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Pharma code Ref. No. 2977

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Package leaflet: Information for the user
Zyrtec 10 MG FILM-COATED TABLETS
Zyrtec 1 MG/ML ORAL SOLUTION
Zyrtec 10 MG/ML ORAL DROPS
Cetirizine dihydrochloride

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you personally.
- Don't pass it on to other people - it may harm them even if their symptoms seem to be the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet

- 1. What Zyrtec is and what it is used for**
- 2. Before you take Zyrtec**
- 3. How to take Zyrtec**
- 4. Possible side effects**
- 5. How to store Zyrtec**
- 6. Further information**

1. What Zyrtec is and what it is used for
Zyrtec contains active ingredient: cetirizine. Cetirizine belongs to a group of anti-allergic medicines called antihistamines.
Zyrtec is used to treat symptoms associated with allergic conditions, such as:

- nasal and ocular symptoms of seasonal and perennial allergic rhinitis,
- rashes and itching of chronic urticaria (hives).

2. Before you take Zyrtec
Don't take Zyrtec

- if you are **allergic (hypersensitive)** to cetirizine, hydroxyzine or any piperazine derivatives (closely related active ingredients of other medicines), or to any other ingredients of Zyrtec (listed in Section 4)
- if you have **severe kidney disease** (severe impairment of kidney function with creatinine clearance below 10ml/min)

→ If you think any of these apply to you, **don't take Zyrtec** until you have checked with your doctor.

Take special care with Zyrtec

Before you take Zyrtec your doctor needs to know:

- if you have **kidney problems** (your doctor may lower your dose of Zyrtec)
- 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)

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

Zyrtec oral drops/oral solution is not recommended for infants and children under 2 years.
Zyrtec film-coated tablets are not recommended for children under 6 years, as this formulation does not allow for appropriate dose adaptation.

While you are taking Zyrtec

- Avoid alcohol while you are taking Zyrtec.
- Zyrtec may affect your **allergy skin test** results. If you are scheduled for allergy testing ask your doctor if you should stop taking Zyrtec for several days before testing.

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.
You must look out for certain symptoms while you are taking Zyrtec, to reduce the risk of any problems. See 'Conditions you need to look out for' in Section 4.

Other medicines and Zyrtec
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 works, or make it more likely that you'll have side effects. Zyrtec 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 clonazepam or **sleeping pills** such as zolpidem. Concurrent administration of Zyrtec with other agents acting on the brain may cause additional reductions in alertness and impairment of performance, see 'Food and drink with Zyrtec' later in Section 2).

→ **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 reductions in alertness and impairment of performance.

Pregnancy and breast-feeding
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 breast-feeding, you must check with your doctor** before you take Zyrtec.

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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** (see 'Possible side effects' in Section 4).

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

Zyrtec 10 mg film-coated tablets contain lactose monohydrate
Patients with rare hereditary problems of galactose intolerance, (the Lapp lactase deficiency or glucose-galactose malabsorption) should not take this medicine.

Zyrtec 1 mg/mL oral solution contains sorbitol
Patients with rare hereditary problems of fructose intolerance should not take this medicine.

Zyrtec 1 mg/mL oral solution and Zyrtec 10 mg/mL oral drops contain Parabens
Zyrtec 1 mg/mL oral solution and Zyrtec 10 mg/mL oral drops contain methyl parahydroxybenzoate or propyl parahydroxybenzoate, which may cause allergic reactions (possibly delayed).

3. How to take Zyrtec
How much to take
Always take Zyrtec exactly as your doctor has told you to. Check with your doctor or pharmacist if you're not sure.

→ **Contact your doctor** if your symptoms worsen or do not improve.

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.

Zyrtec 1 mg/mL oral solution
The usual dose of Zyrtec oral solution, is 10 mL (10 mg), once a day.

Zyrtec 10 mg/mL oral drops
The usual dose of Zyrtec oral drops, is 20 drops (10 mg) of oral drops, once a day.

Zyrtec 10 mg/mL oral solution
The usual dose of Zyrtec oral drops, is 5 drops (2.5mg), twice a day.

Children between 6 and 12 years old
Zyrtec 10 mg film-coated tablets
The usual dose of Zyrtec is half tablet (5 mg) twice a day.

Zyrtec 1 mg/mL oral solution
The usual dose of Zyrtec oral solution, is 5 mL (5mg), twice a day.

Zyrtec 10 mg/mL oral drops
The usual dose of Zyrtec oral drops, is 10 drops (5mg), 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 oral drops, is 2.5 mL (2.5mg), twice a day.

Zyrtec 10 mg/mL oral drops
The usual dose of Zyrtec oral drops, is 5 drops (2.5mg), twice a day.

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 (see 'Don't take Zyrtec', in section 2).
If your child suffers from kidney disease, please contact your doctor or pharmacist who may adjust the dose accordingly.
Don't take any more Zyrtec than your doctor has recommended. Duration of treatment depends on the type, duration and course of your complaints.

