

# Zyrtec<sup>®</sup>-D

## NAME OF THE MEDICINAL PRODUCT

Zyrtec<sup>®</sup>-D

## QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 5 mg cetirizine dihydrochloride in an immediate release form and 120 mg pseudoephedrine hydrochloride in a prolonged-release form.

## EXCIPIENTS

Hypromellose, Microcrystalline cellulose, Colloidal anhydrous silica, Magnesium stearate, Lactose monohydrate, Croscarmellose sodium, Titanium dioxide (E171), Macrogol 400.

## PHARMACEUTICAL FORM

Prolonged release tablet is white to off-white, round biconvex film-coated tablet having a circular logo on one side.

## CLINICAL INFORMATION

### Indications

Zyrtec<sup>®</sup>-D is indicated for the treatment of symptoms associated with seasonal and perennial allergic rhinitis with nasal congestion, and hypersecretion, nose and/or eye itching and watery eyes.

It should be administered when both the anti-allergic properties of cetirizine dihydrochloride and the nasal decongestant activity of pseudoephedrine hydrochloride are desired.

### Dosage and Administration

The tablet should be swallowed whole with some liquid, and must not be broken, chewed or crushed. It may be taken with or without food.

The duration of treatment should not exceed the period of acute symptoms, and should not exceed 2 to 3 weeks. After improvement of nasal symptoms, treatment should be continued only with cetirizine, where appropriate.

### Route of Administration

For oral use.

### Adults and Children aged 12 years and older

One tablet twice daily (morning and evening).

### Children under 12 years of age

Zyrtec-D<sup>®</sup> is contradicted in children under 12 years of age (see sections: *Contraindications; Warnings and Precautions*).

### Elderly

Zyrtec-D<sup>®</sup> should be used with caution in patients over 50 years of age. The dose should be reduced to one tablet daily for patients  $\geq 77$  years old.

### **Renal Impairment**

The dose should be reduced to one tablet daily in patients with mild to moderate renal insufficiency. Zyrtec-D<sup>®</sup> is contraindicated in severe renal insufficiency (*see Section Contraindications*).

### **Hepatic Impairment**

The dose should be reduced to one tablet daily in patients with mild to moderate hepatic insufficiency.

### **Contraindications**

Zyrtec<sup>®</sup>-D is contraindicated in:

- known hypersensitivity to the active substances or excipients, to ephedrine or any other piperazines,
- severe hypertension or severe ischaemic heart disease,
- severe renal insufficiency,
- uncontrolled hyperthyroidism,
- severe arrhythmias,
- pheochromocytoma,
- elevated intraocular pressure,
- urinary retention,
- glaucoma,
- history of stroke,
- high risk of haemorrhagic stroke (*see section Warnings and Precautions*),
- concomitant administration of dihydroergotamine (*see Section Interactions*),
- concomitant treatment with monamine oxidase (MAO) inhibitor and within 2 weeks after their discontinuation,
- children under 12 years of age (*see Section Warnings and Precautions*).

### **Warnings and Precautions**

#### *General precautions*

Due to the presence of pseudoephedrine, Zyrtec<sup>®</sup>-D should be used with caution in patients with diabetes mellitus, hyperthyroidism, arterial hypertension, tachycardia, cardiac arrhythmia, ischaemic heart disease, moderate renal or hepatic insufficiency, and also in the elderly. Caution is also required in patients taking:

- sympathomimetics including decongestants, anorexigenic substances or psychostimulants such as amphetamines (combined effects on the cardiovascular system),
- tricyclic antidepressants, phenothiazines,
- antihypertensives drugs (reduction of antihypertensive effects) (*see Section Interactions*),
- alcohol and other CNS depressants (increased depressing action on the CNS and reduced performance).
- cardiac glycosides such as digoxin or digitoxin (risk of cardiac arrhythmia) (*see section Interactions*)
- as well as in conditions where an anticholinergic action should be avoided, like in cases of prostatic hypertrophy or urinary obstruction.

