

PACKAGE LEAFLET: INFORMATION FOR THE USER

Letizen

10 mg film-coated tablets

CETIRIZINE HYDROCHLORIDE

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 •

What is in this leaflet?

1. What Letizen Tablets are and what they are used for
2. What you need to know before you take Letizen Tablets
3. How to take Letizen Tablets
4. Possible side effects
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1. WHAT LETIZEN TABLETS ARE AND WHAT THEY ARE USED FOR

Cetirizine hydrochloride is the active ingredient of Letizen Tablets.

Letizen Tablets is an antiallergic medication.

In adults and children aged 6 year and above, Letizen Tablets are indicated

- for the relief of symptoms of hay fever (seasonal allergic rhinitis) and allergies such as dust or pet allergies (perennial allergic rhinitis), such as sneezing, itchy, runny and blocked nose, red and watery eyes.
- for the relief of swelling, redness and itchiness of the skin (symptoms of chronic idiopathic urticaria, which is also known as chronic nettle rash).

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE LETIZEN TABLETS

Do not take Letizen Tablets

- if you have a severe kidney disease (severe renal failure with creatinine clearance below 10 ml/min).
- if you are known to be allergic (hypersensitive) to the active substance of Letizen Tablets or any of the other ingredients of these tablets.

- if you are known to be allergic (hypersensitive) to hydroxyzine (closely related active substances of other medicines).
- if you are known to be allergic (hypersensitive) to drugs from the piperazine family, for example buclizine, cyclizine, meclozine, levocetirizine.
- if you are breast-feeding
- if you have problems of urinary retention
- if you have an intolerance to some sugars (this medicine contains lactose).

Warnings and precautions

Check with your doctor before taking Letizen Tablets:

- if you have problems with your kidneys
- if you have predisposition factors of urinary retention (eg: spinalcord lesion, prostatic hyperplasia) as cetirizine increases the risk of urinary retention
- you suffer from epilepsy or are at risk of convulsions
- you want to use for children less than 6 years of age

Take special care with Letizen Tablets

If you have kidney problems, please ask your doctor for advice; if necessary, you may have to take a lower dose. The new dose will be determined by your doctor.

If you are an epileptic patient or a patient at risk of convulsions, you should ask your doctor for advice.

Other medicines and Letizen Tablets

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Due to the profile of cetirizine, no interactions with other drugs are expected.

Taking Letizen Tablets with food and drink

Food does not noticeably affect the absorption of cetirizine.

No interactions having a noticeable impact have been observed between alcohol (at the blood level of 0.5 per millilitre corresponding to one glass of wine) and cetirizine used at the normal doses. However, as it is the case with all antihistamines, it is recommended to avoid consumption of alcohol while taking this medicine.

Pregnancy and breast-feeding

Ask your doctor for advice before taking any medicine.

As with other drugs, use of Letizen Tablets should be avoided by pregnant women. Accidental use of the drug by a pregnant woman should not produce any harmful effects on the foetus. Nevertheless, the administration of the medicine should be discontinued.

You should not take Letizen Tablets during breast-feeding because cetirizine passes into breast milk.

Allergy skin test

If you are going to have an allergy skin test stop taking Letizen Tablets for three days before the test. This medicine may affect your allergy test results.

Driving and using machines

Clinical studies have produced no evidence of impaired attention, alertness and driving capabilities after taking Letizen Tablets at the recommended dose.

If you intend to drive, operate machinery, or perform other tasks that need your full attention, you should not exceed the recommended dose and you should closely observe your response to the drug. If you are a sensitive patient, you may find that the simultaneous use of alcohol or other nervous depressant agents may additionally affect your attention and ability to react.

Letizen Tablets contains lactose

Letizen Tablets contain lactose; if you have been told by your doctor that you have an intolerance to some sugars, please contact your doctor before taking this medicinal product.

3. HOW TO TAKE LETIZEN TABLETS

Always take Letizen Tablets exactly as your doctor has told you. Check with your doctor if you are not sure.

Tablets need to be swallowed with a glass of liquid.

