

ZYRTEC®-R FILM-COATED TABLET 10 MG
ZYRTEC®-R ORAL SOLUTION 1 MG/ML
RAPID RELIEF

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®-R** carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacists 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 gets serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacists. Always read the label to make sure the product is appropriate for your child's age.

What Zyrtec®-R is and what it is used for

Zyrtec®-R contains active ingredient: cetirizine dihydrochloride. Cetirizine belongs to a group of anti-allergic medicines called antihistamines. It blocks the effects of a substance called histamine which occurs naturally in the body. Histamine is involved in allergic reactions.

Zyrtec®-R is used to treat symptoms associated with allergic conditions, such as:

-  Runny, itchy nose
-  Sneezing
-  Watery, itchy eyes
-  Itchy skin rash



Don't take Zyrtec®-R:

- If you are **allergic** (*hypersensitive*) to cetirizine, hydroxyzine, any piperazine derivatives (closely related active ingredients of other medicines), or to any ingredients of **Zyrtec®-R** (listed in section *What does Zyrtec®-R contain*).
- If you have **severe kidney disease** (severe impairment of kidney function with creatinine clearance less than 10 ml/min).
- If you use other antiallergic medicines.
- If you are breastfeeding (see *Pregnancy and breast-feeding*).
- If you have a rare galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption (tablets).
- If you have a rare fructose intolerance (oral solution).

➔ If you think any of these applies to you, **don't take Zyrtec®-R** until you have checked with your doctor or pharmacist.



Take special care with Zyrtec®-R:

Talk to your doctor or pharmacist before using Zyrtec®-R:

- If you have **kidney disease**.
- If you have **difficulty passing urine** (e.g. due to **enlarged prostate** or **spinal cord problems** or bladder problems) as cetirizine increases the risk of urinary retention.
- If you have **epilepsy** or are at risk from convulsions (fits).
- If you are pregnant or breast-feeding (see *Pregnancy and breast-feeding*).

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

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

Zyrtec®-R oral solution is not recommended for infants and children under 2 years.

While you are taking Zyrtec®-R

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

Conditions you need to look out for

Zyrtec®-R can make some existing conditions worse, or cause **severe allergic reactions or urinary retention**. Some people may have suicidal thoughts when taking **Zyrtec®-R**. You must look out for certain symptoms while you are taking **Zyrtec®-R**, to reduce the risk of any problem. See “Conditions you need to look out for” in section *Possible Side Effects*.

Other medicines and Zyrtec®-R:

Tell your doctor or pharmacist if you're taking any other medicines, if you've taken any recently or if you start taking new ones. This includes medicines bought without a prescription. Some medicines may affect how **Zyrtec®-R** works, or make it more likely that you'll have side effects. **Zyrtec®-R** can also affect how some other medicines work. These include:

- Medicines acting on the brain, for example **other antihistamines** such as hydroxyzine, clemastine, **medicines used to treat anxiety** such as diazepam or **sleeping pills** such as zolpidem (concurrent administration of **Zyrtec®-R** with other agents acting on the brain may cause additional reductions in alertness and impairment of performance, see “Food and drink with Zyrtec®-R”).

→ **Tell your doctor or pharmacists** if you are taking any of these.



Caution:

Food and drink with Zyrtec®-R

Avoid alcohol when you are taking **Zyrtec®-R**. In sensitive patients, the concurrent administration of **Zyrtec®-R** and alcohol may cause additional reductions in alertness and impairment of performance.

Pregnancy and breast-feeding

Zyrtec®-R 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®-R**, tell your doctor.

The ingredients in **Zyrtec®-R** can pass into breast milk. **If you are breast-feeding, you must check with your doctors** before you take **Zyrtec®-R**.

Driving and using machines

Zyrtec®-R at the recommended dose is unlikely to affect your ability to drive or use machines. However, some patients being treated with **Zyrtec®-R** may feel **drowsy, tired or weak** (see “*Possible side effects*”).

→ **Don't drive or use machines** unless you are sure you're not affected.

How to take Zyrtec®-R?

How much to take

Always take Zyrtec®-R 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.

Don't take more than the recommended dose.

Don't take Zyrtec®-R 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.

Zyrtec®-R Film-Coated Tablet 10 mg

Children aged from 6 to 12 years: Half of the tablet twice daily.

Adolescents 12 years and above, and adults: 1 tablet once daily. Half of the tablet starting dose may be used if this leads to satisfactory control of the symptoms.

Do not take more than one 10 mg tablet in 24 hours. Swallow the tablet whole, with a glass of water. You can divide the tablet into two equal doses.

Zyrtec®-R film-coated tablets are not recommended for children under 6 years, as the formulation does not allow for appropriate dose adaptation.

Zyrtec®-R Oral Solution 1 mg/mL

Children aged from 2 to 6 years: 2.5 mL of oral solution (half of a spoon) twice daily.

Children aged from 6 years to 12 years: 5 mL oral solution (1 full spoon) twice daily.

