PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Cetirizine Hydrochloride 10 mg Film-coated Tablets
cetirizine hydrochloride

[For medicine available only on prescription:]
Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- 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.

[For medicine available without prescription:]
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. 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 chronic nettle rash (chronic idiopathic urticaria).

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE CETIRIZINE

Do not take Cetirizine:
- if you have a severe kidney disease requiring dialysis;

- if you are allergic to cetirizine dihydrochloride or any of the other ingredients of this medicine (listed in section 6), to hydroxyzine, to piperazine derivatives (closely related active substances of other medicines).

Warnings and precautions:

Talk to your doctor or pharmacist before taking Cetirizine Hydrochloride.

If you have problems passing urine (like spinal cord problems or prostate or bladder problems), please ask your doctor for advice.

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 are an epileptic patient or a patient at risk of convulsions, you should ask your doctor for advice.

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

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.

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 the 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 or pharmacist for advice before taking this medicine.
Cetirizine should be avoided in pregnant women. Accidental use of the medicine by a pregnant woman should not produce any harmful effects on the foetus. Nevertheless, the medicine should be only 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 at the recommended dose.

You should closely observe your response to the medicine 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, contact your doctor before taking this medicinal product.

3. HOW TO TAKE CETIRIZINE

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.

Tablets need to be swallowed with a glass of liquid.
The tablet can be divided into equal doses.

Adults and adolescents above 12 years old
The recommended dose is 10 mg once daily as 1 tablet
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 twice daily as 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 and is determined by your doctor.

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, malaise (feeling unwell), dilating of pupil, itching, restlessness, sedation, somnolence (sleepiness), stupor, abnormal rapid heart rate, tremors and urinary retention (difficulty in completely emptying the bladder) 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 (hives) 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 Cetirizin Sandoz and seek for medical attention without delay if you experience symptoms like:

- swelling in your mouth, face and/or throat
- difficulties in breathing (chest tightness or wheezing)
- sudden drop in your blood pressure with subsequent fainting or shock.

The symptoms can be signs of allergic reactions, anaphylactic shock and angioedema. These reactions may start soon after you first take the medicine, or it might start later.

The following outline contains further side effects listed by their frequency:

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

- fatigue
- dry mouth, nausea, diarrhoea
- dizziness, headache
- somnolence (sleepiness)
- pharyngitis (sore throat), rhinitis (runny,stuffy nose) (in children)

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

- agitation
- abdominal pain
- asthenia (extreme fatigue), malaise (feeling of being generally unwell)
- paresthesia (abnormal feelings of the skin)
-
- pruritus (itchy skin), rash
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Rare: (may affect up to 1 in 1,000 people):

- allergic reactions, some severe (very rare)
- tachycardia (heart beating too fast)
- oedema (swelling)
- liver function abnormal
- weight increased
- convulsions

- aggression, confusion, depression, hallucination, insomnia
- urticaria (hives)

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

- thrombocytopenia (low blood platelets count manifested by bleeding or bruising more easily than normal)
- accommodation disorder (difficulty focusing), blurred vision, oculogyric crisis (eyes having uncontrolled circular movements)
- syncope (fainting), tremor, dysgeusia (altered taste), dyskinesia (involuntary movements), dystonia (abnormal prolonged muscular contractions)
- tics (habit spasm)
- abnormal elimination of urine (bed-wetting, pain and/or difficulty passing water)
- angioedema (serious allergic reaction which causes swelling of the face or throat), fixed drug eruption (drug allergy)

Not known (Frequency cannot be estimated from the available data):

- amnesia (memory loss), memory impairment
- increased appetite
- vertigo (sensation of rotation or movement)
- urinary retention (inability to completely empty the urinary bladder)
- nightmares
- hepatitis (inflammation of the liver)
- arthralgia (joint pain), myalgia (muscular pain)
- acute generalized exanthematous pustulosis (rash with blisters containing pus)
- pruritus (intense itching) and/or urticaria upon discontinuation
- suicidal ideation (recurring thoughts of or preoccupation with suicide)
  If you feel this way, stop taking the tablets and see your doctor.

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: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in 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 on the carton after EXP. The expiry date refers to the last day of that month.
This medicine does not require any special temperature storage conditions.
Store in the original package in order to protect from light.

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 contains

Each tablet contains 10 mg of cetirizine dihydrochloride
- The active substance is cetirizine dihydrochloride.
- The other ingredients are
  Tablet core: cellulose microcrystalline, lactose monohydrate, magnesium stearate, silica, colloidal anhydrous
  Tablet coat: hypromellose, lactose monohydrate , titanium dioxide (E171) and macrogol 4000.

What Cetirizine looks like and contents of the pack

Cetirizine Hydrochloride 10 mg Tablets are white, oblong film-coated tablets, scored on one side.
PVC blister with aluminium foil lidding: 7, 10, 14, 20, 21, 28, 30, 50, 60, 98 and 100 and 50 (50x1) unit-dose.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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