*Posterior reversible encephalopathy (PRES)/reversible cerebral vasoconstriction syndrome (RCVS)*

There have been rare cases of posterior reversible encephalopathy (PRES)/reversible cerebral vasoconstriction syndrome (RCVS) reported with sympathomimetic drugs, including pseudoephedrine. Symptoms reported included sudden onset of severe headache, nausea, vomiting, and visual disturbances. Most cases improved or resolved within a few days following appropriate treatment. Pseudoephedrine should be discontinued immediately and medical advice sought if signs/symptoms of PRES/RCVS develop.

#### *Vasoconstrictor effect*

Caution should also be taken in patients with factors which could increase the risk of haemorrhagic stroke, (concomitant use of vasoconstrictors such as bromocriptine, pergolide, lisuride, cabergoline, ergotamine), or any other decongestant drug used as nasal decongestant, either by oral route or by nasal route (phenylpropanolamine, phenylephrine, ephedrine), due to the risk of vasoconstriction and increased blood pressure.

Due to vasoconstrictor effect of pseudoephedrine, caution is recommended in patients who are at risk for hypercoagulability, as in inflammatory bowel disease.

#### *Use with NSAIDs in hypertensive patients*

Caution is required in hypertensive patients who are treated concomitantly with NSAIDs, because both pseudoephedrine and NSAIDs can increase blood pressure.

#### *Cerebral stimulant*

This product may act as a cerebral stimulant giving rise to insomnia, nervousness, hyperpyrexia, tremor and epileptiform convulsions.

#### *Cases of abuse*

As for other centrally acting stimulants, abuse has been observed for pseudoephedrine.

#### *Children under 12 years of age*

Zyrtec<sup>®</sup>-D is contraindicated in children under 12 years of age due to the presence of pseudoephedrine and because this combination has not been studied in this age group (see section *Contraindications*).

#### *Lactose*

This product contains lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

### **Interactions**

No interaction studies have been performed with the combination cetirizine-pseudoephedrine.

#### *Lack of interactions*

Pharmacokinetic interaction studies were conducted with cetirizine and cimetidine, ketoconazole, erythromycin, azithromycin, antipyrine and pseudoephedrine; no pharmacokinetic interactions were observed.

Studies with cetirizine and cimetidine, glipizide, diazepam, and pseudoephedrine have revealed no evidence of adverse pharmacodynamic interactions.

Studies with cetirizine and azithromycin, erythromycin, ketoconazole, theophylline and pseudoephedrine have revealed no evidence of adverse clinical interactions. In particular, concomitant administration of cetirizine with macrolides or ketoconazole has never resulted in clinically relevant ECG changes.

### *Theophylline*

In a multiple dose study of theophylline (400 mg once a day) and cetirizine, there was a small (16%) decrease in clearance of cetirizine, while the elimination of theophylline was not altered by concomitant cetirizine administration.

### *Ritonavir*

In a multiple dose study of ritonavir (600 mg twice daily) and cetirizine (10 mg daily), the extent of exposure to cetirizine was increased by about 40% while the elimination of ritonavir was slightly altered (-11%) by concomitant cetirizine administration.

### *MAO inhibitors*

Concomitant use of sympathomimetic amines with monoamine oxidase (MAO) inhibitors can result in hypertensive crisis. Due to the long duration of action of MAO inhibitors, this interaction is still possible 15 days after discontinuation of their administration (see section *Contraindications*).

### *Linezolid*

Concomitant administration of linezolid and pseudoephedrine can increase arterial pressure in normotensive patients.

### *Reduction of the antihypertensive effects of drugs*

Sympathomimetic amines may reduce the anti-hypertensive effects of beta-adrenergic blockers and of drugs that interfere with sympathetic nervous system activity such as methyl dopa, guanethidine and reserpine (see *Section Warnings and Precautions*).

### *Tricyclic antidepressants*

Tricyclic antidepressants can potentiate the hypertensive effect of pseudoephedrine.