Adolescents 12 years and above, and adults: 10 mL of oral solution (2 full spoons) once daily. 5 mL oral solution (1 full spoon) starting dose may be used if this leads to satisfactory control of the symptoms.

Do not take more than the recommended dose.

Zyrtec®-R oral solution is not recommended for infants and children under 2 years.

A measuring spoon is supplied with the pack so you can measure your dose accurately. If you are not supplied with a measuring spoon, talk to your doctor or pharmacist.

Patients with kidney and liver disease:

Your doctor will decide on the correct dose of **Zyrtec®-R** 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®-R** (see “*Don’t take Zyrtec®-R*”).

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

If you forget to take Zyrtec®-R

Don’t 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®-R

If you take too much **Zyrtec®-R**, **contact your doctor or pharmacist for advice.** If possible, show them the **Zyrtec®-R** pack. Do not drive if you have taken too much medicine.

If you take too much **Zyrtec®-R**, 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®-R

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

Possible Side Effects

Like all medicines, **Zyrtec®-R** can cause side effects, although not everybody gets them.

Conditions you need to look out for:

The following side effects may occur in some people taking Zyrtec®-R. You must stop taking the medicine and speak to your doctor or pharmacist straight away if you notice these symptoms:

Severe allergic reactions. Signs include:

- Raised and itchy rash (hives)
- Swelling, sometimes of the face or mouth (angioedema), causing difficult 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 had suicidal thoughts when taking **Zyrtec®-R**.

→ Contact a doctor immediately if you get these symptoms. **Stop taking Zyrtec®-R.**

The following side effects have also been reported:

Common side effects (affects **up to 1** in 10 people)

- Tiredness, feeling sleepy
- Diarrhoea (children only), nausea, dry mouth
- Dizziness, headache
- Sore throat - pharyngitis
- Cold-like symptoms of the nose - rhinitis (children only)

Uncommon side effects (affects **up to 1** in 100 people)

- Itching (pruritus) and rash
- Diarrhoea
- Stomach pain
- Feeling weak (unusual weakness) or generally unwell
- Tingling in the hands and feet - paraesthesia
- Feeling agitated

Rare side effects (affects **up to 1** in 1000 people)

- Hypersensitivity (allergic reaction)
- Fast heart beat (Tachycardia)
- Oedema (generalised swelling due to water retention)
- Abnormal liver function test results
- Convulsions
- Increased weight

- Aggression, confusion, depression, hallucination (hearing or seeing things), insomnia (sleeplessness)
- Urticaria (hives)

Very rare side effects (affects **up to** 1 in 10,000 people)

- Unusual bleeding or bruising (thrombocytopenia – low blood platelets count)
- Anaphylactic shock (see “Severe allergic reactions”)
- Blurred vision, difficulty focusing (accommodation disorder)
- Rotation of the eyes (oculogyration)
- Taste disturbance (dysgeusia) or loss of taste
- Tremor, tics
- Involuntary movements and/or jerking of the limbs
- Muscle spasms in the neck and shoulders
- Fainting
- Angioedema (serious allergic reaction which causes swelling of the face or throat), fixed drug eruption.
- Bed wetting, pain when passing urine

Other side effects (frequency cannot be estimated from the available data)

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

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

How to store Zyrtec®-R:

Store in original packaging. Refer to the storage condition on the outer carton.

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

Keep out of reach of children.

Do not use this medicine beyond the expiry date shown on the pack.

What Zyrtec®-R contains

Zyrtec®-R Film Coated Tablet

Each tablet of **Zyrtec®-R** contains cetirizine dihydrochloride 10 mg.

Other ingredients include: microcrystalline cellulose, lactose monohydrate, colloidal anhydrous silica, magnesium stearate, Opadry Y-1-7000 which consists of hydroxypropylmethylcellulose (E464), titanium dioxide (E171), macrogol 400.

Zyrtec®-R Oral Solution

Each mL contains 1 mg cetirizine dihydrochloride, and preservatives methylparaben 1.35 mg/mL and propylparaben 0.15 mg/mL.

Other ingredients include: Sorbitol solution at 70% (non-crystallising), Glycerol (85%), Propylene glycol, Saacharin sodium, Methyl parahydroxybenzoate, Propyl parahydroxybenzoate, Banana flavor 54.330/A, Sodium acetate, Glacial acetic acid, Purified water.

What Zyrtec®-R looks like and contents of the pack

Zyrtec®-R Tablets are white oblong film-coated tablets, with a bisect line and a Y-Y logo. Each box contains 10 film-coated tablets in a blister strip.

Zyrtec®-R Oral Solution is clear and colourless with slightly sweet taste and a banana flavour. Each bottle contains 75 mL solution.

[GSK logo]

Manufacturer for tablets:
UCB Farchim SA
Bulle, Switzerland

Manufacturer and packager for oral solution:
Aesica Pharmaceuticals S.r.l.
Pianezza (TO), Italy

Packager for tablets:
Aesica Pharmaceuticals S.r.l.,
Pianezza (TO), Italy

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