



Zirtek[®] Allergy Relief 10 mg

Film Coated Tablets

Cetirizine dihydrochloride

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.
- 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 a few days.
- In this leaflet Zirtek Allergy Relief 10 mg Film Coated Tablets will be called Zirtek Allergy Relief.

In this leaflet:

1. What Zirtek Allergy Relief is for
2. Before you take Zirtek Allergy Relief
3. How to take Zirtek Allergy Relief
4. Possible side effects
5. How to store Zirtek Allergy Relief
6. Further information.

1. WHAT ZIRTEK ALLERGY RELIEF IS FOR

Cetirizine dihydrochloride, the active ingredient of the tablets is an antihistamine. It blocks the effects of a substance called histamine which occurs naturally in the body. Histamine is involved in allergic reactions.

Zirtek Allergy Relief is used to treat people who have hay fever (seasonal allergic rhinitis), year round allergies such as dust or pet allergies (perennial allergic rhinitis) and urticaria (swelling, redness and itchiness of the skin).

Antihistamines like Zirtek Allergy Relief relieve the unpleasant symptoms and discomfort associated with these conditions, such as sneezing, irritated, runny and blocked up nose, itchy, red and watering eyes and skin rashes.

2. BEFORE YOU TAKE ZIRTEK ALLERGY RELIEF

Do not take Zirtek Allergy Relief if:

- You are allergic to cetirizine dihydrochloride
- You are allergic to any of the other ingredients of Zirtek Allergy Relief (see section 6)

- You are breast-feeding
- You have severe kidney failure (creatinine clearance less than 10 ml/min)
- You have problems of urinary retention
- You have hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose- galactose malabsorption

If any of the above applies to you talk to your pharmacist.

Check with your pharmacist before taking Zirtek Allergy Relief if:

- You have problems with your kidneys
- You have predisposition factors of urinary retention (eg: spinalcord lesion, prostatic hyperplasia) as cetirizine increases the risk of urinary retention
- You suffer from epilepsy or are at risk of convulsions.
- You want to use for children less than 6 years of age

Taking Zirtek Allergy Relief with food and drink

Avoid alcoholic drink while you are taking this medicine.

Pregnancy

If you are pregnant or trying to become pregnant ask your pharmacist for advice before taking Zirtek Allergy Relief.

Allergy Testing

If you are due to have an allergy test, ask your doctor if you should stop taking Zirtek Allergy Relief for several days before testing. This medicine may affect your allergy test results.

Driving and using machines

Some people have reported that they feel drowsy or dizzy while they are taking Zirtek Allergy Relief. If you are affected do not drive or use machines.

This medicine contains lactose

This medicine contains lactose. If you have been told that you have an intolerance to some sugars, contact your doctor before taking these tablets.

3. HOW TO TAKE ZIRTEK ALLERGY RELIEF

Remember. Take the tablet with a glass of water. Do not take more than one tablet each day. If you do not feel better within a few days, consult your doctor.

Children aged 6 to 12:

Take half a tablet twice a day.

Adults and children aged 12 years and over:

Take one tablet daily. If the tablets make you feel drowsy or dizzy, taking half a tablet twice a day may be better than taking one tablet once a day. Zirtek Allergy tablets are not suitable for children under 6.

If you take more Zirtek Allergy Relief than you should

If you accidentally take too many tablets go and see your doctor straightaway.

If you forget to take a tablet

If you forget to take a tablet, you should take one as soon as you remember, but wait at least 24 hours before taking your next tablet.

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

4. POSSIBLE SIDE EFFECTS

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

The following side effect is very rare, but you must stop taking the tablets and speak to your doctor straight away if you notice these symptoms:

- A severe allergic reaction including rash, itchiness and fever, swollen throat, face, eyelids or lips. This reaction may start soon after you first take the medicine, or it might start later.

The following side effects have also been reported.

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

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

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

- Itching and rash
- Diarrhoea
- Feeling weak or generally unwell
- Tingling in the hands and feet
- Feeling agitated.

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

- Fast heart beat
- Oedema (generalised swelling due to water retention)
- Abnormal liver function test results (your doctor will know what to do)
- Convulsions
- Increased weight
- 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
- Rotation of the eyes
- Unusual bleeding or bruising
- Bad taste in the mouth
- Tremor, tics
- Involuntary movements and/or jerking of the limbs

- Muscle spasms in the neck and shoulders
- Swelling of the skin particularly around the face
- Fainting
- A recurring rash
- Bed wetting, pain and/or difficulty passing water

Not known side effects

- Increased appetite
- Vertigo
- Urinary retention

Some cases of memory loss and/or impairment have also been reported.

In very rare cases people have thought about committing suicide and if you feel this way then stop taking the tablets and see your doctor.

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE ZIRTEK ALLERGY RELIEF

Keep out of the reach and sight of children. Do not take the tablets after the expiry date on the carton. The expiry date refers to the last day of that month. Medicines should not be disposed of via wastewater or household waste. Return any medicine you no longer need to your pharmacist.

6. FURTHER INFORMATION

What Zirtek Allergy Relief contains

The active substance is cetirizine dihydrochloride (10 mg). The other ingredients are microcrystalline cellulose, lactose monohydrate, colloidal anhydrous silica and magnesium stearate Opadry Y-1-7000, Hydroxypropylmethylcellulose (E 464), Titanium dioxide (E 171), Macrogol 400. The film coat contains hydroxypropylmethylcellulose, titanium dioxide (E171) and polyethylene glycol.

What Zirtek Allergy Relief looks like

The tablets are small white oblong film-coated tablets, each scored and bearing the code Y/Y. Your medicine is supplied in a blister packs of 7, 30 tablets. Not all pack sizes are marketed.

Marketing Authorisation Holder and Manufacturer

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