

Package leaflet: Information for the user
Cetirizine dihydrochloride Pinewood 10 mg film-coated Tablets
cetirizine dihydrochloride

Read all of this leaflet carefully before you start taking this medicine

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

What is in this leaflet:

1. What Cetirizine Tablets are and what they are 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 are and what they are used for

Cetirizine Tablets contain the active ingredient cetirizine dihydrochloride. This is an antihistamine used to treat seasonal allergic rhinitis (hay fever) and perennial rhinitis, and urticaria (hives) in adults and children over 6 years of age.

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

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

Do not take Cetirizine Tablets if:

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

Warnings 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 difficulty passing urine (e.g. spinal cord lesion, enlarged prostate)

- if you are due to have an allergy test, as this medicine may affect your allergy test result
- if you are an epileptic patient or a patient at risk of convulsions.
- 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 Tablets with alcohol.
- If you are scheduled for allergy testing, ask your doctor if you should stop taking 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:

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription, but particularly if you are taking:

- any other medicines which can cause drowsiness or affect your level of alertness.

Cetirizine tablets with food and drink:

Food does not affect absorption of Cetirizine Tablets.

Pregnancy and Breast-feeding:

Talk to your doctor before taking this medicine if you are pregnant, think you may be pregnant or are planning to become pregnant, or if you are breast-feeding.

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.

Important information about some of the ingredients of Cetirizine Tablets:

Cetirizine Tablets contain:

- **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.
- **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 Tablets

Always take this medicine exactly as your doctor or pharmacist has told you; you should check with him/her if you are not sure.

The tablets should be taken by mouth and swallowed with a glass of liquid. The tablet can be divided into 2 equal doses. You should check with your doctor or pharmacist if you are uncertain what dose to take.

Adults and adolescents over 12 years of age

The recommended dose is one 10 mg tablet once a day.

Children aged 6 to 12 years

The recommended dose is 5 mg twice daily (a half tablet twice daily).

Other form(s) of this medicine may be more suitable for children; ask your doctor or pharmacist.

Children under 6 years

This medicine must NOT be given to children under 6 years of age.

Patients with kidney problems

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 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 and is determined by your doctor.

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, somnolence, stupor, abnormal rapid heart rate, tremors and urinary retention have been reported.

If you forget to take Cetirizine Tablets

If you forget to take a dose, take another one as soon as you remember but wait at least 12 hours before taking the next dose. Do not take a double dose to make up for the forgotten dose.

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 Cetirizine Tablets 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 side effects (may affect up to 1 in 10 patients)

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

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

- 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 side effects (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)
- Angioedema (serious allergic reaction which causes swelling of the face or throat), fixed drug eruption
- 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, 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
- Hepatitis (inflammation of the liver)

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via

Ireland

HPRA Pharmacovigilance

Website: www.hpra.ie

Malta

ADR Reporting

Website: www.medicinesauthority.gov.mt/adrportal

5. How to store Cetirizine Tablets

Keep this medicine out of the sight and reach of children.

This medicinal product does not require any special storage conditions.

Do not use this medicine after the expiry date (shown as 'EXP') on the label. The expiry refers to the last day of that month.

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 contain

- The **active substance** is cetirizine (as cetirizine dihydrochloride). Each tablet contains 10 mg cetirizine dihydrochloride.

The other ingredients are lactose monohydrate, maize starch, pregelatinised starch, dried maize starch, talc, magnesium stearate, hypromellose (E464), titanium dioxide (E171) and polyethylene glycol 6000.

What Cetirizine Tablets look like and contents of the pack

Cetirizine Tablets are white to off white capsule shaped film-coated tablets with break-line on one side and '10' debossed on the other side.

Cetirizine dihydrochloride Pinewood 10 mg film-coated Tablets are available in packs of 7, 10, 14, 20, 30, 50 or 90 Tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

Pinewood Laboratories Limited,
Ballymacarbry,
Clonmel,
Co. Tipperary,
Ireland.

This leaflet was last revised in 11/2021

This medicinal product is authorised in the Member States of the EEA under the following names:

Ireland: Cetirizine dihydrochloride Pinewood 10 mg film-coated Tablets

Malta: Cetirizine dihydrochloride Pinewood 10 mg film-coated Tablets