
Package leaflet: Information for the user

Cetirizine Haleron 10mg Film Coated Tablets

Cetizitine dihydrochloride

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Always use this medicine exactly as described in this leaflet or as your pharmacist has 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

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1. What Cetirizine Haleron 10mg Film Coated Tablets are and what they are used for

Cetirizine dihydrochloride is the active ingredient of Cetirizine Haleron 10mg Film Coated Tablets.

Cetirizine Haleron 10mg Film Coated Tablets is an antiallergic medication.

In adults and children aged 6 years and above, Cetirizine Haleron 10mg Film Coated Tablets 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.

2. What you need to know before you take Cetirizine Haleron 10mg Film Coated Tablets

Do not take Cetirizine Haleron 10mg Film Coated Tablets

- if you have a severe kidney disease requiring dialysis;
- if you are allergic to cetirizine dihydrochloride or any of the other ingredients of this medicine (listed in section 6), to hydroxyzine or to any piperazine derivatives (closely related active ingredients of other medicines).

Warnings and precautions

Talk to your doctor or pharmacist before taking Cetirizine Hialeon 10mg Film Coated 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 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 Hialeon 10mg Film Coated Tablets with alcohol.

If you are scheduled for allergy testing, ask your doctor if you should stop taking Cetirizine Hialeon 10mg Film Coated 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 Hialeon 10mg Film Coated Tablets

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

Cetirizine Hialeon 10mg Film Coated Tablets with food and drink

Food does not affect absorption of Cetirizine Hialeon 10mg Film Coated 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 Hialeon 10mg Film Coated 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. A risk of side effects in breastfed infants cannot be excluded. Therefore, you should not take Cetirizine Hialeon 10mg Film Coated 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 Haleron 10mg Film Coated Tablets at the recommended dose.

You should closely observe your response to the drug after you have taken Cetirizine Haleron 10mg Film Coated Tablets if you are intending to drive, engage in potentially hazardous activities or operate machinery. You should not exceed the recommended dose.

Cetirizine Haleron 10mg Film Coated 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 this medicine.

3. How to take Cetirizine Haleron 10mg Film Coated 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 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 one tablet once a day.

Use in children between 6 and 12 years old:

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

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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 who may adjust the dose accordingly.

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 Haleron 10mg Film Coated Tablets is too weak or too strong, please consult your doctor.

If you take more Cetirizine Haleron 10mg Film Coated Tablets than you should

If you think you have taken an overdose of Cetirizine Haleron 10mg Film Coated 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 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 Haleon 10mg Film Coated Tablets

Do not take a double dose to make up for a forgotten dose.

If you stop taking Cetirizine Haleon 10mg Film Coated Tablets

Rarely, pruritus (intense itching) and/or urticaria may return if you stop taking Cetirizine Haleon 10mg Film Coated 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 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 (sore throat), rhinitis (runny, stuffy nose) (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 (feeling unwell)

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

- Allergic reactions, some severe (very rare)
 - Depression, hallucination, aggression, confusion, insomnia
 - Convulsions
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- 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 (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 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 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 pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the HPRA Pharmacovigilance website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Cetirizine Hialeon 10mg Film Coated 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 carton after 'EXP:'. The expiry date refers to the last day of that month.

6. Contents of the pack and other information

What Cetirizine Haleon 10mg Film Coated Tablets contains

- The active substance is cetirizine dihydrochloride. Each tablet contains 10mg cetirizine dihydrochloride.
- The other ingredients are microcrystalline cellulose, lactose monohydrate, colloidal anhydrous silica, magnesium stearate, hypromellose (E 464), macrogol 4000, titanium dioxide (E 171) and polydextrose.

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

White to off white capsule-shaped tablet with and a deep breakline on one side.

Pack with 4, 7, 12, 14, 28 or 30 tablets. Not all pack sizes may be marketed.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Haleon Ireland Limited, Clocherane, Dungarvan, Co. Waterford, Ireland

Manufacturer

Haleon Alcala S.A.
Carretera Ajalvir Km 2500
Alcala De Henares
Madrid
28806
Spain

This leaflet was last revised in December 2025.

This medicine is authorised in the Member States of the European Economic Area under the following names:

- *Belgium – Cetirizine Haleon 10 mg filmomhulde tabletten*
 - *Denmark – Cetirizindihydrochlorid Haleon*
 - *Finland – Cetirizine Haleon 10mg kalvopäällysteiset tabletit*
 - *Iceland – Cetirizine Haleon 10mg filmuhúðaðar töflur*
 - *Ireland – Cetirizine Haleon 10mg Film Coated Tablets*
 - *Luxembourg – Cetirizine Haleon 10 mg filmomhulde tabletten*
 - *Norway – Cetirizine Haleon*
 - *Sweden – Cetirizine Haleon 10mg filmdragerade tabletter*
 - *The Netherlands – Cetirizine diHCl Haleon 10mg filmomhulde ta*
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