Package leaflet: information for the user

Cetirizine, 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 tablets is and what it is used for
2. What you need to know before you take Cetirizine tablets
3. How to take Cetirizine tablets
4. Possible side effects
5. How to store Cetirizine tablets
6. Contents of the pack and other information

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

Cetirizine dihydrochloride, the active ingredient of the tablets is an antihistamine. It blocks the effects of a substance called histamine which occurs naturally in the body. Histamine is involved in allergic reactions.

In adults and children aged 6 years and above, Cetirizine tablets is used to treat people who have hay fever (seasonal allergic rhinitis), year round allergies such as dust or pet allergies (perennial allergic rhinitis) and urticaria (swelling, redness and itchiness of the skin).

Antihistamines like Cetirizine tablets relieve the unpleasant symptoms and discomfort associated with these conditions, such as sneezing, irritated, runny and blocked up nose, itchy and watering eyes and skin rashes.

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

Do not take Cetirizine tablets:

- if you have a severe kidney disease (severe renal failure with creatinine clearance below 10 ml/min);
- if you are allergic to Cetirizine dihydrochloride, to any of the other ingredients (listed in section 6), to hydroxyzine or to any piperazine derivatives (closely related active ingredients of other medicines).

Warning and precautions

Talk to your doctor or pharmacist before taking Cetirizine tablets.

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 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 tablets with alcohol.

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

Other medicines and Cetirizine tablets

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

Cetirizine tablets with food and drink

Food does not affect absorption of Cetirizine tablets.

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 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 medicine should only be administered if necessary and after medical advice.

Cetirizine passes into breast milk. Therefore, you should not take Cetirizine tablets 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 tablets at the recommended dose.

You should closely observe your response to the drug after you have taken Cetirizine tablets if you are intending to drive, engage in potentially hazardous activities or operate machinery. You should not exceed the recommended dose.

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

Cetirizine tablets contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per film-coated tablet, that is to say essentially 'sodium-free'.

3. How to take Cetirizine tablets
Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or your pharmacist if you are not sure.

The tablets need to be swallowed with a glass of liquid.

The tablet can be divided into equal doses. Do not take more than one tablet each day.

Children aged 6 to 12

The recommended dose is 5mg twice daily as half a tablet twice a day.

Adults and adolescents aged 12 years and over

The recommended dose is 10 mg once daily as one tablet daily. If the tablets make you feel drowsy or dizzy, taking half a tablet twice a day may be better than taking one tablet once a day.

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 5mg 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 tablets 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 tablets than you should
If you think you have taken an overdose of Cetirizine tablets 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, ailing, dilating of pupil, itching, restlessness, sedation, stupor, abnormal rapid heart rate, tremors and urinary retention have been reported.

If you forget to take Cetirizine tablets
Do not take a double dose to make up for a forgotten tablet. If you forget to take a tablet, you should take one as soon as you remember, but wait at least 24 hours before taking your next tablet.

If you stop taking Cetirizine tablets
Rarely, pruritus (intense itching) and/or urticaria may return if you stop taking Cetirizine 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 tablets 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).
- Suicidal ideation (recurring thoughts of or preoccupation with suicide)
- Rash with blisters containing pus
- Hepatitis (inflammation of the liver)

These reactions may start soon after you first take the medicine, or it might start later.

Common (may affect up to 1 in 10 patients)

- Somnolence (sleepiness)
- Dizziness, headache
- Pharyngitis, rhinitis (in children)
- Diarrhea, nausea, dry mouth

- Fatigue

Uncommon (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 (may affect up to 1 in 1,000 patients)

- 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 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)
- Fixed drug eruption
- Abnormal elimination of urine (bed wetting, pain and/or difficulty passing water)

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

- Increased appetite
- Nightmare
- 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 Rash

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Cetirizine tablets

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 blister and the carton. 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 protect the environment.

6. Contents of the pack and other information

What Cetirizine tablets contains

- The active substance is Cetirizine dihydrochloride. One film-coated tablet contains 10 mg of Cetirizine dihydrochloride.
- The other ingredients are lactose monohydrate, microcrystalline cellulose, maize starch, colloidal anhydrous silica, magnesium stearate, talc, hypromellose, titanium dioxide (E171), macrogol 4000 and sodium citrate.

What Cetirizine tablets looks like and contents of the pack

White coloured, circular, bi-convex film coated tablets with "A" embossed on one side and a deep score on the other.

20 tablets (2 blister packs of 10 tablets each) are packed in a cardboard box together with a leaflet insert.

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