

Package leaflet: Information for the user

Cetirizine Dihydrochloride 10 mg Film-coated Tablets

Cetirizine dihydrochloride

The name of this medicine is Cetirizine Dihydrochloride 10 mg Film-coated Tablets, which will be referred to as Cetirizine Tablets throughout this leaflet.

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 has 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 **Cetirizine Tablet** is and what it is used for
2. What you need to know before you take **Cetirizine Tablets**
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1. What Cetirizine Tablet is and what it is used for

Cetirizine dihydrochloride is the active ingredient of Cetirizine tablet, which belongs to a group of medicines called antihistamines. Cetirizine is an antiallergic medication.

In adults and paediatric patients 6 years and above, Cetirizine is indicated

- for the relief of hay fever (allergic rhinitis) and year round allergies such as dust or pet allergies (perennial allergic rhinitis)
- for the relief of chronic nettle rash (chronic idiopathic urticaria).

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 Cetirizine Tablets

Do not take Cetirizine Tablets

- if you are allergic to cetirizine dihydrochloride or any of the other ingredients of this medicine (listed in section 6) or to hydroxyzine or to any piperazine derivatives (closely related active ingredients of other medicines)
- if you have a severe kidney disease (severe renal failure with creatinine clearance below 10 ml/min)

Warnings and precautions

Talk to your doctor or pharmacist before taking cetirizine tablets.

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 g/l 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 taking cetirizine tablets with alcohol.

If you are scheduled for allergy testing, ask your doctor if you should stop taking Cetirizine Tablets for several days before testing. This medicine may affect your allergy test results.

Children

Cetirizine Tablets are not recommended for use in children below 6 years of age because the tablet formulation does not allow the necessary dose adjustments.

Other medicines and Cetirizine Tablets

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

- medication for anxiety or stress (CNS depressants)

Cetirizine Tablets with food and alcohol

Avoid alcoholic drink while you are taking this medicine.

Food does not affect absorption of cetirizine dihydrochloride.

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.

Cetirizine Tablets 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 medicine should only be administered if necessary and after medical advice.

Caution should be exercised when taking Cetirizine tablets during breast-feeding because cetirizine passes into breast milk. A risk of side effects in breastfed infants cannot be excluded. Therefore, you should not take cetirizine tablets 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 cetirizine dihydrochloride at the recommended dose.

You should closely observe your response to the drug after you have taken cetirizine tablets if you are intending to drive, engage in potentially hazardous activities or operate machinery. You should not exceed the recommended dose.

Cetirizine Tablets contains lactose monohydrate

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Cetirizine Tablets

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The tablets need to be swallowed with a glass of liquid.

The tablet can be divided into 2 equal doses.

The recommended dose is

- Adults and adolescents over 12 years of age: One tablet (10mg) once daily.

Your doctor may prescribe you starting dose 5 mg (a half tablet) if this leads to satisfactory control of the symptoms.

-Children aged from 6 to 12 years: 5mg twice daily (a half tablet twice daily).

- Children under 6 years: Not recommended.

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 your child suffers from kidney disease, please contact your doctor or pharmacist who may adjust the dose according to your child's needs.

If you feel that the effect of Cetirizine Tablets 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. Please ask your doctor or pharmacist for advice.

If you take more Cetirizine Tablets than you should

If you accidentally take too many tablets go and see your doctor straightaway.

After an overdose, the side effects described in section 4 below may occur with increased intensity. The following side effects have been reported:

- confusion
- diarrhoea
- dizziness
- tiredness
- headache
- a vague feeling of discomfort
- dilating of pupils of the eyes
- itching
- restlessness
- sedation
- sleepiness
- stunned state in which it is difficult to get a response
- abnormal rapid heart rate

- tremors
- urinary retention

If you forget to take Cetirizine Tablets

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

If you forget to take a tablet, you should take one as soon as you remember, but wait at least 24 hours before taking your next tablet.

If you stop taking Cetirizine Tablets

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

Stop taking this medicine and speak to your doctor straight away if you notice these symptoms:

- serious allergic reaction which causes difficulty in breathing or dizziness, swelling of the face or throat
- reduction in blood platelets, which increases risk of bleeding or bruising (thrombocytopenia)
- suicidal ideation (recurring thoughts of or preoccupation with suicide)
- fits
- fixed drug eruption, acute generalized exanthematous pustulosis (appearance of red or blistered skin in the same place after taking this medicine)

These reactions may start soon after you first take the medicine, or it might start later.

The following side effects have also been reported.

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

- fatigue
- dry mouth, nausea, diarrhoea
- dizziness, headache
- sleepiness
- sore throat
- sneezing, a blocked, congested or itchy nose (children only).

Uncommon: (may affect up to 1 in 100 people)

- paraesthesia (feeling of pins and needles)
- feelings of weakness and/or extreme tiredness (asthenia), feeling unwell (malaise)
- agitation
- itching, rash
- stomach ache

Rare: (may affect up to 1 in 1,000 people)

- oedema (swelling of the feet or ankles)
- weight increase
- abnormal liver function test results (your doctor will know what to do), fast heart beat (tachycardia), aggression, confusion, depression, seeing or hearing things (hallucination), difficulty in sleeping (insomnia)
- hives

Very rare: (may affect up to 1 in 10,000 people)

- difficulty with focussing the eyes, blurred vision, eyes having uncontrolled circular movements
- fainting, tremor, altered taste
- difficult, painful or involuntary urination
- tics
- loss of urinary control (enuresis)
- dyskinesia (involuntary movements)
- dystonia (abnormal prolonged muscular contractions)

Not known: (frequency can not be estimated from the available data)

- forgetfulness, memory impairment
- urinary retention (inability to completely empty the urinary bladder)
- vertigo (sensation of rotation or movement)
- increased appetite
- inflammation of liver (hepatitis)
- nightmare
- pain in joint

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: 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 Cetirizine Tablets

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

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

Keep the blister in the outer carton in order to protect from light.

Do not use this medicine after the expiry date which is stated on the carton after 'EXP'. 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 medicine you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information**What Cetirizine Tablets contain**

- The active substance is cetirizine dihydrochloride. Each film-coated tablet contains 10 mg cetirizine dihydrochloride.

- The other ingredients are microcrystalline cellulose, lactose monohydrate, colloidal anhydrous silica, maize starch, purified talc, magnesium stearate. The film-coat contains hypromellose 15cP, lactose monohydrate, titanium dioxide (E171), macrogol 4000 and sodium citrate.

What Cetirizine Tablets look like and contents of the pack

Cetirizine Tablets are white coloured, circular, biconvex film-coated tablets, marked with 'A' on one side and a breakline score on the other.

The diameter of each tablet is 8 mm.

The tablet can be divided into equal halves.

Cetirizine tablets are presented in blister packs of 7, 14, 21, 28, 30 or 60 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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