Zyrtec-D

NAME OF THE MEDICINAL PRODUCT

Zyrtec-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-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.

After consultation with the doctor, 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 is contraindicated in children under 12 years of age (see Sections *Contraindications; Warnings and Precautions*).

Elderly

Zyrtec-D should be used with caution in patients over 50 years of age. The dose should be reduced to one tablet daily for patients ≥ 77 years old.

Renal Impairment

The dose should be reduced to one tablet daily in patients with mild to moderate renal insufficiency. Zyrtec-D 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-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,
- phaeochromocytoma,
- 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 monoamine 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-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 (eg. phenylpropanolamine, phenylephrine, ephedrine), 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 central nervous system (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*)
- patients with medical conditions where anticholinergic activity is undesirable and specifically in patients with predisposing factors of urinary retention (e.g. spinal cord lesion, prostatic hyperplasia, prostatic hypertrophy, or bladder outflow obstruction) as cetirizine/pseudoephedrine may increase the risk of urinary retention.

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 (including 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 (for example 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 non-steroidal anti-inflammatory drugs (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.

Ischaemic colitis

Some cases of ischemic colitis with pseudoephedrine-containing medicines have been reported. The use of the medicine should be discontinued and it is advisable to consult a doctor if abdominal pain, rectal bleeding or other symptoms of ischemic colitis occur suddenly.

Ischaemic optic neuropathy

Cases of ischaemic optic neuropathy have been reported with pseudoephedrine.
The use of the medicine should be discontinued if sudden loss of vision or decreased visual acuity such as scotoma occurs.

Children under 12 years of age

Zyrtec-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 (phenazone) 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, antipyrine (phenazone) 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 steady-state AUC (area under the curve) value for 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 methyldopa, 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-D therefore should be avoided in patients treated with cardiac glycosides (see Section *Warnings and Precautions*).

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

Studies conducted in rats showed no significant effect on fertility. There are no available data on fertility in humans.

Pregnancy

Zyrtec-D should not be used during pregnancy.

There are no adequate data on the use of Zyrtec-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 postnatal development.

Lactation

Zyrtec-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, where 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 ≥1/10
Common ≥1/100 to <1/10
Uncommon ≥1/1000 to <1/100
Rare ≥1/10000 to <1/1000
Very rare <1/10000
Not known (cannot be estimated from the available data).

Immune system disorders

Rare: hypersensitivity reactions (including anaphylactic shock)

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, ischaemic optic neuropathy

Cardiac disorders

Common: tachycardia

Rare: arrhythmia

Not known: palpitations

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

Not known: acute generalized exanthematous pustulosis

Renal and urinary disorders

Rare: dysuria

Not known: urinary retention

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 overdosage with Zyrtec-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.

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_1-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 (≥ 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. There are no carcinogenicity studies of pseudoephedrine in combination with cetirizine. The combination cetirizine/pseudoephedrine is neither mutagenic nor clastogenic. Reproduction toxicology studies in male and female rats using oral doses up to 160 mg/kg/day (containing 6.4 mg/kg cetirizine and 153.6 mg/kg pseudoephedrine, 1:24), producing systemic exposure to cetirizine 2- to 3-fold higher than the therapeutic exposure in humans, have shown 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.

At higher doses of 160 mg/kg/day, no teratogenic effects were observed, but effects on the mother and offspring were seen (total or partial loss of the litter, reduced growth of the offspring, delayed general development) (see Section *Pregnancy and Lactation*).

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 or child resistant OPA/Alu/PVC-Alu/Paper 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: NCDS06(SI)

Version date: 18 November 2019

[GSK LOGO]

NAME OF PRODUCT
Zyrtec-D

WHAT ZYRTEC-D IS
Zyrtec-D is a combination of an anti-histamine (cetirizine dihydrochloride) and a decongestant (pseudoephedrine hydrochloride).

Zyrtec-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-D USED FOR?
Zyrtec-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-D is indicated for adults and adolescents from 12 years of age and above.

BEFORE YOU TAKE ZYRTEC-D
Do not take Zyrtec-D:
- if you are **allergic** to cetirizine, ephedrine, or any other ingredients (see Section *What Zyrtec-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-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-D
Talk to your doctor or pharmacist **before** taking Zyrtec-D:
- if you are taking any other medicines, including those administered by a different route (see Section *Other medicines and Zyrtec-D*)
- if you have **liver problems** (your doctor may lower your dose of Zyrtec-D)
- if you have **kidney problems** (your doctor may lower your dose of Zyrtec-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** or unable to pass urine
- 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** (such as from chronic inflammatory bowel disease)
- if you are scheduled for allergy testing (Zyrtec-D may affect your allergy test results)
- if you have sudden abdominal pain or rectal bleeding due to inflammation of the colon (ischaemic colitis)
- if you have reduced blood flow to the optic nerve (Ischaemic optic neuropathy)

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

Conditions you need to look out for

Medicines like Zyrtec-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-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-D

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

Do not take Zyrtec-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-D works, or make it more likely that you'll have side effects. Zyrtec-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-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-D, tell your doctor

Breast-feeding is not recommended during treatment with Zyrtec-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-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-D CONTAINS LACTOSE
Zyrtec-D tablets contain lactose. If you have an intolerance to some sugars:

➔ **Check with your doctor** that Zyrtec-D is suitable for you.

HOW TO TAKE ZYRTEC-D
How much to take
Always take Zyrtec-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-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-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-D with or without food.

Don't take Zyrtec-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-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-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-D

If you take too many tablets of Zyrtec-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-D pack.

POSSIBLE SIDE EFFECTS

Like all medicines, Zyrtec-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-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) including anaphylactic shock, 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, ischaemic optic neuropathy
- uncomfortable sensitivity to light (photophobia)
- difficulty getting and keeping an erection
- shortness of breath (dyspnoea)
- severe skin reactions characterized by fever and numerous small, superficial pustules, arising within large areas of redness (Acute generalized exanthematous pustulosis)
- irregular heart beat (palpitations)
- pain when passing urine (dysuria) or inability to pass urine (urinary retention)

➔ **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-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-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-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.

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