

Cetirizine hydrochloride tablets 10 mg

Cetirizine hydrochloride oral solution 1 mg/mL

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 ZYRTEC 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.
- Contact a doctor if your symptoms worsen or do not improve after 3 days.
- If any of the side effects become serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.
- Always read the label to make sure the product is appropriate for your child's age.

1. WHAT ZYRTEC IS AND WHAT IT IS USED FOR

ZYRTEC contains the active ingredient cetirizine hydrochloride. Cetirizine belongs to a group of anti-allergy medicines called antihistamines. ZYRTEC is used to treat symptoms associated with allergic conditions, such as:

- hayfever (seasonal and perennial allergic rhinitis),
- allergic skin conditions that can cause itching or rashes.

2. BEFORE YOU TAKE ZYRTEC

Do not take ZYRTEC:

- if you are **allergic** (hypersensitive) to cetirizine, hydroxyzine, any piperazine derivatives (closely related active ingredients of other medicines), or to any other ingredients of ZYRTEC
- if you have **severe kidney disease** (severe impairment of kidney function with creatinine clearance below 10 ml/min)
- if you use other anti-allergy medicines.

If you think any of these apply to you, **do not take ZYRTEC** until you have checked with your doctor.

Take special care with ZYRTEC

Talk to your doctor or pharmacist before using ZYRTEC

- if you have **kidney problems**
- if you have **difficulty passing urine** or you have conditions that make you more likely to be unable to empty your bladder, such as **spinal cord injury** or **enlarged prostate**
- if you have **epilepsy** or you are at risk of convulsions (fits)
- if you are pregnant or breastfeeding.

Check with your doctor if you think any of these may apply to you.

ZYRTEC oral solution is not recommended for infants and children under 2 years.

ZYRTEC film-coated tablets are not recommended for children under 6 years.

While you are taking ZYRTEC

- Avoid alcohol while you are taking ZYRTEC.
- ZYRTEC may affect your **allergy test** results. If you are scheduled for allergy testing, ask your doctor if you should stop taking ZYRTEC before testing.
- Contact your doctor if you have high temperature (fever), shivering or chills, as you may require another type of treatment.

Conditions you need to look out for

ZYRTEC can make some existing conditions worse or cause **severe allergic reactions or urinary retention**. Some people may have suicidal thoughts when taking ZYRTEC. Speak to your doctor or seek medical

attention if you experience any symptoms while taking ZYRTEC that concern you.

Other medicines and ZYRTEC

Tell your doctor or pharmacist if you are taking any other medicines, if you have taken any recently, or if you start taking new ones. This includes medicines bought without a prescription. Some medicines may affect how ZYRTEC works, or make it more likely that you will have side effects. ZYRTEC can also affect how some other medicines work. These include:

- **other antihistamines** such as hydroxyzine, clemastine, **medicines used to treat anxiety** such as diazepam or **sleeping pills** such as zolpidem (concurrent administration of ZYRTEC with other agents acting on the brain may cause additional drowsiness and impairment of performance).

Tell your doctor or pharmacist if you are taking any of these.

Food and drink with ZYRTEC

Avoid alcohol when you are taking ZYRTEC. In sensitive patients, the concurrent administration of ZYRTEC and alcohol may cause additional drowsiness and impairment of performance.

Pregnancy and breastfeeding

ZYRTEC is not recommended for use during pregnancy.

- **Tell your doctor if you are pregnant** or planning to become pregnant.
- **If you do become pregnant during treatment** with ZYRTEC tell your doctor.

The ingredients in ZYRTEC can pass into breast milk. **If you are breastfeeding, check with your doctor** before you take ZYRTEC.

Driving and using machines

ZYRTEC at the recommended dose is unlikely

to affect your ability to drive or use machines. However, some patients being treated with ZYRTEC **may feel drowsy, tired or weak.**

Do not drive or use machines unless you are sure you are not affected.

