

Cetirizine 10 mg film-coated tablets

(Cetirizine hydrochloride)

font: Helvetica
size: 9 pt
PIL dimension: 155mm x 300mm

Read all of this leaflet carefully before you start taking this medicine because it contains important information for 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.
- If you have any further questions, ask your doctor or pharmacist.
- You must contact a doctor if your symptoms worsen or do not improve after 3 days.
- 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.
- 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 hydrochloride 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 (severe renal failure with creatinine clearance below 10 ml/min).
- if you are known to be allergic (hypersensitive) to the active substance of Cetirizine 10 mg Tablets or any of the other ingredients of these tablets (these are listed below, in section 6 "Further information").
- if you are known to be allergic (hypersensitive) to hydroxyzine (closely related active substances of other medicines).
- if you are known to be allergic (hypersensitive) to drugs from the piperazine family, for example buclizine, cyclizine, meclizine, 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 (eg: 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

Please tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines, including medicines obtained without a prescription.

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

Taking Cetirizine 10 mg Tablets with food and drink

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, as it is the case with all antihistamines, it is recommended to avoid consumption of alcohol while taking this medicine.

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 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. 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 stop taking Cetirizine 10 mg Tablets for three 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. If you are a sensitive patient, 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

Cetirizine 10 mg Tablets contain lactose; if you have been told by your doctor that you have an intolerance to some sugars, please contact your doctor before taking this medicinal product.

3. HOW TO TAKE CETIRIZINE 10 MG TABLETS

Always take Cetirizine 10 mg Tablets exactly 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.

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 moderate to severe 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 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 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, ailing, dilating (widening) of the pupil, itching, restlessness, sedation, somnolence, stupor, abnormal rapid heart rate, tremors and urinary retention 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 may return if you stop taking Cetirizine 10 mg Tablets.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Cetirizine 10 mg Tablets 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.

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

At the first signs of a severe allergic (hypersensitivity) 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 side effects (may affect up to 1 in 10 patients)

- Fatigue, somnolence (sleepiness)
- Dizziness, headache,
- Dry mouth, nausea (feeling sick), diarrhoea (children only)
- Pharyngitis (sore throat), rhinitis (swelling and irritation inside the nose (children only))

Uncommon side effects (may affect up to 1 in 100 patients)

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

Rare side effects (may affect up to 1 in 1,000 patients)

- 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 side effects (may affect up to 1 in 10,000 patients)

- Thrombocytopenia (low level of blood platelets), which increases risk of bleeding or bruising
- Accommodation disorder (impaired ability of the eye to focus), blurred vision, oculogyration (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)
- Swelling of the skin particularly around the face, 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 of side effects (frequency cannot be estimated from the available data)

- Increased appetite
- Suicidal ideation (recurring thoughts of or preoccupation with suicide), nightmare
- Amnesia (loss of memory), 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
- Rash with blisters containing pus

Reporting of suspected adverse reactions

If you think you have any side effects not mentioned in this leaflet, please inform 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 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 10 MG TABLETS

Keep out of the sight and reach of children.

Do not use Cetirizine 10 mg Tablets after the expiry date which is stated on the box and blister.

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 of Cetirizine 10 mg Tablets is cetirizine hydrochloride. One film coated tablet contains 10 mg cetirizine hydrochloride.
- The other ingredients are: pregelatinized starch, lactose, 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., Dexcel®-Pharma Ltd., 7 Sopwith Way, Drayton Fields, Daventry, Northamptonshire, NN11 8PB, UK.

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