Package leaflet: Information for the user CIA71784G

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 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
- 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

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

In adults and children aged 2 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 (severe renal failure with creatinine clearance below 10 ml/min);
- if you are allergic to cetirizine dihydrochloride, to any of the other ingredients (listed in section 6), to hydroxyzine or to any piperazine derivatives (closely related active ingredients of other medicines).

Warnings and precautions
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. 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; 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.

Zirtek oral solution contains methylparahydroxybenzoate (E 218), propylparahydroxybenzoate (E 216) that may cause allergic reactions (possibly delayed).

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:
10 mg once daily as 10 ml oral solution (2 full measuring spoons)

Children between 6 and 12 years old:
5 mg twice daily as 5 ml (one full measuring spoon) twice daily.

Children between 2 and 6 years old
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 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 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, ailing, dilating of pupil, itching, restlessness, sedation, somnolence, stupor, abnormal rapid heart rate, tremors and urinary retention have been reported.

If you forget to take Zirtek
Do not take a double dose to make up for a forgotten dose.
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, rhinitis (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

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, dyskinesia (involuntary movements), dystonia (abnormal prolonged muscular contractions), tremor, dysgeusia (altered taste)
- Blurred vision, accommodation disorder (difficulty focusing), oculogyration (eyes having uncontrolled circular movements)
- Angioedema (serious allergic reaction which causes swelling of the face or throat), fixed drug eruption
- 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)
- Amnesia, memory impairment
- Vertigo (sensation of rotation or movement)
- Urinary retention (inability to completely empty the urinary bladder)

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

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 bottle. 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.

6. Contents of the pack and other information
What Zirtek contains
- The active substance o is cetirizine. 10 ml (equals to 2 measuring spoons) contain 10 mg of cetirizine dihydrochloride.
- The other ingredients are sorbitol (E 420), glycerol, propylene glycol, saccharin sodium, methylparahydroxybenzoate (E 218), propylparahydroxybenzoate (E 216), banana flavor 54.330/A (Firmenich), sodium acetate, glacial acetic acid, 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 flavor.
Pack with a bottle containing volumes of 60, 75, 100, 150, or 200 ml solution.
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:
UCB Pharma Limited, 208 Bath Road, Slough, Berkshire, SL1 3WE, United Kingdom

This medicinal product is authorised in the Member States of the EEA under the following names:
Austria: Zirtek 1 mg/ml – orale Lösung
Belgium: Zirtek
Cyprus: Zirtek
Denmark: Zirtek
Estonia: Zirtek
Finland: Zirtek
France: Zirtek
Ireland: Zirtek oral solution 1mg/ml
Italy: Zirtec 1mg/ml soluzione orale
Latvia: Zirtek
Lithuania: Zirtek
Luxembourg: Zirtek
Malta: Zirtek
Netherlands: Zirtek
Norway: Zirtek
Poland: Zirtek
Portugal: Zirtek
Slovenia: Zirtek1 mg/ml peroralna raztopina
Spain: Zirtek solución oral
Sweden: Zyrlex
United Kingdom: Zirtek allergy solution

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