3. HOW TO TAKE ZYRTEC

How much to take

Always take ZYRTEC exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

Do not take more than the recommended dose.

Do not take ZYRTEC for longer than **7 days**, without advice of your doctor or pharmacist.

Contact your doctor if your symptoms worsen or do not improve after 3 days.

Adults and adolescents above 12 years old

ZYRTEC 10 mg film-coated tablets

The usual dose of ZYRTEC is one 10 mg tablet, once a day.

Some people may only require half the daily dose, i.e. 5 mg, e.g. people with kidney problems or those who may feel drowsy if they take the recommended dose of 10 mg.

Others may need to take 20 mg, e.g. larger people or those who find that 10 mg is not enough.

The maximum recommended daily dose is 20 mg, do not exceed this dose, unless told to do so by your doctor.

ZYRTEC 1 mg/mL oral solution

The usual dose of ZYRTEC oral solution is 10 mL, once a day.

Children between 6 and 12 years old

ZYRTEC 10 mg film-coated tablet

In children over 6 years of age, the daily dose of 10 mg is given as a single or divided dose.

ZYRTEC 1 mg/mL oral solution

The usual dose of ZYRTEC oral solution is 5 mL, twice a day.

Children between 2 and 6 years old

ZYRTEC 10 mg film-coated tablets

ZYRTEC film-coated tablets **are not recommended for children under 6 years**, as this formulation does not allow for appropriate dose adaptation.

ZYRTEC 1 mg/mL oral solution

The usual dose of ZYRTEC is 2.5 mL twice a day or 5 mL once daily.

Tablets: 1 tablet = 10 mg

Solution: 10 mL solution = 2 spoonfuls = 10 mg
5 mL solution = 1 spoonful = 5 mg

2.5 mL solution = 1/2 spoonful = 2.5 mg

Patients with kidney and liver disease

Your doctor will decide on the correct dose of ZYRTEC depending on the illness and the results of blood tests carried out before treatment. Patients who have end stage impairment of kidney function must not take ZYRTEC.

If your child suffers from kidney disease, please contact your doctor or pharmacist who may adjust the dose accordingly.

How to take ZYRTEC

ZYRTEC 10 mg film-coated tablets

Swallow the tablet whole, with a glass of water. You can divide the tablet into two equal doses.

ZYRTEC 1 mg/mL oral solution

The solution can be swallowed as such.

If you forget to take ZYRTEC

Do not take an extra dose to make up for a missed dose. Just take your next dose at the usual time.

If you are not sure what to do, ask your doctor or pharmacist.

If you take too much ZYRTEC

If you take too much ZYRTEC **contact your doctor or pharmacist or the Poisons Information Centre**

(telephone: New Zealand 0800 764 766) for advice. If possible, show them the ZYRTEC pack.

If you take too much ZYRTEC you may be **more likely to have side effects such as:** confusion, diarrhoea, dizziness, tiredness, headache, malaise, dilating of pupil, itching, restlessness, sedation, somnolence (feeling drowsy), stupor, abnormal rapid heart rate, tremor, urinary retention.

If you stop taking ZYRTEC

Rarely, pruritus (intense itching) and/or urticaria may occur if you stop taking ZYRTEC.

4. POSSIBLE SIDE EFFECTS

Like all medicines, ZYRTEC can cause side effects, but not everybody gets them.

Conditions you need to look out for: Severe allergic reactions.

Signs include:

- raised and itchy rash (hives)
- swelling, sometimes of the face or mouth (angioedema), causing difficulty in swallowing or breathing
- collapse or loss of consciousness.

Urinary retention. Signs include:

- pain when passing urine or inability to pass urine.

Suicidal thoughts. Some people have suicidal thoughts when taking ZYRTEC.