### *Cardiac glycosides*

The ectopic pacemaker activity can be increased when pseudoephedrine is used with cardiac glycosides, such as digoxin or digitoxin; the use of Zyrtec<sup>®</sup>-D therefore should be avoided in patients treated with cardiac glycosides.

### *Drugs increasing or decreasing cetirizine/pseudoephedrine absorption*

Antacids and proton pump inhibitors increase the rate of pseudoephedrine absorption; kaolin decreases it.

### *Halogenated anaesthetic agents*

Concurrent use with halogenated anaesthetic agents may provoke or worsen ventricular arrhythmia.

### *Allergy tests*

Antihistamines can interfere with allergy tests and an appropriate wash-out period is required before conducting such tests.

### *Fat meal*

A high fat meal was not found to modify the bioavailability of both active ingredients, but it resulted however in a reduced and delayed peak plasma concentration of cetirizine.

## **Pregnancy and Lactation**

## **Fertility**

A study in animals has demonstrated that the combination of cetirizine/pseudoephedrine (1:24) has not impact on fertility at a dose of up to 10 times the recommended dose. There are no available data on fertility in humans.

## **Pregnancy**

Zyrtec<sup>®</sup>-D should not be used during pregnancy.

There are no adequate data on the use of Zyrtec<sup>®</sup>-D in pregnant women. The use of pseudoephedrine during pregnancy has been associated with an increased frequency of gastroschisis (a developmental defect in the abdominal wall with intestinal herniation) and a small bowel atresia (congenital obstruction of small bowel).

Due to the vasoconstrictive properties of pseudoephedrine, this product should not be used during pregnancy as it can induce a reduction in uteroplacental circulation. Data on a limited number of exposed pregnancies indicate no adverse effects of cetirizine on pregnancy or on the health of the foetus/newborn child. There is insufficient animal data with respect to pregnancy, embryonal/foetal development, parturition or post natal development.

## **Lactation**

Zyrtec<sup>®</sup>-D should not be used during breast-feeding. Cetirizine and pseudoephedrine are excreted into human milk.

## **Ability to perform tasks that require judgement, motor or cognitive skills**

Patients intending to drive, engaging in potentially hazardous activities or operating machines should not exceed the recommended dose and should take their individual response to the medicinal product into account. However it should be noted that the effects of these drugs may vary depending on the individual response: clinical studies have shown cases of drowsiness. Effects on the central nervous system may occur with doses higher than those usually recommended. If patients experience drowsiness or vertigo, they should not drive.

Objective measurements of driving ability, sleep latency and assembly line performance, following the administration of cetirizine, have not demonstrated any clinically relevant effects at the recommended dose of 10 mg/day. No negative effects associated with the use of pseudoephedrine have been reported and are expected to occur. Concurrent use of cetirizine with alcohol or other CNS depressants may cause additional reductions in alertness and impairment of performance.

## **Adverse Reactions**

### **Clinical Trial Data**

In controlled clinical trials, adverse reactions reported in more than 1% of the patients receiving the combination cetirizine/pseudoephedrine, were not different from those reported for cetirizine or pseudoephedrine alone.

### **Post-Marketing Data**

Undesirable effects encountered with cetirizine are mainly related to CNS depressant or paradoxical CNS stimulation effects, to anti-cholinergic activity or hypersensitivity reactions (including anaphylactic shock), while the undesirable effects of pseudoephedrine are more likely related to CNS stimulation, and cardiovascular disorders. Cases of abnormal hepatic function with increased hepatic enzymes levels, accompanied by elevated bilirubin, were reported; the majority of the cases were resolved after interrupting the treatment with cetirizine dihydrochloride. Isolated cases of stroke and ischaemic colitis associated with pseudoephedrine use have been identified in literature.

Adverse drug reactions (ADRs) are listed below by MedDRA system organ class and by frequency.

