Package leaflet: Information for the user

Zirtek 10 mg/ml oral drops, solution

Cetirizine dihydrochloride

Read all of this leaflet carefully before you start using 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

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

In adults and paediatric patients aged 2 years and above, Zirtek 10 mg/ml oral drops, 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, to any of the other ingredients (listed in section 6), to hydroxyzine or to any 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 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 women 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 drops solution contains methylparahydroxybenzoate (E 218), propylparahydroxybenzoate (E 216), propylene glycol (E 1520) and sodium.

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

This medicine contains 350 mg propylene glycol (E 1520) in each 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 your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The drops should be poured in a spoon or diluted in water, and taken orally. If dilution is used, it should be considered, especially for administration to children, that the volume of water to which the

drops are added, needs to be adapted according to the quantity of water the patient is able to swallow. The diluted solution should be taken immediately.

When counting the drops, the bottle should be held vertically (top down). In case of lack of flow of drops, if the right amount of drops has not been delivered, turn the bottle over in upright position, then hold it top down again and continue counting the drops.

Adults and adolescents above 12 years old:
The recommended dose is 10 mg once daily as 20 drops

Use in children between 6 and 12 years old:
The recommended dose is 5 mg twice daily as 10 drops twice daily.

Use in children between 2 and 6 years old
The recommended dose is 2.5 mg twice daily administered as 5 drops twice daily

Patients with renal impairment
Patients with moderate renal impairment are recommended to take 5 mg as 10 drops 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
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 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 is cetirizine dihydrochloride. One ml (equals to 20 drops) contains 10 mg of cetirizine dihydrochloride. One drop contains 0.5 mg of cetirizine dihydrochloride.
- The other ingredients are glycerol (E 422), propylene glycol (E 1520), saccharin sodium, methylparahydroxybenzoate (E 218), propylparahydroxybenzoate (E 216), sodium acetate, glacial acetic acid, purified water.

What Zirtek looks like and contents of the pack
Zirtek is supplied as a clear and colorless liquid.

Pack with a bottle containing volumes of 10, 15, or 20 ml.

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 under the following names:

Austria: Zyrtec 10 mg/ml Tropfen
Belgium: Zyrtec
Bulgaria: Zyrtec

Czech Republic: Zyrtec
Denmark: Zyrtec
Estonia: Zyrtec
Finland: Zyrtec
France: Zyrtec
Greece: Ziptek
Hungary: Zyrtec 10 mg/ml belsőleges oldatos cseppek
Ireland: Zirtek oral drops 10mg/ml
Italy: Zirtec 10 mg/ml gocce orali, soluzione
Latvia: Zyrtec
Lithuania: Zyrtec
Luxembourg: Zyrtec
Norway: Zyrtec
Poland: Zyrtec
Romania: Zyrtec
Slovak Republic: Zyrtec
Spain: Zyrtec 10 mg/ml gotas orales en solución

This leaflet was last revised in After Approval.