

# Cetirizine 10 mg Film-Coated Tablets

## Cetirizine dihydrochloride

### Package leaflet: Information for the user

**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 is and what it is used for
2. What you need to know before you take Cetirizine
3. How to take Cetirizine
4. Possible side effects
5. How to store Cetirizine
6. Contents of the pack and other information

## 1 What Cetirizine is and what it is used for

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

In adults and children aged 6 years and above, Cetirizine is indicated

- for the relief of nasal and ocular symptoms of seasonal and perennial allergic rhinitis.
- for the relief of urticaria.

## 2 What you need to know before you take Cetirizine

### Do not take Cetirizine

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

### Warnings and precautions

Talk to your doctor or pharmacist before taking Cetirizine

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 mille (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 with alcohol.

If you are going to have an allergy skin test please tell your doctor that you currently take Cetirizine. Usually you will need to stop taking any medicines for a period of 3 days before the allergy skin test.

### Children

Do not give this medicine to children below the age of 6 years because the tablet formulation does not allow the necessary dose adjustments.

## Other medicines and Cetirizine

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

## Cetirizine with food and drink

Food does not affect absorption of cetirizine.

## 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 for advice before taking this medicine.

Cetirizine 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.

Cetirizine passes into breast milk. A risk of side effects in breastfed infants cannot be excluded. Therefore, you should not take Cetirizine 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 if you are intending to drive, engage in potentially hazardous activities or operate machinery. You should not exceed the recommended dose.

## Cetirizine 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 medicine.

## Cetirizine contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per film-coated tablet, that is to say essentially 'sodium-free'.

## 3 How to take Cetirizine

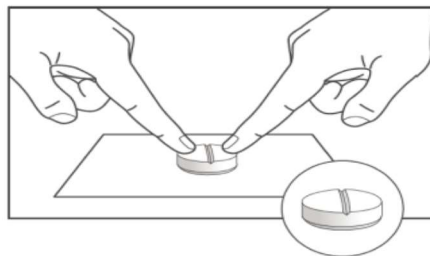
Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

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

The tablet can be divided into equal doses.

### Directions for use

If your treatment with Cetirizine stipulates that you have to split tablets, you should ideally do so as follows. Place the tablet on a hard, flat surface (such as a table top or plate) with the score line facing upwards. Then press with both of your index fingers (or thumbs) at the same time briefly and firmly on the outer edges to the left and right of the score line as shown in the graphical representation below.



### Adults and adolescents above 12 years old

The recommended dose is 10 mg (1 tablet) once daily.

Other form(s) of this medicine may be more suitable for children; ask your doctor or pharmacist.

### Use in children between 6 and 12 years old

The recommended dose is 5 mg (a half tablet) twice daily.

Other form(s) of this medicine may be more suitable for children; ask your doctor or pharmacist.

### 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 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 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 than you should**

If you think you have taken an overdose of Cetirizine 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 of pupil, itching, restlessness, sedation, somnolence, stupor, abnormal rapid heart rate, tremors and urinary retention have been reported.

### **If you forget to take CETIRIZINE**

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

### **If you stop taking Cetirizine**

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

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.

**Common side effects** (may affect up to 1 in 10 patients)

- Somnolence (sleepiness)
- Dizziness, headache
- Pharyngitis, rhinitis (in children)
- Diarrhea, nausea, dry mouth
- Fatigue

**Uncommon side effects** (may affect up to 1 in 100 patients)

- Agitation
- Paresthesia (abnormal feelings of the skin)
- Abdominal pain
- Pruritus (itchy skin), rash
- Asthenia (extreme fatigue), malaise

**Rare side effects** (may affect up to 1 in 1,000 patients)

- Allergic reactions, some severe (very rare)
- Depression, hallucination, aggression, confusion, insomnia
- Convulsions
- Tachycardia (heart beating too fast)
- Liver function abnormal
- Urticaria (hives)
- Oedema (swelling)
- Weight increased

**Very rare side effects** (may affect up to 1 in 10,000 patients)

- Thrombocytopenia (low levels of blood platelets)
- Tics (habit spasm)
- Syncope, dyskinesia (involuntary movements), dystonia (abnormal prolonged muscular contractions), tremor, dysgeusia (altered taste)
- Blurred vision, accommodation disorder (difficulty focusing), oculogyration (eyes having uncontrolled circular movements)
- Angioedema (serious allergic reaction which causes swelling of the face or throat), fixed drug eruption

- Abnormal elimination of urine (bed wetting, pain and/or difficulty passing water)

### **Not known frequency of side effects**

(frequency cannot be estimated from the available data)

- Increased appetite
- Suicidal ideation (recurring thoughts of or preoccupation with suicide), nightmare
- Amnesia, memory impairment
- Vertigo (sensation of rotation or movement)
- Urinary retention (inability to completely empty the urinary bladder)
- Pruritus (intense itching) and/or urticaria upon discontinuation
- Joint pain
- Rash with blisters containing pus
- Hepatitis (inflammation of the liver)

### **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 Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) 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**

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 any medicines you no longer use. These measures will help protect the environment.

## **6 Contents of the pack and other information**

### **What Cetirizine contains**

- The active substance is cetirizine dihydrochloride.
- Each film-coated tablet contains 10 mg cetirizine dihydrochloride.
- The other ingredients are lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, colloidal anhydrous silica, magnesium stearate, titanium dioxide (E171), hypromellose (E464) and macrogol.

### **What Cetirizine looks like and contents of the pack**

The film-coated tablet is white to almost white, round, biconvex with a score line on one side and is approximately 6.5 mm in diameter.

PVC//PVDC/alu blisters.

Cetirizine is available in blister packs of 7, 14, 15, 20, 28, 30, 50 and 100 tablets. Not all pack sizes may be marketed.

### **Marketing Authorisation Holder**

Teva UK Limited, Eastbourne, BN22 9AG, UK

### **Manufacturer**

Merckle GmbH, Ludwig-Merckle-Strasse 3, D-89143 Blaubeuren, GERMANY

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