Frequencies are defined as:

Very common  $\geq 1/10$

Common  $\geq 1/100$  to  $< 1/10$

Uncommon  $\geq 1/1000$  to  $< 1/100$

Rare  $\geq 1/10000$  to  $< 1/1000$

Very rare  $< 1/10000$

Not known (cannot be estimated from the available data).

*Immune system disorders*

*Rare:* hypersensitivity

*Psychiatric disorders*

*Common:* nervousness, insomnia

*Uncommon:* anxiety, agitation

*Rare:* hallucination

*Very rare:* psychotic disorder

*Nervous system disorders*

*Common:* vertigo, dizziness, headache, somnolence

*Rare:* convulsions, tremor

*Very rare:* dysgeusia, cerebrovascular accident (stroke)

*Eye disorders*

*Not known:* accommodation disorder, vision blurred, mydriasis, eye pain, visual impairment, photophobia

*Cardiac disorders*

*Common:* tachycardia

*Rare:* arrhythmia

*Vascular disorders:*

*Rare:* pallor, hypertension

*Very rare:* circulatory collapse

*Respiratory, thoracic and mediastinal disorders*

*Not known:* dyspnoea

*Gastrointestinal disorders*

*Common:* dry mouth, nausea

*Rare:* vomiting

*Very rare:* colitis ischaemic

#### *Hepatobiliary disorders*

*Rare:* hepatic function disorders (increase in transaminases, alkaline phosphatase, gamma-GT, bilirubin)

#### *Skin and subcutaneous tissue disorders*

*Rare:* dry skin, rash, hyperhidrosis, urticaria

*Very rare:* fixed drug eruption, angioneurotic oedema

#### *Renal and urinary disorders*

*Rare:* dysuria

#### *Reproductive system and breast disorders:*

*Not known:* erectile dysfunction

#### *General disorders and administration site conditions*

*Common:* asthenia

## **Overdosage**

### **Symptoms and Signs**

#### *Cetirizine*

Symptoms observed after an overdose of cetirizine are mainly associated with CNS effects or with effects that could suggest an anti-cholinergic effect.

#### *Pseudoephedrine*

In large doses, sympathomimetics may induce a toxic psychosis with delusions and hallucinations. Some patients may develop cardiac arrhythmias, circulatory collapse, convulsions, coma, and respiratory failure, which can be fatal.

#### *Cetirizine/Pseudoephedrine*

Acute overdose with Zyrtec<sup>®</sup>-D may cause vomiting, diarrhoea, dizziness, fatigue, headache, malaise, mydriasis, urinary retention, tachycardia, cardiac arrhythmia, arterial hypertension, signs of CNS depression (sedation, apnoea, unconsciousness, cyanosis and cardiovascular collapse) or stimulation (insomnia, hallucinations, tremor, seizures) which could be fatal.

## **Treatment**

Treatment, preferably in hospital, should be symptomatic and supportive. Consideration should be given to the possible concomitant ingestion of other drugs. If spontaneous vomiting does not occur, it should be induced.

No antidote is known. Sympathomimetic amines should not be used. Hypertension and tachycardia can be controlled with use of alpha-blockers and/or beta-blockers. Epileptic seizures can be treated with diazepam intravenously (or by the rectal route in children).

Cetirizine and pseudoephedrine are poorly eliminated by haemodialysis.

Further management should be as clinically indicated or as recommended by the national poisons centre, where available.

## **Clinical Pharmacology**

### **Pharmacodynamics**

#### **Pharmacotherapeutic group**

Nasal decongestants for systemic use.

#### **ATC Code**

R01BA52

### **Mechanism of Action and Pharmacodynamic effects**

The pharmacodynamic activity of cetirizine – pseudoephedrine is directly related to the additive effect of the action of its constituents.

#### *Cetirizine*

Cetirizine is a potent and selective antagonist of the H<sub>1</sub>-receptor with anti-allergic properties; it inhibits the early phase of the histamine-related allergic reaction; in addition it reduces the migration of some type of inflammatory cells and the release of mediators associated with the late allergic response; it inhibits the reactions induced by histamine and pollens in nasal provocative tests.

