

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.

This medicine is available without prescription. However, you still need to use Cetirizine 10 mg Tablets carefully to get the best results from it.

- 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.
- In this leaflet Cetirizine 10 mg film-coated tablets will be called Cetirizine 10 mg Tablets.

What is in this leaflet:

1. What Cetirizine 10 mg Tablets are and what they are used for
2. What you need to know before you take Cetirizine 10 mg Tablets
3. How to take Cetirizine 10 mg Tablets
4. Possible side effects
5. How to store Cetirizine 10 mg Tablets
6. Contents of the pack and other information

1. WHAT CETIRIZINE 10 MG TABLETS ARE AND WHAT THEY ARE USED FOR

Cetirizine dihydrochloride is the active ingredient of Cetirizine 10 mg Tablets.

Cetirizine 10 mg Tablets is an antiallergic medication.

In adults and children aged 6 year and above, Cetirizine 10 mg Tablets are indicated

- for the relief of symptoms of hay fever (seasonal allergic rhinitis) and allergies such as dust or pet allergies (perennial allergic rhinitis), such as sneezing, itchy, runny and blocked nose, itchy, red and watery eyes.
- for the relief of swelling, redness and itchiness of the skin (symptoms of chronic idiopathic urticaria, which is also known as chronic nettle rash).

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE CETIRIZINE 10 MG TABLETS

Do not take Cetirizine 10 mg Tablets

- if you have a severe kidney disease requiring dialysis.
- if you are allergic (hypersensitive) to cetirizine dihydrochloride or any of the other ingredients of this medicine (listed in section 6).
- if you are allergic (hypersensitive) to hydroxyzine (closely related active substances of other medicines).
- if you are allergic (hypersensitive) to drugs from the piperazine family, for example buclizine, cyclizine, meclozine, levocetirizine.

Warnings and precautions

Talk to your doctor or pharmacist before taking Cetirizine 10 mg Tablets.

If you have kidney problems, please ask your doctor for advice; if necessary, you may have to take a lower dose. The new dose will be determined by your doctor.

If you have predisposition factors of urinary retention (e.g.: spinal cord lesion, prostatic hyperplasia) as cetirizine increases the risk of urinary retention, 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.

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 10 mg Tablets

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

Due to the profile of cetirizine, no interactions with other drugs are expected.

Cetirizine 10 mg Tablets with food, drink and alcohol

Food does not noticeably affect the absorption of cetirizine.

No interactions having a noticeable impact 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 consumption of alcohol while taking this medicine.

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 for advice before taking this medicine.

Cetirizine 10mg 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. Side effects associated with cetirizine may be seen in breastfed infants. Therefore, you should not take Cetirizine 10 mg Tablets during breast-feeding unless you have contacted a doctor.

Allergy skin test

If you are going to have an allergy skin test, ask your doctor if you should stop taking Cetirizine 10 mg Tablets for several days before the test. This medicine may affect your allergy test results.

Driving and using machines

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

You should closely observe your response to the drug after you have taken Cetirizine 10 mg Tablets if you are intending to drive, engage in potentially hazardous activities or operate machinery. You should not exceed the recommended dose. You may find that the simultaneous use of alcohol or other nervous depressant agents may additionally affect your attention and ability to react.

Cetirizine 10 mg Tablets 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 10 MG TABLETS

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

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

Use in children aged 6 to 12 years:

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

Adults and children aged 12 years and over:

The recommended dose is 10 mg once daily as one tablet.

Patients with renal impairment:

Patients with moderate renal impairment are recommended to take 5 mg once daily as a half tablet.

If you suffer from severe kidney disease, please contact your doctor who may adjust the dose accordingly.

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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 10 mg 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 10 mg Tablets than you should

If you think you have taken an overdose of Cetirizine 10 mg 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, malaise (feeling unwell), dilating (widening) of the pupil, itching, restlessness, sedation, somnolence (sleepiness), stupor (lowered consciousness), abnormal rapid heart rate, tremors and urinary retention (difficulty in completely emptying the bladder) have been reported.

If you forget to take Cetirizine 10 mg Tablets

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

If you stop taking Cetirizine 10 mg Tablets

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

In very rare cases people have thought about committing suicide and if you feel this way then stop taking the tablets and see your doctor immediately.

If you develop one of the very rare side effects described below, please inform your doctor straight away.

At the first signs of allergic (hypersensitivity) reactions, including a severe allergic reaction (symptoms include: rash, itchiness and fever, difficulty breathing, swelling of the neck, throat, tongue, face, eyelids or lips) stop taking the tablets and contact your doctor immediately.

This reaction may start soon after you first take the medicine or it might start later.

Your doctor will then assess the severity and decide on any further measures that may be necessary.

The following side effects have also been reported.

Common: may affect up to 1 in 10 people

- Fatigue, somnolence (sleepiness)
- Dizziness, headache
- Dry mouth, nausea (feeling sick), diarrhoea (children only)
- Pharyngitis (sore throat), rhinitis (runny, stuffy nose) (in children)

Uncommon: may affect up to 1 in 100 people

- Pruritus (itching), rash
- Abdominal pain
- Agitation
- Asthenia (feeling of weakness), malaise (feeling unwell)
- Paraesthesia (abnormal feelings of the skin), tingling in the hands and feet

Rare: may affect up to 1 in 1,000 people

- Tachycardia (heart beating fast)
- Oedema (generalised swelling due to water retention)
- Liver function abnormal
- Convulsions
- Weight increased
- Aggression, confusion, depression, hallucination

(hearing or seeing things), insomnia (difficulty sleeping)

- Urticaria (swelling, redness and itchiness of the skin)

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

- Thrombocytopenia (low level of blood platelets), which increases risk of bleeding or bruising
- Accommodation disorder (impaired ability of the eye to focus), blurred vision, oculogyric crisis (eyes moving in an uncontrolled circular manner)
- Syncope (fainting), dyskinesia (involuntary movements), dystonia (abnormal prolonged muscular contractions), tremor, dysgeusia (altered taste)
- Tics (sudden abnormal repetitive muscle movement)
- Fixed drug eruption (may look like round or oval patches of redness and swelling of the skin)
- 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 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
- Arthralgia (joint pain), myalgia (muscular pain)
- Acute generalized exanthematous pustulosis (rash with blisters containing pus)
- 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 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 provide more information on the safety of this medicine.

5. HOW TO STORE CETIRIZINE 10 MG 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 box and blister after EXP. The expiry date refers to the last day of the month.

This medicine does not require any special storage conditions.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Cetirizine 10 mg Tablets contain

- The active substance is cetirizine dihydrochloride. One film-coated tablet contains 10 mg cetirizine dihydrochloride.
- The other ingredients are: pregelatinized starch, lactose monohydrate, maize starch, povidone, magnesium stearate, macrogol 6000, basic polymethacrylate, titanium dioxide (E171), talc.

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

White, capsule shaped film-coated tablets with a score on one side.

There are 7, 10 or 30 tablets in a pack.

Not all pack sizes may be marketed.

Marketing Authorization Holder and Manufacturer:

Dexcel®-Pharma Ltd.
2nd Floor, Bourn, 1 Manor House Drive,
Coventry, CV1 2FX, UK

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