Zirtek® Allergy 10mg Tablets

1519
21.08.23[17]

(cetirizine dihydrochloride)

PATIENT INFORMATION LEAFLET

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 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.

Your medicine will be referred to as Zirtek throughout the following leaflet.

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 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 Zirtek 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 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 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 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.

Use in children between 6 and 12 years old:
The recommended dose is 5 mg twice daily as a half tablet 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 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 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)
- Diarrhoea, nausea, dry mouth
- Fatigue

Uncommon side effects (may affect up to 1 in 100 patients)
- Agitation
- Paraesthesia (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 the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**. By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE ZIRTEK
Keep out of the sight and reach of children.

Do not use Zirtek after the expiry date which is stated on the box and blister.

If your tablets become discoloured or show any other signs of deterioration, consult your pharmacist who will tell you what to do.

Medicines should not be disposed of via wastewater or household waste.

Ask you pharmacist how to dispose of medicine no longer required.

These measures will help to protect the environment

6. CONTENTS OF THE PACK AND OTHER INFORMATION
What Zirtek contains
Each film-coated tablet contains 10 mg cetirizine dihydrochloride as the active ingredient.

The other ingredients are microcrystalline cellulose, lactose monohydrate, colloidal anhydrous silica, magnesium stearate, Opadry Y-1-7000 (hypromellose (E 464), titanium dioxide (E 171), macrogol 400).

What Zirtek looks like and contents of the pack
The tablets are white oblong film-coated tablets with the markings 'Y/Y' and a scoreline on one side. Your medicine is supplied in blister packs of 20 and 30 tablets.

Manufacturer and Product Licence holder
Manufactured by Aesica Pharmaceuticals S.r.l., Via Praglia 15, I-10044 Pianezza (TO), Italy and is procured from within the EU by Product Licence holder:

Star Pharmaceuticals Ltd., 5 Sandridge Close, Harrow, Middlesex, HA1 1XD.
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