#### *Pseudoephedrine*

Pseudoephedrine, a stereoisomer of ephedrine, is an orally active sympathomimetic, whose alpha-mimetic effects are greater than its beta-mimetic activity; due to its vasoconstrictor action, it has a decongestant effect on the nasal mucosa.

### **Pharmacokinetics**

There was no evidence for a relevant pharmacokinetic interaction between cetirizine and pseudoephedrine.

### **Absorption and Distribution**

#### *Cetirizine*

After oral administration, cetirizine is rapidly and almost completely absorbed. Peak plasma concentrations are generally obtained within 1 hour under fasting conditions. The absorption is independent of the dose.



Inter- and intra-subjects variations are low.

Cetirizine is highly bound to plasma proteins (93 %).

Its volume of distribution is small: approximately 0.5 l/kg.

#### *Pseudoephedrine*

Pseudoephedrine given as the sustained-release formulation cetirizine/pseudoephedrine provides maximum plasma levels 2 to 6 hours after multiple dosing.

### **Metabolism and Elimination**

#### *Cetirizine*

Cetirizine does not undergo any appreciable first pass metabolism. The plasma half-life of cetirizine is approximately 9 hours. This value is increased in patients with reduced renal function. After repeated oral administration, the daily urinary excretion of unchanged cetirizine is approximately 65 % of the dose. The elimination is independent of the dose.

#### *Pseudoephedrine*

It is excreted mainly unchanged in the urine. The rate of urinary excretion is increased when the pH of urine is reduced, and reduced in case of alkalinization of urine. After repeated oral administration (every 12 hours), at steady-state, the apparent elimination half-life is estimated to be approximately 9 hours.

### **Special patient populations**

#### **Renal impairment**

The dose should be reduced to half the usual recommended dose.

#### **Clinical Studies**

Not relevant for this product

### **NON-CLINICAL INFORMATION**

Animal studies have shown no toxic doses equal or higher than 30 mg/kg/day in rats and 40 mg/kg/day in the Cynomolgus monkey ( $\geq 8$  and 11 times the recommended dose in humans). The systemic exposure to these doses was higher in the monkey but lower in rats, compared to that obtained in humans. Reproduction toxicology studies in rats showed no effects at a dose of 40 mg/kg/day. Due to the low levels of systemic exposure in these species, these results cannot be considered significant to demonstrate a safe use in pregnant and lactating women.

Cetirizine/pseudoephedrine is neither mutagenic nor clastogenic and therefore this combination likely presents no risk of carcinogenicity in humans.

In reproduction toxicology studies, fertility in male and female rats was unimpaired at doses up to 160 mg/kg/day (1:24), which represents an estimated systemic exposure to pseudoephedrine 10 times higher than the therapeutic exposure in humans.

### **PHARMACEUTICAL INFORMATION**

#### **Shelf-Life**

As registered locally.

### **Storage**

Store in original packaging, below 30°C in a dry place.

Keep out of the reach and sight of children.

Do not use after the expiry date stated on the carton box and blister.

### **NATURE AND CONTENTS OF THE CONTAINER**

The tablets are packed in PVC-Aclar Rx 160/Aluminium foil blisters placed in a cardboard box containing 10 and 50 tablets.

### **INCOMPATIBILITIES**

There are no relevant data available.

### **USE AND HANDLING**

There are no special requirements for use or handling of this product.

### **MANUFACTURER**

#### *Manufacturer tablets*

UCB Farchim S.A.

Z.I. de Planchy

10 Chemin de Croix Blanche

CH- 1630 Bulle - Switzerland

#### *Packager*

Aesica Pharmaceuticals S.r.l.

Via Praglia 15

I – 10044 Pianezza - Italy

**Version number: NCDS04(SI)**

**Version date: 4 October 2016**

[GSK LOGO]

## NAME OF PRODUCT

Zyrtec<sup>®</sup>-D

## WHAT ZYRTEC<sup>®</sup>-D IS

Zyrtec<sup>®</sup>-D is a combination of an anti-histamine (cetirizine dihydrochloride) and a decongestant (pseudoephedrine hydrochloride).

