

## **Package leaflet: Information for the user**

### **Zirtek 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.**

- 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- 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.

#### **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. Contents of the pack and other 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 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 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 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 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**

Always take this medicine exactly 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.

**Use in 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 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 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 and is determined by your doctor.

**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 urticaria (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)
- 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 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:

HPRA Pharmacovigilance

Website: [www.hpra.ie](http://www.hpra.ie)

By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Zirtek**

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 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 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, 40, 45, 50, 60, 90, 100 or 100 (10x10) 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

### **This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:**

Austria: Zyrtec 10 mg Filmtabletten  
Belgium: Zyrtec  
Bulgaria: Zyrtec  
Cyprus: Zyrtec  
Czech Republic: Zyrtec  
Denmark: Zyrtec  
Estonia: Zyrtec  
Finland: Zyrtec  
France: Zyrtec  
Germany: Zyrtec  
Greece: Ziptek  
Hungary: Zyrtec 10 mg filmtabletta  
Ireland: Zirtek tablets  
Italy: Zirtec 10 mg compresse rivestite con film  
Latvia: Zyrtec  
Lithuania: Zyrtec  
Luxembourg: Zyrtec  
Malta: Zyrtec  
Netherlands: Zyrtec  
Norway: Zyrtec  
Poland: Zyrtec

Portugal: Zyrtec

Slovak Republic: Zyrtec

Slovenia: Zyrtec 10 mg filmsko obložene tablete

Spain: Zyrtec 10 mg comprimidos recubiertos con película

United Kingdom (Northern Ireland): Zirtek allergy tablets

**This leaflet was last revised in After approval.**