The recommended dose is:

Use in adults and adolescents above 12 years old: 10 mg once daily as one tablet.

Use in children between 6 and 12 years old: 5 mg twice daily as half a tablet.

Patients with kidney problems:

Patients with moderate renal impairment are recommended to take 5 mg once daily as a half tablet.

If you feel that the effect of Letizen Tablets is too weak or too strong, please consult your doctor.

If you take more Letizen Tablets than you should

If you think you have taken an overdose of Letizen Tablets, please inform your doctor. Your doctor will then decide what measures, if any, should be taken.

After an overdose, the side effects described below may occur with increased intensity.

Adverse effects such as confusion, diarrhoea, dizziness, tiredness, headache, ailing, dilating (widening) of the pupil, itching, restlessness, sedation, somnolence, stupor, abnormal rapid heart rate, tremors and urinary retention have been reported.

If you forget to take Letizen Tablets

If you forget to take a tablet, take it as soon as you remember, but wait at least 24 hours before taking the next tablet. Do not take a double dose to make up for a forgotten dose.

If you stop taking Letizen Tablets

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Letizen Tablets can cause side effects, although not everybody gets them.

The following side effect is very rare, but you must stop taking the tablets and speak to your doctor straight away if you notice these symptoms:

- A severe allergic reaction including rash, itchiness and fever, swollen throat, face, eyelids or lips. This reaction may start soon after you first take the medicine, or it might start later.

The following side effects have also been reported.

Common side effects (affects less than 1 in 10 people)

- Fatigue, somnolence (sleepiness)
- Dizziness, headache,
- Dry mouth, nausea (feeling sick), diarrhoea (children only)
- Pain in the abdomen
- Pharyngitis (sore throat), rhinitis (swelling and irritation inside the nose (children only))

Uncommon side effects (affects less than 1 in 100 people)

- Pruritus (itching), rash
- Diarrhoea
- Agitation
- Asthenia (feeling of weakness), malaise (feeling of being generally unwell)
- Paraesthesia (abnormal feelings of the skin), tingling in the hands and feet

Rare side effects (affects less than 1 in 1,000 people)

- Tachycardia (heart beating fast)
- Oedema (generalised swelling due to water retention)
- Allergic reactions
- Liver function abnormal (your doctor will know what to do)
- Convulsions
- Weight increased
- Aggression, confusion, depression, hallucination (hearing or seeing things), insomnia (difficulty sleeping)
- Urticaria (swelling, redness and itchiness of the skin)

Very rare side effects (affects less than 1 in 10,000 people)

- Severe allergic reactions
- Thrombocytopenia (low level of blood platelets)
- Accommodation disorder (impaired ability of the eye to focus), blurred vision, oculogyration (eyes moving in an uncontrolled circular manner)
- Unusual bleeding or bruising
- Syncope (fainting), tremor, dysgeusia (altered taste)
- Tics (sudden abnormal repetitive muscle movement)
- Bed wetting, pain and/or difficulty passing water
- Swelling of the skin particularly around the face, fixed drug eruption
- Muscle spasms in the neck and shoulders
- Fainting
- A recurring rash

Not known side effects

- Loss of memory, memory impairment
- Increased appetite
- Vertigo
- Urinary retention

In very rare cases people have thought about committing suicide and if you feel this way then stop taking the tablets and see your doctor.

If you develop one of the side effects described above, please inform your doctor.

At the first signs of an allergic (hypersensitivity) reaction, stop taking Letizen Tablets and contact your doctor immediately. Symptoms of an allergic (hypersensitivity) reaction include difficulty breathing, swelling of the face, neck, tongue or throat. Your doctor will then assess the severity and decide on any further measures that may be necessary.

If you think you have any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

This includes any possible side effects not listed in this leaflet.

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

5. HOW TO STORE LETIZEN TABLETS

Keep out of the reach and sight of children.

Do not use Letizen Tablets after the expiry date which is stated on the box and blister.

This medicine does not require any special storage conditions.

This leaflet was last revised in December 2013