Package leaflet: Information for the user

Cetriz 10 mg Film-coated Tablets

Cetirizine dihydrochloride

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.
• Keep this leaflet. You may need to read it again.
• Ask your pharmacist if you need more information or advice.
• 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.
• You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

What is in this leaflet:

1 What Cetriz is and what it is used for

Cetirizine dihydrochloride is the active ingredient of Cetriz 10 mg Film-coated Tablets. Cetriz 10 mg Film-coated Tablets are an antiallergic medication.

In adults and children aged 6 years and above, Cetriz 10 mg Film-coated Tablets are indicated:
• for the relief of symptoms of hayfever (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).

You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

2 What you need to know before you take Cetriz

Do not take Cetriz
• if you are allergic to cetirizine, to any of the other ingredients of this medicine (listed in section 6), to hydroxyzine or to drugs from the piperazine family, for example buclizine, cyclizine, meclozine, levocetirizine.

• if you have a severe kidney disease (severe renal failure with creatinine clearance below 10 ml/min).

You should not take Cetriz 10 mg tablets:
• if you have hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption.

Warnings and precautions
Talk to your doctor or pharmacist before taking Cetriz.
If you are a patient with renal insufficiency, please ask your doctor for advice; if necessary, you will take a lower dose. The new dose will be determined by your doctor.
If you have problems passing urine (like spinal cord problems or prostate or bladder problems), please ask your doctor for advice.
If you are an epileptic patient or a patient at risk of convulsions, you should ask your doctor for advice.
No clinically significant interactions have been observed between alcohol (at the blood level of 0.5 per ml corresponding to one glass of wine) and cetirizine used at the recommended doses. However, there are no data available on the safety when higher doses of cetirizine and alcohol are taken together. Therefore, as it is the case with all antihistamines, it is recommended to avoid concurrent consumption of alcohol.
If you need to perform an allergy test, ask your doctor if you should stop taking Cetriz several days before the test, as this medicine may affect your allergy test results.

Children
Do not give this medicine to children below the age of 6 years.

Other medicines and Cetriz
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.
Due to the profile of cetirizine, no interactions with other drugs are expected.

Cetriz with food, drink and alcohol
Food does not affect the absorption of Cetriz.
As it is the case with all antihistamines, it is recommended to avoid concurrent consumption of alcohol (see Warnings and precautions).

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you might be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.
Cetriz should be avoided in 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 only be administered if necessary and after medical advice.
Cetirizine passes into breast milk. A risk of side effects in breastfed infants cannot be excluded. Therefore, you should not take Cetriz during breast-feeding unless you have contacted a doctor.
Driving and using machines

Clinical studies have produced no evidence of impaired attention, alertness and driving capabilities after taking Cetriz at the recommended dose. If you are intending to drive, engage in potentially hazardous activities or operate machinery, you should not exceed the recommended dose. 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.

Cetriz contains 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 Cetriz

How and when should you take Cetriz?
Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.
These guidelines apply unless your doctor has given you different instructions on how to use Cetriz. Please follow these instructions, otherwise Cetriz may not be fully effective.

Adults and adolescents above 12 years old:
The recommended dose is 10 mg once daily as 1 tablet.
Children between 6 and 12 years old:
The recommended dose is 5 mg twice daily as a half tablet twice daily.
Patients with renal impairment
Patients with moderate renal impairment are recommended to take 5 mg once daily.
If you suffer from severe kidney disease, please contact your doctor or pharmacist who may adjust the dose accordingly.
If you feel that the effect of Cetriz is too weak or too strong, please consult your doctor.
Duration of treatment:
The duration of treatment depends on the type, duration and course of your complaints and is determined by your doctor.

Tablets need to be swallowed with a glass of liquid.
The tablets can be divided into 2 equal doses.

If you take more Cetriz than you should
If you think you have taken an overdose of Cetriz 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, malaise (feeling unwell), dilating of pupil, itching, restlessness, sedation, somnolence (sleepiness), stupor, abnormal rapid heart rate, tremors and urinary retention (difficulty in completely emptying the bladder) have been reported.

If you forget to take Cetriz

Do not take a double dose to make up for forgotten dose.

If you stop taking Cetriz
Rarely, pruritus (intense itching) and/or urticaria may return if you stop taking Cetriz.

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 are rare or very rare, but you must stop taking the medicine and speak to your doctor straight away if you notice them:
- Allergic reactions, including severe reactions and angioedema (serious allergic reaction which causes swelling of the face or throat).
These reactions may start soon after you first take the medicine, or it might start later.

The following side effects have been reported in post marketing experience.

Common side effects (may affect up to 1 in 10 people)
- Fatigue
- Dry mouth, nausea, diarrhoea
- Dizziness, headache
- Somnolence (sleepiness)
- Pharyngitis (sore throat), rhinitis (nasal inflammation) (in children)

Uncommon side effects (may affect up to 1 in 100 people)
- Abdominal pain
- Asthenia (extreme fatigue), malaise (feeling unwell)
- Paresthesia (abnormal feelings of the skin)
- Agitation
- Pruritus (itchy skin), rash

Rare side effects (may affect up to 1 in 1,000 people)
- Tachycardia (heart beating too fast)
- Oedema (swelling)
- Allergic reactions (hypersensitivity), some severe (very rare)
- Liver function abnormal
- Weight increased
- Convulsions
- Aggression, confusion, depression, hallucination, insomnia
- Urticaria (hives)

Very rare side effects (may affect up to 1 in 10,000 people)
- Severe forms of allergic reactions (anaphylactic shock)

- Thrombocytopenia (low levels of blood platelets)
- Accommodation disorder (difficulty focusing),), blurred vision, oculogyric crisis (eyes having uncontrolled circular movements)
- Syncope (fainting), tremor, dysgeusia (altered taste), abnormal prolonged muscular contractions (dystonia), involuntary movements (dyskinesia)
- Tics (habit spasm)
- Abnormal elimination of urine, bed wetting (enuresis), painful and/or difficult urination (dysuria)
- Angioedema (serious allergic reaction which causes swelling of the face or throat), fixed drug eruption (drug allergy)

Not known frequency of side effects (frequency can not be estimated from the available data)
- Vertigo (sensation of rotation or movement)
- Increased appetite
- Amnesia, memory impairment
- Suicidal ideation (recurring thoughts of or preoccupation with suicide), nightmare
- Urinary retention (inability to completely empty the bladder)
- Acute generalized exanthematous pustulosis (rash with blisters containing pus)
- Pruritus (intense itching) and/or urticaria upon discontinuation
- Arthralgia (joint pain), myalgia (muscular pain)
- Hepatitis (inflammation of the liver)

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 HPRA Pharmacovigilance, Website: www.hpra.ie
By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Cetriz

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 medicine 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 Cetriz contains
• The active substance is cetirizine dihydrochloride. Each tablet contains 10 mg cetirizine dihydrochloride.

• The other ingredients are *tablet core:* microcrystalline cellulose, lactose monohydrate, crospovidone, colloidal anhydrous silica, magnesium stearate; *film-coat:* hypromellose, macrogol stearate, microcrystalline cellulose, propylene glycol, titanium dioxide (E171).

What Cetriz looks like and contents of the pack
Film-coated, white or almost white convex, oval shaped, tablets. Scored on one side. The tablet can be divided into equal halves.

Blister pack with 7, 10, 14, 28 or 30 tablets.

Not all pack sizes may be marketed

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This leaflet was last revised in February 2023.