Zyrtec<sup>®</sup>-D is a medicine that is used to relieve allergic symptoms, especially when the anti-allergy properties of cetirizine are combined with the effects of pseudoephedrine in reducing swelling of the mucous membranes inside the nose.

## WHAT IS ZYRTEC<sup>®</sup>-D USED FOR?

Zyrtec<sup>®</sup>-D is indicated for the treatment of symptoms associated with seasonal and perennial allergic rhinitis such as blocked nose, runny nose, itchy nose or itchy eyes and watery eyes.

Zyrtec<sup>®</sup>-D is indicated for adults and adolescents from 12 years of age and above.

## BEFORE YOU TAKE ZYRTEC<sup>®</sup>-D

Do not take Zyrtec<sup>®</sup>-D

- if you are **allergic** to cetirizine, ephedrine, or any other ingredients (see Section *What Zyrtec<sup>®</sup>-D Contains*), or to piperazine derivative (closely related active substances of other medicines)
- if you have **high blood pressure** or **coronary heart disease**
- if you have **severe kidney disease**,
- if you have **uncontrolled overactive thyroid gland**
- if you have **serious disturbances of heart rhythm**
- if you have a tumour called a **phaeochromocytoma**
- if you have **increased pressure inside the eye** or **glaucoma**
- if you have **urination problems**
- if you have had a **cerebrovascular event (stroke)** or you are at high risk of one
- if you are taking **dihydroergotamine**
- if you are taking **monoamine oxidase inhibitors** (MAOI; antidepressants) or have taken them within the last two weeks

➔ If you think any of these apply to you, do not take Zyrtec<sup>®</sup>-D until you have checked with your doctor.

**Don't give this medicine to children under 12 years of age.**

## TAKE SPECIAL CARE WITH ZYRTEC<sup>®</sup>-D

Talk to your doctor or pharmacist **before** taking Zyrtec<sup>®</sup>-D:

- if you are taking any other medicines, including those administered by a different route (see *Other medicines and Zyrtec<sup>®</sup>-D*)
- if you have **liver problems** (your doctor may lower your dose of Zyrtec<sup>®</sup>-D)
- if you have **kidney problems** (your doctor may lower your dose of Zyrtec<sup>®</sup>-D)
- if you are **over 50**
- if you are a **diabetic**
- if you are **drinking alcohol**
- if you have **overactive thyroid**
- if you have **heart problems** (too fast or irregular rhythm, angina)

- if your **prostate** is **enlarged** or you have **problems urinating**
- if you suffer from **high blood pressure** and are **taking non-steroidal anti-inflammatory drugs** (such as aspirin, ibuprofen, diclofenac etc.)
- if you are at risk of **excessive blood clotting** e.g. from chronic inflammatory bowel disease
- if you are scheduled for allergy testing (Zyrtec<sup>®</sup>-D may affect your allergy test results)

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

### Conditions you need to look out for

Medicines like Zyrtec<sup>®</sup>-D can cause allergic reactions and serious conditions called *posterior reversible encephalopathy (PRES)* or *reversible cerebral vasoconstriction (RCVS)*. You must look out for certain symptoms while you are taking Zyrtec<sup>®</sup>-D, to reduce the risk of any problems. See *Conditions you need to look out for* in Section *Possible Side Effects*.

### OTHER MEDICINES AND ZYRTEC<sup>®</sup>-D

**Tell your doctor or pharmacist if you're taking any other medicines**, if you've taken any recently, or if you starting taking new ones. This includes medicines bought without a prescription.

