Package leaflet: Information for the user

Cetirizine hydrochloride 10 mg film-coated tablets

Cetirizine dihydrochloride

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

1. What Cetirizine hydrochloride is and what it is used for

Cetirizine dihydrochloride is the active ingredient of the Cetirizine.
Cetirizine is an anti-allergic medication.

In adults and children aged 6 years and above, Cetirizine hydrochloride 10 mg film-coated tablets are indicated
- for the relief of nasal and ocular symptoms of seasonal and perennial allergic rhinitis.
- for the relief of urticaria.

You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

2. What you need to know before you take Cetirizine hydrochloride

Do not take Cetirizine hydrochloride
- if you are allergic to cetirizine dihydrochloride, to any of the other ingredients (listed in section 6), to hydroxyzine or to piperazine derivatives (closely related active ingredients of other medicines);
- if you have a severe kidney disease requiring dialysis

Warnings and precautions
Talk to your doctor or pharmacist before taking Cetirizine hydrochloride.

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 hydrochloride used at the recommended doses. However, there are no data available on the safety when higher doses of Cetirizine hydrochloride and alcohol are taken together. Therefore, as it is the case with all antihistamines, it is recommended to avoid taking Cetirizine hydrochloride with alcohol.

If you are scheduled for allergy testing, ask your doctor if you should stop taking Cetirizine hydrochloride 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 the necessary dose adjustments

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

Cetirizine hydrochloride with food and drink
Food does not affect absorption of Cetirizine hydrochloride.

Pregnancy, breast-feeding and fertility
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 hydrochloride 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 hydrochloride passes into breast milk. A risk of side effects in breastfed infants cannot be excluded. Therefore, you should not take Cetirizine hydrochloride 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 hydrochloride at the recommended dose.
You should closely observe your response to the drug after you have taken Cetirizine hydrochloride if you are intending to drive, engage in potentially hazardous activities or operate machinery. You should not exceed the recommended dose.

Cetirizine hydrochloride contains lactose monohydrate
This medicine contains lactose monohydrate. If you have been told that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Cetirizine hydrochloride contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially ‘sodium free’.

3. How to take Cetirizine hydrochloride

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.
The tablets need to be swallowed with a glass of liquid.
The tablet can be divided into 2 equal doses.

Adults and adolescents above 12 years old:
The recommended dose is 10 mg once daily as 1 tablet.

Use in children between 6 and 12 years old:
The recommended dose is 5 mg twice daily as a half tablet twice 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 that the effect of Cetirizine hydrochloride 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 hydrochloride than you should
If you think you have taken an overdose of Cetirizine hydrochloride 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 hydrochloride
Do not take a double dose to make up for a forgotten dose.

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

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: (may affect up to 1 in 10 people)
- Somnolence (sleepiness)
- Headache, dizziness
- Pharyngitis (sore throat), rhinitis (runny, stuffy nose) (in children)
- Diarrhoea, nausea, dry mouth
- Fatigue

Uncommon: (may affect up to 1 in 100 people)**:**
- Agitation
- Paresthesia (abnormal feelings of the skin)
- Abdominal pain
- Pruritus (itchy skin), rash
- Asthenia (extreme fatigue), malaise (feeling unwell)

Rare: (may affect up to 1 in 1000 people)**:**
- 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: (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 cannot be estimated from the available data):
- Arthralgia (joint pain), myalgia (muscular pain)
- Acute generalized exanthematous pustulosis (rash with blisters containing pus)
- Increased appetite
- Suicidal ideation (recurring thoughts of or preoccupation with suicide), nightmare
- Amnesia (memory loss) 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);
- Hepatitis (inflammation of the liver)

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 national reporting system listed in Yellow Card Scheme, Website: 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 to provide more information on the safety of this medicine.

5. How to store Cetirizine hydrochloride

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 label, carton or bottle 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 medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Cetirizine hydrochloride contains
- The active substance is Cetirizine dihydrochloride.
  Each film-coated tablet contains 10 mg cetirizine dihydrochloride.
- The other ingredients are:
  Tablet Core:
  Lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, silica colloidal anhydrous, magnesium stearate.
  Tablet Coating:
  Hypromellose (5cp), titanium dioxide (E 171), macrogol 400.

What Cetirizine hydrochloride looks like and contents of the pack
Film-coated tablet.

White to off-white, film-coated, off-rectangular tablets, debossed with ‘10’ on one side and plain on the other side. Score line between ‘1’ and ‘0’. The tablet can be divided into equal doses.

Cetirizine hydrochloride film-coated tablets are available in blister packs and HDPE bottles.

Pack sizes:
Blister packs: 7, 10, 14, 20, 28, 30, 50 and 100 film-coated tablets.
HDPE bottle: 250 film-coated tablets

Not all pack sizes may be marketed.

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