How to take
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.
A dosing graduated spoon with (2.5 ml and 5 ml) graduation is supplied with the pack so you can measure your dose accurately. If you are not supplied with a graduated spoon, speak to your doctor or pharmacist.

Zyrtec 10 mg/mL oral drops
Dilute drops in water. The diluted drops should be swallowed immediately.

If you forget to take Zyrtec
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
If you take too much Zyrtec, **contact your doctor or pharmacist 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

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Urinary retention. Signs include:

- pain when passing urine or inability to pass urine

Suicidal thoughts. Some people had 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:

- Agitation
- Dizziness, headache
- Pharyngitis (sore throat and discomfort when swallowing), rhinitis (in children)
- Diarrhoea (in children), nausea, dry mouth
- Fatigue

Uncommon side effects
These may affect **up to 1 in 100** people:

- Tingling or numbness of the hands or feet (paraesthesia)
- Diarrhoea
- Stomach pain
- Pruritus (itching), rash
- Asthenia (unusual weakness), malaise (generally feeling unwell)

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

- Allergic reactions (hypersensitivity)
- Aggression, confusion, depression, hallucination (seeing or hearing things that are not really there), insomnia (sleeplessness)
- Convulsions
- Tachycardia (fast heart beat)
- Abnormal liver function (increased amounts of liver enzymes in the blood, that may show up in 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), small patches of swelling and redness of the skin, which may blister (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 thoughts (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 any side effects not listed in this leaflet.

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. By reporting side effects, you can help provide more information on the safety of this medicine.
To report Product Complaint/s or Adverse Event/s associated with the use of GSK product/s, please contact us via: gulf.safety@gsk.com.

5. How to store Zyrtec
Zyrtec 10 mg film-coated tablets
Store below 30 °C.

Zyrtec 1 mg/mL oral solution
Store below 30 °C.

Zyrtec 10 mg/mL oral drops
Store up to 30 °C.

Do not use this medicine after the expiry date which is stated on the outer carton after "EXP".
Tablets
Don't 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.

Oral solution, oral drops:
Throw away the bottle (3 months after first opening it, but don't 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 dihydrochloride.
Each film-coated tablet contains 10 mg of cetirizine dihydrochloride.
Excipients with known effect:
- Each tablet contains 66.40 mg lactose monohydrate.
Each 1 mL of oral solution contains 1 mg of cetirizine dihydrochloride.
Excipients with known effect:
- One mL of solution contains 450 mg sorbitol solution at 70% (non-crystallising)
- One mL of solution contains 1.35 mg methyl parahydroxybenzoate
- One mL of solution contains 0.15 mg propyl parahydroxybenzoate
Each 1 mL of oral drops solution contains 10 mg of cetirizine dihydrochloride, one drop of solution contains 0.5 mg cetirizine dihydrochloride.
Excipients with known effect:
- One mL of solution contains 1.35 mg methyl parahydroxybenzoate
- One mL of solution contains 0.15 mg propyl parahydroxybenzoate

List of Excipients:
Zyrtec 10 mg film-coated tablets
Microcrystalline cellulose, lactose monohydrate, colloidal anhydrous silica, magnesium stearate, Opadry Y-1-7000 which consists of (Hydroxypropylmethylcellulose (E464), titanium dioxide (E171), Macrogol 400).

Zyrtec 1 mg/mL oral solution
Sorbitol solution of 70% (non-crystallising), Glycerol (85%), Propylene glycol, Saccharin sodium, Methyl parahydroxybenzoate, Propyl parahydroxybenzoate, Banana flavour 54.330/A, Sodium acetate, Glacial acetic acid, Purified water.

Zyrtec 10 mg/mL oral drops
Glycerol (85%), Propylene glycol, Saccharin sodium, Methyl parahydroxybenzoate, Propyl parahydroxybenzoate, Sodium acetate, Glacial acetic acid, Purified water.

What Zyrtec looks like and contents of the pack
Zyrtec 10 mg film-coated tablets
Zyrtec 10 mg film-coated tablet is supplied for oral use as a white, oblong film coated tablet with a bisect line and a Y-Y logo.

Zyrtec 1 mg/mL oral solution
Zyrtec Oral Solution is a banana flavoured clear colourless liquid, containing 1 mg of Cetirizine dihydrochloride drug substance per mL (5 mg/5 mL) and intended for oral administration.

Zyrtec 10 mg/mL oral drops
Zyrtec Oral Drops, solution is a clear and colourless liquid, containing 10 mg of Cetirizine dihydrochloride per mL, intended for oral administration.

Manufacturer
Zyrtec 10 mg film-coated tablets
Manufacture and batch release by:
UCB Farchim SA
Bulle
Switzerland

Primary and secondary packaging by:
Aesica Pharmaceuticals S.r.l.
PianeZZa (TO)
Italy

Zyrtec 1 mg/mL oral solution and Zyrtec 10 mg/mL oral drops
Manufactured by:
Aesica Pharmaceuticals S.r.l.
PianeZZa (TO)
Italy

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- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of the reach of children.

Council of Arab Health Ministers
Union of Arab Pharmacists

GSK0451A

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