Do not take Zyrtec<sup>®</sup>-D with these medicines:

- **MAO inhibitors** (used to treat **depression** and **Parkinson's disease**) such as moclobemide, selegiline
- **dihydroergotamine** (used to treat **migraines**)

Some medicines may affect how Zyrtec<sup>®</sup>-D works, or make it more likely that you'll have side effects. Zyrtec<sup>®</sup>-D can also affect how some other medicines work. These include:

- **sympathomimetics** and **psychostimulants** (some **cough** and **cold** preparations and **weight reducing** medicines) such as phenylpropanolamine, phenylephrine, ephedrine
- **anti-hypertensives** (used to help lower **high blood pressure**) such as beta-blockers (i.e. metoprolol, bisoprolol) or methyldopa, guanethidine and reserpine
- **medicines used to treat heartburn and indigestion - antacids** such as aluminium hydroxide or **proton pump inhibitors** such as rabeprazole, pantoprazole, lansoprazole
- **CNS depressants** (used to treat **difficulties in sleeping, anxiety**) such as alprazolam, diazepam, zolpidem
- **tricyclic anti-depressants** (used to treat **depression**) such as amitriptyline, nortriptyline
- **cardiac glycosides** (used to treat **heart diseases**) such as digoxin, digitoxin
- **bromocriptine, pergolide, lisuride, carbergoline, ergotamine** (medicines with blood vessel narrowing action, used for various diseases i.e. **migraine, Parkinson's disease**)
- **theophylline** (used to treat **respiratory diseases** such as **asthma**)
- **ritonavir** (used to treat **HIV/AIDS**)
- **linezolid** (antibiotic used to treat **infections**)

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

### PREGNANCY AND BREAST-FEEDING

Zyrtec<sup>®</sup>-D 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<sup>®</sup>-D, tell your doctor.

**Breast-feeding is not recommended** during treatment with Zyrtec<sup>®</sup>-D. The ingredients can pass into your breast-milk, and so may harm your baby. Talk to your doctor about this.

### **DRIVING AND USING MACHINES**

Zyrtec<sup>®</sup>-D **can make you feel drowsy or sleepy.**

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

### **ZYRTEC<sup>®</sup>-D CONTAINS LACTOSE**

Zyrtec<sup>®</sup>-D tablets contain lactose. If you have an intolerance to some sugars:

→ **Check with your doctor** that Zyrtec<sup>®</sup>-D is suitable for you.

### **HOW TO TAKE ZYRTEC<sup>®</sup>-D**

#### **How much to take**

**Always take Zyrtec<sup>®</sup>-D exactly as recommended in this leaflet or as your doctor has told you to.** Check with your doctor or pharmacist if you are not sure.

**Do not give** this medicine to children **under 12 years of age.**

#### **Adults and children aged 12 years and older:**

The recommended dose of Zyrtec<sup>®</sup>-D is one tablet twice daily (morning and evening).

→ If you suffer from **kidney or liver disease**, talk to your doctor or pharmacist.

### **HOW TO TAKE**

**Swallow your Zyrtec<sup>®</sup>-D tablet whole with some water. Do not chew, crush or split the tablets** – if you do, there is danger you could overdose, because the medicine may be released into your body too quickly.

You may take Zyrtec<sup>®</sup>-D with or without food.

Don't take Zyrtec<sup>®</sup>-D for longer than **7 days**, without doctor's advice.

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

The duration of treatment with Zyrtec<sup>®</sup>-D should not exceed the period of acute symptoms. If your nasal symptoms (blocked nose, runny nose) improved, you should continue treatment only with anti-allergy substance (cetirizine).

→ **Consult your doctor or pharmacist** if you are not sure.

### **IF YOU FORGET TO TAKE ZYRTEC<sup>®</sup>-D**

If you forget to take a tablet, take it as soon as you remember. However, the subsequent tablets must be spaced 12 hours apart.

Do not take more than two tablets in 24 hours.

### **IF YOU TAKE TOO MUCH ZYRTEC<sup>®</sup>-D**

If you take too many tablets of Zyrtec<sup>®</sup>-D you may experience the following systems: irregular heartbeat, rapid heart rate, high blood pressure, vomiting, diarrhoea, dilated pupils, dizziness, fatigue, headache, malaise, inability to pass urine, depression of the central nervous system (sedation, breathing difficulties, loss of consciousness, bluish discolouration due to oxygen deficiency (cyanosis) collapse due to very low blood pressure (circulatory collapse) or stimulation of the central nervous system (difficulty in sleeping (insomnia), seeing or hearing things that are not really there (hallucinations), tremor, fits (seizures)).

