

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**
- 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)

→ 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 starting 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,
- 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)

➔ **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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