

## Package leaflet: Information for the user

# Zirtek® allergy 10mg 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. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

The name of your medicine is Zirtek allergy 10mg film-coated tablets but will be referred to as Zirtek throughout this leaflet.

### What is in this leaflet:

1. What Zirtek is and what it is used for
2. What you need to know before you take Zirtek
3. How to take Zirtek
4. Possible side effects
5. How to store Zirtek
6. Content of the pack and further information

### 1. What Zirtek is and what it is used for

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

In adults and children aged 6 years and above, Zirtek 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

#### Do not take Zirtek

- if you have a severe kidney disease 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.

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 with alcohol.

If you are scheduled for allergy testing, ask your doctor if you should stop taking Zirtek 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 Zirtek

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

#### Zirtek with food and drink

Food does not affect absorption of Zirtek.

#### 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 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 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 at the recommended dose.

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

**Zirtek 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

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 10mg once daily as 1 tablet.

#### Use in children between 6 and 12 years old:

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

#### Patients with renal impairment

Patients with moderate renal impairment are recommended to take 5mg 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 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 Zirtek than you should

If you think you have taken an overdose of Zirtek 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

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

#### If you stop taking Zirtek

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

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
- Paraesthesia (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
- 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 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](http://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 Zirtek

Keep out of the sight and reach of children.

This product does not require any special storage conditions.

Do not take the tablets after the expiry date which is stated on the carton and blister labels after 'Exp'. The expiry date refers to the last day of that month.

If the tablet becomes discoloured or shows any signs of deterioration, seek the advice of your pharmacist.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

#### 6. Contents of the pack and further information

##### What Zirtek contains

The active ingredient in the Zirtek is cetirizine dihydrochloride. Each film-coated tablet contains 10mg cetirizine dihydrochloride.

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

##### What Zirtek looks like and contents of the pack

Zirtek is white, oblong, film-coated tablet, with breakline and Y-Y logo on one side and plain on the reverse.

Zirtek is supplied in blister packs containing 30 tablets.

**Manufactured by:** UCB Pharma Limited, 208 Bath Road, Slough, Berkshire, SL1 3WE, UK.

##### OR

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

**Procured from within the EU and repackaged by the Product Licence holder:** B&S Healthcare, Unit 4, Bradfield Road, Ruislip, Middlesex, HA4 0NU, UK.

**Zirtek® allergy 10mg film-coated tablets; PL 18799/2450**

Leaflet date: 25.04.2023

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Zirtek is the registered trademark of UCB Biopharma SPRL.

## Blind or partially sighted?

## Is this leaflet hard to see or read?

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- You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

The name of your medicine is Cetirizine dihydrochloride 10mg film-coated tablets but will be referred to as Cetirizine throughout this leaflet.

#### What is in this leaflet:

1. What Cetirizine is and what it is used for
2. What you need to know before you take Cetirizine
3. How to take Cetirizine
4. Possible side effects
5. How to store Cetirizine
6. Content of the pack and further information

#### 1. What Cetirizine is and what it is used for

Cetirizine dihydrochloride is the active ingredient of Cetirizine. Cetirizine is an antiallergic medication.

In adults and children aged 6 years and above, Cetirizine 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 Cetirizine

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