Contact a doctor immediately if you get these symptoms. **Stop taking ZYRTEC.**

Common side effects

These may affect up to **1 in 10** people:

- Somnolence (sleepiness)
- Dizziness, headache
- Pharyngitis, rhinitis (in children)
- Diarrhoea (in children), nausea, dry mouth
- Fatigue.

Uncommon side effects

These may affect up to **1 in 100** people:

- Agitation
- Paraesthesia (tingling or numbness of the hands or feet)
- Diarrhoea
- Stomach pain
- Pruritus (itching), rash
- Asthenia (unusual weakness), malaise.

Rare side effects

These may affect up to **1 in 1,000** people:

- Hypersensitivity
- Aggression, confusion, depression, hallucination, insomnia (sleeplessness)
- Convulsions
- Tachycardia (fast heart beat)
- Liver function abnormal (reflected in the blood tests)
- Urticaria
- Oedema (swelling)
- Increased weight.

Very rare side effects

These may affect up to **1 in 10,000** people:

- Thrombocytopenia (low blood platelets count)
- Anaphylactic shock (see 'Severe allergic reactions' earlier in section 4)
- Tics (uncontrolled body movement)
- Dysgeusia (taste disturbance or loss of taste), dyskinesia (uncontrollable movements), dystonia (uncontrolled muscle spasm), syncope (fainting), tremor
- Accommodation disorder (difficulty focusing), blurred vision, oculogyration (eyes having uncontrolled circular movements)
- Angioedema (serious allergic reaction which causes swelling of the face or throat), fixed drug eruption
- Dysuria (pain when passing urine) (see 'Urinary retention' earlier in section 4), enuresis (bed wetting).

Other side effects

Have occurred but their exact frequency is unknown:

- Increased appetite
- Suicidal ideation (see 'Suicidal thoughts' earlier in section 4), nightmare
- Amnesia, memory impairment
- Vertigo (spinning sensation)
- Inflammation of the liver
- Urinary retention (difficulty passing urine)
- (see 'Urinary retention' earlier in section 4)
- Joint pain
- Rash with blisters containing pus
- Intense itching (pruritus) upon discontinuation.

Tell your doctor or pharmacist if any of the side effects listed becomes severe or troublesome, or if you notice side effects not listed in this leaflet.

5. HOW TO STORE

Keep all medicines out of the reach of children. This medicine will keep for up to 36 months when stored at or below 30°C.

Make sure you do not use your Zyrtec after the expiry date as it may become less effective. Return any expired Zyrtec to your pharmacy for proper disposal.

Disposal

Do not dispose of the medicine in wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. This will help to protect the environment.

6. FURTHER INFORMATION

What ZYRTEC contains

The active substance is cetirizine hydrochloride

Each tablet contains 10 mg of cetirizine hydrochloride.

Each 10 mL of oral solution contains 10 mg of cetirizine hydrochloride.

List of Excipients

Zyrtec tablets: Microcrystalline cellulose, Lactose monohydrate, Colloidal anhydrous silica, Magnesium stearate, Hypromellose (E464), Macrogol 4000, Titanium dioxide (E171), Polydextrose.

Zyrtec oral solution Glycerol, Propylene glycol, Liquid Sorbitol (non-crystallising) (E420), Methyl Parahydroxybenzoate (E218), Propyl Parahydroxybenzoate (E216), Sodium acetate, Acetic acid, Saccharin sodium, Banana flavour, Purified water.

What ZYRTEC looks like and contents of the pack

Film-coated tablets: White to off-white capsule-shaped tablet, debossed on one face embossed with “Y” on each side of the break line and blank on the other face. Packs of 10 and 30 film coated tablets.


Oral solution: Clear, colourless liquid with a slight sweet taste and banana flavour. 75 mL amber glass bottle with child-resistant polypropylene screw cap with a tamper evident seal.

Marketed by: GlaxoSmithKline Consumer Healthcare
Auckland, New Zealand

Do not throw this leaflet away. You may want to read it again.

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 **NZ: 0800 540 144**