

Cetirizine Dihydrochloride 1 mg/ml Oral Solution

Patient Information Leaflet

The name of this medicine is Cetirizine Dihydrochloride 1 mg/ml Oral Solution which will be referred to as Cetirizine Oral Solution 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, pharmacist or nurse 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, pharmacist or nurse. 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 Oral Solution is and what it is used for
2. What you need to know before you take Cetirizine Oral Solution
3. How to take Cetirizine Oral Solution
4. Possible Side Effects
5. How to store Cetirizine Oral Solution
6. Contents of the pack and other information

1. What Cetirizine Oral Solution is and what it is used for

Cetirizine Oral Solution contains the active substance Cetirizine Dihydrochloride which belongs to a group of medicines called antihistamines, which is used to relieve the symptoms of allergies including hayfever, eye irritation, sneezing, runny and itchy nose and other allergies such as skin, pet and dust allergies. It can also be used to treat raised symptoms of urticaria which is often known as hives and nettle rash.

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

2. What you need to know before you take Cetirizine Oral Solution

This medicine is suitable for most children aged 2 years and over, if you are in doubt talk to your doctor, pharmacist or nurse.

Do not take Cetirizine Oral Solution:

- If you are allergic (hypersensitive) to Cetirizine Dihydrochloride or any of the other ingredients in this medicine (listed in section 6), to hydroxyzine or to any piperazine derivatives (closely related active ingredients of other medicines)
- If you have severe kidney problems requiring dialysis.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Cetirizine Oral Solution.

- 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, 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 Oral Solution with alcohol.

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

Other medicines and Cetirizine Oral Solution

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

Cetirizine Oral Solution with food and drink

Food does not affect absorption of Cetirizine Oral Solution.

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 Oral Solution should be avoided in pregnant women. Accidental use of the drug by pregnant women should not produce any harmful effects on the fetus. 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 Oral Solution during breast-feeding unless on the advice of your doctor.

Driving and using machines

Clinical studies have produced no evidence of impaired attention, alertness and driving capabilities after taking Cetirizine Oral Solution at the recommended dose. You should closely observe your response to the drug after you have taken Cetirizine Oral Solution if you are intending to drive, engage in potentially hazardous activities or operate machinery. You should not exceed the recommended dose.

Cetirizine Oral Solution contains sorbitol (E420), methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216) and propylene glycol (E1520)

This medicinal product contains 3.21 g sorbitol per 5 ml dose i.e. one ml of solution contains 643 mg sorbitol as 70% non-crystallizing solution, equivalent to 450 mg of sorbitol (E420). Sorbitol is a source of fructose. If you have been told by your doctor that you have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot breakdown fructose, contact your doctor before taking this medicine. Sorbitol may cause gastrointestinal discomfort and a mild laxative effect.

This medicinal product contains 50 mg propylene glycol (E1520) per 1 ml dose.

Cetirizine Oral Solution contains methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216) that may cause allergic reactions (possibly delayed).

This medicine contains less than 1 mmol sodium (23 mg) per 5 ml dose, that is to say essentially 'sodium-free'.

3. How to take Cetirizine Oral Solution

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

Taking this medicine

- Water or other liquid is not needed to swallow the medicine
- The medicine may be taken with or without food.

For oral use only.

- **Adults and children over 12 years:** Two 5 ml spoonfuls (10 ml oral solution) to be swallowed once daily.
- **Children from 6-12 years:** One 5 ml spoonful (5 ml oral solution) in the morning and one 5 ml spoonful (5 ml oral solution) in the evening.
- **Children 2-6 years:** One 2.5 ml spoonful (2.5 ml oral solution) in the morning and one 2.5 ml spoonful (2.5 ml oral solution) in the evening.

Not recommended for use in children under 2 years. Do not take more medicine than the label tells you to.

- Do not take more than the amount recommended above
- If symptoms persist or worsen, stop use and consult your doctor or pharmacist.

Patients with renal impairment

Patients with moderate renal impairment are recommended to take 5 mg (equivalent to 5 ml oral solution) once daily. If you suffer from kidney problems, contact your doctor or pharmacist who may adjust the dose accordingly. If your child suffers from kidney disease, please contact your doctor who may adjust the dose according to your child's needs.

If you feel that the effect of Cetirizine Oral Solution 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 forget to take Cetirizine Oral Solution

If you forget to take your dose, take the next dose when needed provided that you do not take more than the recommended dose in 24 hours.

Do not take a double dose to make up for a forgotten dose. If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

If you take more Cetirizine Oral Solution than you should

If you take too much contact your doctor or your nearest hospital casualty department. Take the medicine pack with you.

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 pupils, itching, restlessness, sedation, somnolence (sleepiness), stupor, abnormal rapid heart rate, tremors and urinary retention (difficulty in emptying the bladder) have been reported.

If you stop taking Cetirizine Oral Solution

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

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.

Other side effects which may occur:

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

- Headache, dizziness
- Somnolence (sleepiness)
- Pharyngitis (sore throat), rhinitis (runny, stuffy nose) (in children)
- Dry mouth, nausea, diarrhoea
- Fatigue.

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

- Agitation
- Paraesthesia (abnormal feelings of the skin)
- Abdominal pain
- Pruritus (itchy skin), rash
- Asthenia (extreme fatigue), malaise (feeling unwell).

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

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

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

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

Not known frequency side effects (frequency cannot be estimated from the available data)

- Increased appetite
- Amnesia (memory loss), memory impairment
- Urinary retention (inability to completely empty the urinary bladder)
- Vertigo (sensation of rotation or movement)
- Arthralgia (joint pain), myalgia (muscular pain)
- Acute generalized exanthematous pustulosis (rash with blisters containing pus)
- Hepatitis (inflammation of the liver)
- Pruritus (intense itching) and/or urticaria when you stop giving this medicine
- Suicidal ideation (recurring thoughts of or preoccupation with suicide), nightmares.

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 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 Oral Solution

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 box and bottle. Do not use after 6 months of first opening the bottle. This medicine does not require any special storage conditions.

6. Contents of the pack and other information

What Cetirizine Oral Solution contains:

The active substance is Cetirizine Dihydrochloride. Each 1 ml of the solution contains 1 mg Cetirizine Dihydrochloride.

The other ingredients are: sorbitol (E420), sodium acetate trihydrate, propylene glycol (E1520), glycerine (E422), saccharin sodium, acetic acid, methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), banana flavour (propylene glycol (E1520) natural flavouring substance and natural flavouring preparation) and purified water.

What Cetirizine Oral Solution looks like and contents of the pack

Cetirizine Oral Solution is a clear, colourless solution with a banana flavour. Cetirizine Oral Solution is supplied in an amber 200 ml bottle with a tamper evident child resistant polypropylene cap. A double ended plastic spoon with 2.5 ml and 5 ml measuring ends is included with the bottle.

Marketing Authorisation Holder and Manufacturer:

Relonchem Limited, Cheshire House, Gorse Lane, Widnes, Cheshire, WA8 0RP, UK.

Product Licence Number: PL 20395/0448

C73-0044 Version A



This leaflet was last revised in October 2025.

For information in large print, Braille or on CD, please contact the licence holder at the above address.