

ZYRTEC FILM-COATED TABLET/ORAL SOLUTION/ORAL DROPS

Cetirizine dihydrochloride (10mg, 1mg/ml, 10mg/ml)

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What ZYRTEC is used for

Zyrtec is used to treat adults and children aged 2 and over who have hay fever (seasonal allergic rhinitis), year round allergies such as dust or pet allergies (perennial allergic rhinitis) and itchy rashes.

How ZYRTEC works

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

Before you use ZYRTEC

- When you must not use it

Do not take Zyrtec if:

- You are allergic (hypersensitive) to cetirizine dihydrochloride
- You are allergic (hypersensitive) to any of the other ingredients of Zyrtec
- You are breast-feeding
- You have severe kidney failure (Estimated Glomerular Filtration Rate) below 15 ml/min.
- You have problems of urinary retention.
- For Zyrtec oral solution: You have fructose intolerance.

- For Zyrtec tablets: 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.

- Before you start to use it

Check with your pharmacist before taking Zyrtec if:

- You have problems with your kidneys
- You have predisposition factors of urinary retention (eg: spinal cord 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 2 years of age.

Zyrtec should be avoided in pregnant women.

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

This medicine contains lactose and sucrose. If you have been told that you have an intolerance to some sugars, contact your doctor before taking this medicine because it contains sorbitol.

Zyrtec oral drops contains the preservatives methyl and propyl parahydroxybenzoate. These can sometimes cause allergic reactions (possibly delayed).

Zyrtec tablet contains lactose and Zyrtec oral solution contains sorbitol. If you have been told that you have an intolerance to some sugars, contact your doctor before taking any of these.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a

pharmacy, supermarket or health food shop.

How to use ZYRTEC

- How much to use

Adults

Take 20 drops or 10 ml oral solution or one tablet once daily. A starting dose of 10 drops or 5 ml oral solution or half a tablet may be proposed if this leads to satisfactory control of the symptoms.

Children

Children aged from 2 to 6 years

Take 5 drops or 2.5 ml of oral solution in the morning and in the evening.

Children aged from 6 to 12 years

Take 10 drops or 5 ml of oral solution or half a tablet in the morning and in the evening.

Children over 12 years of age

Take 20 drops or 10 ml of oral solution or one tablet once daily.

Take the tablet with a glass of water. Do not take more than one tablet each day. The drops have to be diluted in liquid. The solution can be swallowed as such. Do not take more than 10 ml each day.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking Zyrtec for as long as your doctor recommends.

- If you forget to use it

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

- If you use too much (overdose)

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

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

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Avoid alcoholic drink while you are taking this medicine.

If you do not feel better within a few days, consult your doctor.

Tell all the doctors, dentists and pharmacists treating you that you are taking Zyrtec.

Tell your doctor immediately if you become pregnant while taking this medication.

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

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give Zyrtec to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

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

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

Side Effects

Like all medicines Zyrtec 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 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
- Pain in the abdomen
- Headache
- Dizziness
- Dry mouth
- Sore throat
- Nausea
- Cold-like symptoms of the nose (children only).
- Diarrhoea (children only)

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

- Itching (pruritus) and rash
- Tingling or numbness of the hands or feet (paraesthesia)
- Diarrhoea
- Feeling agitated.
- Feeling unusually weak (asthenia) or generally unwell (malaise)

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

- Hypersensitivity
- Fast heart beat (tachycardia)
- 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)

- Low blood platelets count (thrombocytopenia)
- Severe allergic reactions (anaphylactic shock)
- Blurred vision, difficulty focusing
- Eyes having uncontrolled circular movements (oculogyric crisis)
- Taste disturbance or loss of taste (dysgeusia)
- Fainting
- Bed wetting, pain and/or difficulty passing water
- Tremor, tics (uncontrolled body movements)
- Uncontrollable movements (dyskinesia)
- Uncontrolled muscle spasm (dystonia)
- Serious allergic reaction which causes swelling of the face or throat (angioedema)
- Small patches of swelling and redness of the skin, which may blister (fixed drug eruption)

Not known side effects

- Increased appetite
- Nightmare
- Spinning sensation (vertigo)
- Inflammation of the liver (hepatitis)
- Rash with blisters containing pus
- Joint pain (arthralgia, myalgia)
- Urinary retention (difficulty passing urine)
- Intense itching (pruritus) upon discontinuation

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 Zyrtec 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 may report any side effects of adverse drug reactions directly to the National Centre for Adverse Drug

Reaction Monitoring by visiting the website
npra.gov.my [(Consumers → Reporting of Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of ZYRTEC

- Storage

Do not store above 30°C. Keep tablets in a dry place.

Keep out of the reach and sight of children.

Do not take the medicine after the expiry date on the carton. The expiry date refers to the last day of that month.

Return any medicine you no longer need to your pharmacist.

- Disposal

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

Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

Zyrtec tablets are white, oblong film-coated tablets, with a bisect line and a Y-Y logo, each containing 10 mg cetirizine dihydrochloride. It contains 66.40 mg lactose per film-coated tablet.

Zyrtec oral drops contain 10 mg cetirizine dihydrochloride per ml. It contains methylparaben 1.35 mg/ml and propylparaben 0.15 mg/ml as preservatives. The solution is a clear and colourless liquid.

Zyrtec oral solution contains 1 mg cetirizine dihydrochloride per ml. It contains methylparaben 1.35 mg/ml and propylparaben 0.15 mg/ml as preservatives. The solution is a banana flavoured, clear and colourless liquid.

- Ingredients

- Active ingredient(s)

Cetirizine dihydrochloride

- Inactive ingredient(s)

Zyrtec Tablets

Microcrystalline cellulose, Colloidal anhydrous silica, lactose monohydrate, magnesium stearate, Opadry Y-1-7000 which consists of, Hydroxypropylmethylcellulose (E464), Titanium dioxide (E 171), Macrogol 400

Zyrtec Oral Drop

Glycerol (85%), methyl parahydroxybenzoate, sodium acetate, propylene glycol, sodium saccharinate, propyl parahydroxybenzoate, glacial acetic acid, purified water.

Zyrtec Oral Solution

Sorbitol solution at 70% (non crystallizing), Banana flavor 54.330/A, sodium acetate, glacial acetic acid, glycerol (85%), methyl parahydroxybenzoate, sodium saccharinate, propyl parahydroxybenzoate, propylene glycol, purified water.

- MAL number

Zyrtec 10mg Film-coated Tablet
MAL19890575ACRZ

Zyrtec 1mg/ml Oral Solution
MAL20000739ARZ

Zyrtec Oral Drops 10mg/ml
MAL19940322ARZ

Manufacturer

Zyrtec Tablet

UCB Farchim S.A,
Z.I. De Planchy, Chemin De Croix-Blanche 10,
CH-1630 Bulle, Switzerland

Zyrtec Oral Solution and Oral Drops

Aesica Pharmaceuticals S.R.L,
Via Praglia, 15 – 10044 Pianezza,
10044, Italy.

Product Registration Holder

GlaxoSmithKline Pharmaceutical Sdn Bhd
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1 Powerhouse,
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47800 Petaling Jaya

Selangor, Malaysia

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