

PATIENT INFORMATION LEAFLET

Read all of this leaflet carefully because it contains important information for you.

- This medicine is available without prescription. However, you still need to take it carefully to get the best results from it.
- Keep this leaflet. You may need to read it again
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve after 3 days.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.



In this leaflet:

1. What Zirtek is and what it is used for
2. Before you take Zirtek
3. How to take Zirtek
4. Possible side effects
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6. Further information.

1. WHAT ZIRTEK IS AND WHAT IT IS USED FOR

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

In adults and children aged 2 years and above, Zirtek is used

- for the relief of nasal and ocular symptoms of seasonal and perennial allergic rhinitis (hayfever and year-round allergies affecting the nose and eyes).
- for the relief of chronic nettle rash (chronic idiopathic urticaria).

2. 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 known to be hypersensitive to the active substance of Zirtek, to any of its excipients (other constituents), to hydroxyzine or to any piperazine derivatives (closely related active substances of other medicines).

You should not take Zirtek 1 mg/ml oral solution:

- if you have rare hereditary problems of fructose intolerance.

Take special care with 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 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 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.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Taking Zirtek with food and drink

Food does not affect absorption of Zirtek.

Pregnancy

Ask your doctor or pharmacist for advice before taking any medicine. As with other drugs, use of 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.

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.

Important information about some of the ingredients of Zirtek

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 methyl (4-hydroxybenzoate) E 218, propyl (4-hydroxybenzoate) E 216 that may cause allergic reactions (possibly delayed).

3. HOW AND WHEN SHOULD YOU TAKE ZIRTEK?

These guidelines apply unless your doctor has given you different instructions on how to use Zirtek. Please follow these instructions, otherwise Zirtek may not be fully effective. The solution may 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 moderate to severe kidney impairment

Patients with moderate kidney impairment are recommended to take 5 mg or 5 ml once daily.

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 Allergy Solution 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 a dose

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

If you stop taking Zirtek

If you have any other questions about taking this medicine, ask your pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines Zirtek Allergy Solution can cause side effects, although not everybody gets them.

The following side effect is 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 cause swelling of the face and throat).

These reactions may start soon after you first take the medicine, or it might start later.

The frequency of possible side effects listed below is defined using the following convention:

Common (affects 1 to 10 patients in 100)

Uncommon (affects 1 to 10 patients in 1000)

Rare (affects 1 to 10 patients in 10,000)

Very rare (affects less than 1 patient in 10,000)

Not known (frequency cannot be estimated from available data)

The following side effects have also been reported.

Common side effects (affects less than 1 in 10 people)

- Tiredness, feeling sleepy
- Headache
- Nausea
- Sore throat
- Dry mouth
- Diarrhoea
- Dizziness
- Cold-like symptoms of the nose (children only).

Uncommon side effects (affects less than 1 in 100 people)

- Itching and rash
- Asthenia (extreme fatigue) or generally unwell
- Feeling agitated
- Tingling in the hands and feet
- Pain in the abdomen.

Rare side effects (affects less than 1 in 1000 people)

- Tachycardia (heart beating too fast)
- Oedema (generalised swelling due to water retention)
- Abnormal liver function test results (your doctor will know what to do)

- Convulsions
- Weight increased
- Aggression, confusion, depression, hallucination (hearing or seeing things), sleeplessness
- Urticaria (hives).

Very rare side effects (affects less than 1 in 10,000 people)

- Blurred vision, difficulty focussing
- Oculogyration (eyes having uncontrolled circular movements)
- Fainting
- Low level of blood platelets causing unusual bleeding or bruising
- A recurring rash.
- Bad taste in the mouth
- Abnormal elimination of urine (bedwetting, pain and/or difficulty passing water)
- Tremor, tics (habit spasm)
- Involuntary movements and/or jerking of the limbs
- Muscle spasms in the neck and shoulders
- Swelling of the skin particularly around the face or throat.

Not known frequency of side effects

- Memory loss and forgetfulness

If you develop one of the side effects described above, please inform your doctor or pharmacist. At the first signs of a hypersensitivity reaction, stop taking Zirtek. Your doctor will then assess the severity and decide on any further measures that may be necessary.

If you think you have any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

5. HOW TO STORE ZIRTEK ALLERGY SOLUTION

Keep out of the reach and sight of children. Do not use Zirtek after the expiry date which is stated on the box and bottle.

Do not use after 3 months of first opening the bottle. This medicine does not require any special storage conditions.

6. FURTHER INFORMATION

What Zirtek Allergy Solution contains

The active substance of Zirtek 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, methyl (4-hydroxybenzoate) / propyl (4-hydroxybenzoate) = E 218 / E 216, flavouring agent, sodium acetate,

acetic acid, purified water.

10 ml Zirtek oral solution (=2 measuring spoons) contain: 3.15 g glucose equivalents (sorbitol).

What Zirtek Allergy Solution looks like and contents of pack

Clear colourless liquid with slightly sweet taste and a banana flavour solution. Pack with a bottle containing 60 ml, 75 ml, 100 ml, 150 ml or 200 ml solution. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

UCB Pharma Ltd, 208 Bath Road, Slough, Berkshire, SL1 3WE, United Kingdom