

Cetirizine Hydrochloride 10 mg Film-Coated Tablets

(cetirizine hydrochloride)

RelonChem

PATIENT INFORMATION 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 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

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1. What Cetirizine Hydrochloride 10 mg Tablets are and what they are used for

The active ingredient in your Tablets is cetirizine hydrochloride, which belongs to a group of medicines called antihistamines. These are used to relieve the symptoms of seasonal allergic rhinitis (e.g. hayfever), perennial allergic rhinitis (e.g. year round allergies often due to house dust mites or animal allergies) and urticaria (itchy, red, swollen skin). These symptoms include itchy skin rashes; sneezing; itchy, runny or blocked nose; red, itchy and watering eyes.

2. What you need to know before you take Cetirizine Hydrochloride 10 mg Tablets

Do not take Cetirizine Hydrochloride 10 mg Tablets if you:

- **are allergic** to cetirizine hydrochloride, hydroxyzine, piperazine derivatives or any of the other ingredients in Cetirizine Hydrochloride 10 mg Tablets (these are listed in section 6)
- have a severe kidney disease (severe renal failure with creatine clearance below 10 ml/min).

Warnings and precautions

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 interactions susceptible to have a noticeable impact 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 normal 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 10 mg Tablets with alcohol.

If you are scheduled for allergy testing, ask your doctor if you should stop taking Cetirizine Hydrochloride 10 mg Tablets for several days before testing. This medicine may affect your allergy test results.

Children

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

Taking other medicines

Please tell your doctor if you are taking or have recently taken any of the following medicines, as they may decrease or increase the effect of Cetirizine Hydrochloride 10 mg Tablets and vice versa.

- medication for anxiety or stress (CNS depressants)

Taking your medicine with food and drink

Cetirizine Hydrochloride 10 mg Tablets can be taken with or without food.

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 for advice before taking this medicine. As with other drugs, the use of Cetirizine Hydrochloride 10 mg 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 administration of the medicine should be discontinued.

Cetirizine passes into breast milk. A risk of side effects in breastfed infants cannot be excluded. Therefore, you should not take Cetirizine Hydrochloride 10 mg Tablets during breast-feeding unless you have contacted a doctor.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Clinical studies have produced no evidence of impaired attention, alertness and driving capabilities after taking Cetirizine Hydrochloride 10 mg Tablets 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.

Important information about some of the ingredients of Cetirizine Hydrochloride 10 mg Tablets

This product contains **lactose**. 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 Hydrochloride 10 mg Tablets

Always take this medicine exactly as your doctor or pharmacist has told you to do so. You should check with your doctor or pharmacist if you are not sure.

Dosage

The usual dosage is:

Adults, elderly and children over 12 years: Take one tablet (10 mg) once daily.

Children aged 6 - 12 years: Take half a tablet (5 mg) twice daily (morning and evening).

Children weighing less than 30 kg: Half a tablet (5 mg) should be taken once 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 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 the effect of Cetirizine is too weak or too strong, please contact 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 drowsiness occurs, your tablet can be taken in the evening.

Method of administration: For oral use.

If you take more Cetirizine Hydrochloride 10 mg Tablets than you should

If you have accidentally taken more than the recommended dose, contact your nearest hospital casualty department or tell your doctor or pharmacist **immediately**.

Remember to take the pack and any remaining tablets with you.

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 Hydrochloride 10 mg Tablets

If you have forgotten to take your tablet, take it as soon as you remember and then wait 24 hours before taking your next dose. Do not take a double dose to make up for a forgotten dose.

If you stop taking Cetirizine Hydrochloride 10 mg Tablets

Rarely, pruritus (intense itching) and/or urticaria may return if you stop taking Cetirizine Hydrochloride 10 mg 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.

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.

- Suicidal ideation (recurring thoughts of or preoccupation with suicide).

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

- Somnolence (sleepiness)
- Dizziness, headache
- Pharyngitis, rhinitis (in children)
- Diarrhoea, 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 (fits)
- 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
- 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
- Nightmare
- 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 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 Hydrochloride 10 mg Tablets

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

Do not use this medicine after the expiry date (Exp.) stated. The expiry date refers to the last day of that month. This medicinal product does not require any special storage conditions.

Do not throw away any medicines via waste water or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and further information

What Cetirizine Hydrochloride 10 mg Tablets contain:

The active ingredient is cetirizine hydrochloride. Each tablet contains 10 mg of cetirizine hydrochloride.

The other ingredients are: lactose monohydrate, microcrystalline cellulose, colloidal anhydrous silica, maize starch, talc, magnesium stearate, titanium dioxide (E171), hypromellose, macrogol, sodium citrate.

What Cetirizine Hydrochloride 10 mg Tablets look like and the contents of the pack:

Cetirizine Hydrochloride 10 mg Tablets are white coloured, circular, biconvex film coated tablets with a break line. Your medicine is available in packs containing 7, 10, 14, 28, 30, 60 and 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

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