**→ Do not delay. Contact your doctor or your nearest hospital emergency department immediately.** If possible, show them the Zyrtec<sup>®</sup>-D pack.

## **POSSIBLE SIDE EFFECTS**

Like all medicines, Zyrtec<sup>®</sup>-D can cause side effects, but not everybody gets them.

### **Conditions you need to look out for:**

**Allergic reaction or potentially serious skin reaction.** Signs include:

- **skin rash**
- **raised and itchy rash** (hives)
- **swelling of the face, tongue or throat** (angioedema), causing **difficulty in breathing**
- small patches of **swelling** and **redness of the skin**, which may blister (fixed drug eruption)
- **collapse or loss of consciousness**

**Sudden onset of severe headache, nausea, vomiting, and visual disturbances**, these may be signs of a condition called posterior reversible encephalopathy (PRES) or reversible cerebral vasoconstriction syndrome (RCVS).

**→ Contact a doctor immediately** if you get these symptoms. **Stop taking Zyrtec<sup>®</sup>-D.**

### **Common Side Effects**

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

- rapid heart rate
- dry mouth
- feeling sick (nausea)
- weakness (asthenia), dizziness, feeling drowsy, headache, spinning sensation, nervousness, difficulty in sleeping (insomnia)

### **Uncommon Side Effects**

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

- anxiety, agitation

### **Rare Side Effects**

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

- allergic reaction (hypersensitivity), rash, hives (see ‘Allergic reaction or potentially serious skin reaction’ as in above section)
- high blood pressure, irregular heart beat
- pale skin, excessive sweating, dry skin,
- seeing or hearing things that are not really there (hallucination)
- abnormal liver function (increase in certain enzymes),

- pain when passing urine
- fits (seizures), tremor
- being sick (vomiting)

### **Very Rare Side Effects**

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

- fixed drug eruption, angioneurotic oedema (see ‘Allergic reaction or potentially serious skin reaction’ as in above section)
- inflammation and injury of the large intestine (colitis ischaemic)
- collapse due to very low blood pressure (circulatory collapse)
- taste disturbance (dysgeusia)
- psychosis
- stroke

### **Other Side Effects**

Other side effects have also occurred in a very small number of people but their exact frequency is unknown:

- blurred vision, dilated pupils, eye pain, visual impairment,
- uncomfortable sensitivity to light (photophobia)
- difficulty getting and keeping an erection
- shortness of breath (dyspnoea)

➔ **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.

### **HOW SHOULD YOU KEEP THIS MEDICINE?**

Keep out of reach and sight of children.

Do not take Zyrtec<sup>®</sup>-D after the expiry date shown on the pack.

Store in original packaging, below 30°C in a dry place.

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.

### **WHAT ZYRTEC<sup>®</sup>-D CONTAINS**

The active substances are cetirizine dihydrochloride and pseudoephedrine hydrochloride.

Each tablet contains 5 mg cetirizine dihydrochloride in an immediate release form and 120 mg pseudoephedrine hydrochloride in a prolonged-release form.

The other ingredients are:

Hypromellose, Microcrystalline cellulose, Colloidal anhydrous silica, Magnesium stearate, Lactose monohydrate, Croscarmellose sodium, Titanium dioxide (E171), Macrogol 400.

### **WHAT ZYRTEC<sup>®</sup>-D LOOKS LIKE AND CONTENTS OF PACK**

Prolonged-release tablet – white to off-white, round biconvex film-coated tablet having a circular logo on one side.

**UCB Farchim SA**

**Z.I. de Planchy**

**10 Chemin de Croix Blanche**

**CH-1630 Bulle - Switzerland**