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.

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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 6)
- 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
- 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 hydroxizine, 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 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

Zvrtec 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.

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

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.

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

Zvrtec 10 mg/mL oral drops

The usual dose of Zyrtec oral drops, is 20 drops (10 mg) of oral drops, once

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 solution, 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

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:

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

Uncommon side effects

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

Agitation

- 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),
- 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 up to 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"

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 at 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

UCB Farchim SA

Zvrtec 10 mg film-coated tablets Manufacture and batch release by:

Bulle Switzerland

Primary and secondary packaging by: Aesica Pharmaceuticals S.r.l.

Pianezza (TO)

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

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- NCDS Version Number: 06, Version Date: 02 April 2019 THIS IS A MEDICAMENT Medicament is a product which affects your health and its consumption
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- 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.

Union of Arab Pharmacists

contrary to instructions is dangerous for you.

The doctor and the pharmacist are the experts in medicines, their

Keep all medicaments out of the reach of children. Council of Arab Health Ministers



