

## Package leaflet: Information for the user

### Zirtek® 1 mg/ml oral solution

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 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:

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 2 years and above, Zirtek 1 mg/ml oral solution 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 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 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.

#### 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 oral solution contains sorbitol (E 420), methylparahydroxybenzoate (E 218), propylparahydroxybenzoate (E 216), propylene glycol (E 1520) and sodium.

This medicine contains 1575 mg sorbitol (E 420) in each 5 ml which is equivalent to 315 mg/ml. Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine. Sorbitol may cause gastrointestinal discomfort and mild laxative effect.

This medicine contains methylparahydroxybenzoate (E 218) and propylparahydroxybenzoate (E 216) which may cause allergic reactions (possibly delayed).

This medicine contains 250 mg propylene glycol (E 1520) in each 5 ml which is equivalent to 50 mg/ml.

This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

#### 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 solution can be swallowed as such.

##### Adults and adolescents above 12 years old:

The recommended dose is 10 mg once daily as 10 ml oral solution (2 full measuring spoons)

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

The recommended dose is 5 mg twice daily as 5 ml (one full measuring spoon) twice daily.

##### Use in children between 2 and 6 years old

The recommended dose is 2.5 mg twice daily as 2.5 ml oral solution (a half-measuring spoon) twice daily

##### 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. 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 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 bottle and the carton after 'EXP'. The expiry date refers to the last day of that month.

Do not use after 3 months of first opening the bottle.

This medicine does not require any special storage conditions.

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 Zirtek contains**

- The active substance is cetirizine dihydrochloride. 10 ml (equals to 2 measuring spoons) contains 10 mg of cetirizine dihydrochloride.
- The other ingredients are sorbitol (E 420), glycerol (E 422), propylene glycol (E 1520), sodium saccharin, methyl parahydroxybenzoate (E 218), propyl parahydroxybenzoate (E 216), banana flavour 54.330/A (Firmenich), sodium acetate, glacial acetic acid and purified water.
- 10 ml Zirtek oral solution (=2 measuring spoons) contain: 3.15 g glucose equivalents (sorbitol).

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

Clear and colorless liquid with slightly sweet taste and a banana flavour.

Amber glass bottle containing volumes of 200 ml. A 5 ml measuring spoon with a line at 2.5 ml is provided with the bottle.

##### **Manufacturer**

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

##### **Product procured from within the EU, repackaged and distributed by the parallel product authorisation holder:**

PCO Manufacturing Ltd., Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath, Ireland.

##### **Parallel Product Authorisation Number:** PPA0465/502/001

Zirtek is a registered trademark of UCB Biopharma SPRL

##### **This medicinal product is authorised in the Member States of the European Economic Area under the following names:**

Austria: Zyrtec 1 mg/ml orale Lösung  
Belgium: Zyrtec  
Cyprus: Zyrtec  
Denmark: Zyrtec  
Estonia: Zyrtec  
Finland: Zyrtec  
France: Zyrtec  
Ireland: Zirtek oral solution 1mg/ml  
Italy: Zirtec 1 mg/ml soluzione orale  
Latvia: Zyrtec  
Lithuania: Zyrtec  
Luxembourg: Zyrtec  
Malta: Zyrtec  
Netherlands: Zyrtec  
Norway: Zyrtec  
Poland: Zyrtec  
Portugal: Zyrtec  
Slovenia: Zyrtec 1 mg/ml peroralna raztopina  
Spain: Zyrtec 1 mg/ml solución oral

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