taken with or without food.

If you take more Levocetirizine Teva 5 mg Film-coated Tablets than you should

It is important not to take too many tablets. Contact your nearest hospital Accident and Emergency department or a doctor for advice if you have swallowed too many tablets or if you think a child has swallowed any. Symptoms of overdose may include drowsiness in adults and initially agitation and restlessness, followed by drowsiness in children

Take this leaflet and any of the remaining tablets with you to show the doctor.

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

If you forget to take a tablet, just carry on with the next one as usual. Do not take a double dose to make up for a forgotten dose.

If you stop taking Levocetirizine 5 mg Film-coated Tablets

There are no harmful effects if you stop taking 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.

The following side effects have been reported at the approximate frequencies shown:

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, aggressive or agitated behaviour, hallucination, depression, insomnia, recurring thoughts of or preoccupation with suicide, hepatitis, abnormal liver function, vomiting, increased appetite and nausea, have also been reported.

At the first signs of a **hypersensitivity reaction**, stop taking {Trademark} 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.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V*. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Levocetirizine Teva 5 mg Film-coated Tablets

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

There are no special storage conditions

Do not use this medicine after the expiry date which is stated on the blister foil and carton. 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 to protect the environment.

6. Contents of the pack and other information

What Levocetirizine Teva 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 and macrogol 400.

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

Levocetirizine Teva 5 mg Film-coated Tablets are white to off white, film coated oval shaped tablet; one side of the tablet is debossed with "LC5". The other side of the tablet is plain.

Levocetirizine Teva 5 mg Film-coated Tablets are available in 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

[To be completed nationally]

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

DE: Levocetirizin Teva 5 mg Filmtabletten

BE: Levocetiriteva 5 mg filmomhulde tabletten/comprimés pelliculés/Filmtabletten

DK: Levocetirizindihydrochlorid Teva

ES: Levocetirizina Teva 5 mg comprimidos recubiertos con película EFG

FR: Levocetirizine teva 5 mg, comprimé pellicule

HU: Novocetrin 5 mg filmtabletta

IE: Levocetirizine Teva 5 mg film coated tablets

IT: Levocetirizina Teva 5 mg compresse rivestite con film

MT: Levocetirizine Teva 5 mg film coated tablets

NL: Levocetirizine diHCl 5 PCH, filmomhulde tabletten 5mg

SK: Levocetirizin Teva 5 mg filmom obalene tablety

UK: Levocetirizine 5mg Film coated tablets

This leaflet was last revised in {MM/YYYY}

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