

Package leaflet: Information for the user
Zirtek Allergy Relief 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 side effects not listed in this leaflet.
- 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 Zirtek Allergy Relief is and what it is used for
2. What you need to know before you take Zirtek Allergy Relief
3. How to take Zirtek Allergy Relief
4. Possible side effects
5. How to store Zirtek Allergy Relief
6. Contents of the pack and other information

1. What Zirtek Allergy Relief is and what it is used for

Cetirizine dihydrochloride is the active ingredient of Zirtek Allergy Relief.
Zirtek Allergy Relief is an antiallergic medication.

In adults and children aged 6 years and above, Zirtek Allergy Relief is 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 Zirtek Allergy Relief

Do not take Zirtek Allergy Relief

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

Warning and precautions

Talk to your doctor or pharmacist before taking Zirtek Allergy Relief.

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 Zirtek Allergy Relief with alcohol.

If you are scheduled for allergy testing, ask your doctor if you should stop taking Zirtek Allergy Relief for several days before testing. This medicine may affect your allergy test results.

Other medicines and Zirtek Allergy Relief

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

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.

Zirtek Allergy Relief with food and drink

Food does not affect absorption of Zirtek Allergy Relief.

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.

Zirtek Allergy Relief 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 Zirtek Allergy Relief 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 Zirtek Allergy Relief at the recommended dose.

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

Zirtek Allergy Relief 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 medicinal product.

3. How to take Zirtek Allergy Relief

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 10 mg once daily as 1 tablet.

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

Children between 6 and 12 years old:

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

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 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 Zirtek Allergy Relief is too weak or too strong, please consult your doctor.

Duration of treatment

Duration of continuous treatment should not be longer than 30 days, after this period, you should also consult with your doctor.

If you take more Zirtek Allergy Relief than you should

If you think you have taken an overdose of Zirtek Allergy Relief 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 Zirtek Allergy Relief

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

If you stop taking Zirtek Allergy Relief

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

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)
- Diarrhea, 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 1000 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 10000 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)

- Arthralgia (joint pain), myalgia (muscular pain)
- Acute generalized exanthematous pustulosis (rash with blisters containing pus)
- 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
- 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 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 Zirtek Allergy Relief

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. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

6. Contents of the pack and other information

What Zirtek Allergy Relief contains

– The active substance is cetirizine dihydrochloride. One film-coated tablet contains 10 mg cetirizine dihydrochloride.

– The other ingredients are microcrystalline cellulose, lactose-monohydrate, colloidal anhydrous silica, magnesium stearate, Opadry Y-1-7000 (hydroxypropylmethylcellulose (E 464), titanium dioxide (E 171), macrogol 400).

What Zirtek Allergy Relief looks like and contents of the pack

White, oblong, film-coated tablet, with breakline and Y-Y logo.

Pack with 1, 4, 5, 7, 10, 14, 15, 20, 21, 30 tablets.

Not all pack sizes may be marketed

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation holder:

UCB Pharma Ireland Ltd
United Drug House
Magna Drive
Citywest Road
Dublin 24

Manufacturer:

Aesica Pharmaceutical S.r.l
Via Praglia, 15
I-10044 Pianezza (Torino)
Italy

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