

PACKAGE LEAFLET INFORMATION FOR THE USER  
Cetirizine Hydrochloride 10mg Tablets

**Read all 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
- You must talk to your doctor if you do not feel better or if you feel worse after 3 days.

**What is in this leaflet:**

1. What Cetirizine Hydrochloride Tablets are and what they are used for
2. What you need to know before you take Cetirizine Hydrochloride Tablets
3. How to take Cetirizine Hydrochloride Tablets
4. Possible side effects
5. How to store Cetirizine Hydrochloride Tablets
6. Contents of the pack and other information

**1. What Cetirizine Hydrochloride Tablets are and what they are used for**

The active ingredient (which makes this medicine work) is called cetirizine hydrochloride, which belongs to a family of medicines called antihistamines. Cetirizine Hydrochloride 10mg Tablets are used for the relief of symptoms of hay fever and other allergic conditions (e.g. sneezing, runny or itchy nose) or for skin rashes (chronic nettle rash, idiopathic urticaria) in adults and children over 6 years of age.

**2. What you need to know before you take Cetirizine Hydrochloride Tablets**

**Do not take Cetirizine Hydrochloride Tablets if you**

- Are **allergic** to cetirizine hydrochloride, or any of the ingredients of this medicine (listed in section 6), to hydroxyzine or to any piperazine derivatives (closely related active substances of other medicines)
- Suffer from **severe kidney disease** (severe renal failure with creatinine clearance below 10 ml/min)
- If you have rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption.

**Warnings and precautions:**

- If you have **liver or kidney problems**, 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 are an **epileptic patient** or a patient at risk of convulsions, you should ask your doctor for advice.
- If you are scheduled for allergy testing, ask your doctor if you should stop taking Cetirizine Hydrochloride Tablets for several days before testing. This medicine may affect your allergy test results.

**Children and Cetirizine Hydrochloride Tablets**

The use of this medicine is not recommended in children aged less than 6 years since this formulation does not allow for appropriate dose adaptation.

**Other medicines and Cetirizine Hydrochloride Tablets**

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

**Cetirizine Hydrochloride Tablets with food and drink and alcohol**

Food does not affect absorption of Cetirizine Hydrochloride Tablets. 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 Hydrochloride Tablets with alcohol.

**Pregnancy and breastfeeding**

You should not take these tablets if you are **pregnant** without first **consulting your doctor or pharmacist**.

**Do not take** these tablets if you are **breast-feeding**.

**Driving and using machines**

**Do not drive or operate machinery** if the tablets make you feel drowsy. At the recommended dose, these tablets do not cause drowsiness in the majority of people.

**Cetirizine Hydrochloride Tablets contain lactose**

This medicine contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking these tablets.

**3. How to take Cetirizine Hydrochloride Tablets**

The tablets should be swallowed with water.

**Adults, elderly patients and children 12 years and over:** 1 tablet daily.

**Children aged 6 to 12 years:** Half a tablet twice daily.

**Children under 6 years:** Not recommended.

If you have **kidney problems** (or **liver and kidney problems together**) please ask your doctor for advice: you may need to take a lower dose. The new dose will be determined by your doctor.

**Duration of treatment**

The duration of the treatment depends on the type, duration and course of your complaints. Please ask your pharmacist for advice.

**If you take more than you should**

If you accidentally take too much medicine, contact your doctor or nearest casualty department at once.

**If you forget to take a tablet**

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

**4. Possible side effects**

Like all medicines Cetirizine Hydrochloride 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 immediately if you notice them**

- Allergic reactions including sudden wheeziness, difficulty in breathing or dizziness, rash itchiness and fever, swollen throat, face, eyelids or lips. This reaction might start soon after you first take the medicine, or it might start later.
- bruising or bleeding more easily than normal

The frequency of possible side effects listed below is defined using the following convention:

Common (affects 1 to 10 patients in 100)

Uncommon (affects 1 to 10 patients in 1000)

Rare (affects 1 to 10 patients in 10,000)

Very rare (affects less than 1 patient in 10,000)

Not known (frequency cannot be estimated from available data)

**The following side effects have also been reported.**

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

- Tiredness, feeling sleepy
- Headache
- Dry mouth
- Nausea
- Dizziness
- Sore throat
- Cold-like symptoms of the nose (children only).

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

- Itching and rash
- Asthenia (extreme fatigue) or generally unwell
- Tingling in the hands and feet
- Feeling agitated
- Pain in the abdomen.
- Diarrhoea

**Rare side effects** (affects less than 1 in 1000 people)

- Tachycardia (heart beating too fast)
- Oedema (generalised swelling due to water retention)
- Abnormal liver function test results (your doctor will know what to do)
- Convulsions (fits)
- Weight increased
- Aggression, confusion, depression, hallucination (hearing or seeing things), sleeplessness
- Urticaria (hives).

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

- Blurred vision, difficulty focusing
- Oculogyration (eyes having uncontrolled circular movements)
- Low levels of blood platelets causing unusual bleeding or bruising
- Bad taste in mouth
- Tremor, tics (habit spasm)
- Involuntary movements and/or jerking of the limbs
- Muscle spasms in the neck and shoulders
- Swelling of the skin particularly around the face or throat
- Fainting
- A recurring rash
- Abnormal elimination of urine (bedwetting, pain and/or difficulty passing water).

**Not known frequency of side effects**

- Memory loss and forgetfulness.

**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)

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

**5. How to store Cetirizine Hydrochloride Tablets**

Keep this medicine out of the sight and reach of children. Do not take the tablets after the expiry date, which is stated on the blister 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 protect the environment.

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

Each tablet contains 10mg of cetirizine hydrochloride (the active ingredient). They also contain: lactose, microcrystalline cellulose, maize starch, colloidal anhydrous silica, magnesium stearate, talc, hypromellose, titanium dioxide (E171), macrogol 4000 and sodium citrate.

**What Cetirizine Hydrochloride Tablets look like and contents of the pack**

The tablets are white circular bi-convex, film-coated tablets marked C on one side and a breakline on the other.

Available in cartons containing 7, 14, 21, 28 and 30 tablets.

**Marketing authorisation holder and manufacturer**

Dr Reddy's Laboratories(UK) Ltd  
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Yorkshire. HU17 0LD

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