

PART III: CONSUMER INFORMATION

^{Pr}**CETIRIZINE**
Cetirizine Hydrochloride Tablets

This leaflet is part III of a three-part "Product Monograph" published when CETIRIZINE was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about CETIRIZINE. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION**What the medication is used for:**

Adults and children 12 years of age and over: CETIRIZINE is indicated for the fast relief of nasal and non-nasal seasonal (e.g. tress, grass, pollen, ragweed/hay fever) and year-round (e.g. dust, animal dander, mold) allergy symptoms, including: sneezing, runny nose, post-nasal discharge nasal congestion/stuffiness, itchy, watery eyes, itchy nose/throat, and itching and hives due to allergic skin reactions.

What it does:

Your allergy symptoms are simply your body's over reaction in trying to protect you from allergens such as dust, ragweed, grass and tree pollen, animal dander or mold. When allergens are detected, the cells in your body release a chemical called histamine which binds to specific histamine receptors in your skin and tissues. The resulting reaction causes itchy, watery eyes, sneezing and runny nose. CETIRIZINE help relieve your allergy symptoms by blocking these receptor sites before histamine binds there, preventing or reducing many of the symptoms of an allergic reaction. CETIRIZINE anti-inflammatory properties also help by reducing swelling and related symptoms, including redness and hives (red, itchy bumps or welts on your skin).

CETIRIZINE can start to work in just 20 minutes, and provides effective relief of your worst allergy symptoms for a full 24 hours!

When it should not be used:

CETIRIZINE (cetirizine hydrochloride) is contraindicated in those patients with a known hypersensitivity to it or to its parent compound, hydroxyzine, in patients who are hypersensitive to any other ingredient in the formulation (see list of non-medicinal ingredients – below), or in patients with severe kidney impairment (less than 10 mL/min creatinine clearance).

What the medicinal ingredient is:

Cetirizine hydrochloride

What the nonmedicinal ingredients are:

corn starch, hypromellose, lactose, magnesium stearate, polyethylene glycol, povidone and titanium dioxide.

What dosage forms it comes in:

Tablets: 20 mg.

WARNINGS AND PRECAUTIONS

BEFORE you use CETIRIZINE Tablets talk to your doctor or pharmacist if you are pregnant or nursing a baby, or have liver or kidney disease. Some people can experience drowsiness due to allergies or antihistamine use. If drowsiness does occur with CETIRIZINE use, do not drive a car or operate machinery. **KEEP OUT OF REACH OF CHILDREN.**

INTERACTIONS WITH THIS MEDICATION

Do not use CETIRIZINE with sedating substances such as alcohol and some other medications, including: anti-anxiety medications, sleep aids, antihistamines, antidepressants, muscle relaxants, or prescription analgesics.

PROPER USE OF THIS MEDICATION**Usual dose:****Tablets (taken with or without food):**

Adults and children 12 years of age and over: 5 mg to 10 mg, depending on the severity of symptoms, once daily. If sufficient relief is not obtained, consult a physician.

Adults 65 years of age and over: 5 mg once daily. Consult a doctor if unsure about dosage.

If you do not get the results you expect, talk with your doctor. Cetirizine hydrochloride tablets come in different doses (5 mg, 10 mg and 20 mg). Cetirizine hydrochloride 5 mg and 10 mg tablets are also available without prescription; please consult your physician. You and your doctor can determine the dose that works best for you.

DO NOT EXCEED RECOMMENDED DOSAGE. Prolonged use only as directed by a doctor. Not recommended for use in children under 12 years of age.

Overdose:

Overdose has been reported with cetirizine hydrochloride. Symptoms reported after an overdose of at least five times the recommended daily dose are: confusion, diarrhea, dizziness, sleepiness, headache, fatigue, feeling of bodily discomfort, excessive dilation of the pupil, itching, restlessness, sedation, lowered level of consciousness, rapid heartbeat, tremor and inability to urinate. In case of suspected overdose or if any of these symptoms occur, stop taking the drug and immediately contact your doctor or the Poison Control centre at once. Treatment in a hospital setting is preferred. Notify of any other medications you may have been taking. **VOMITING SHOULD NEVER BE INDUCED IN UNCONSCIOUS INDIVIDUALS OR IN CHILDREN UNDER 1 YEAR WITHOUT MEDICAL HELP.**

For management of a suspected drug overdose, contact your health care practitioner, hospital emergency department, or regional Poison Control Center immediately, even if there are no symptoms.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

The most common side effects associated with CETIRIZINE are headache, sleepiness and dry mouth. If these side effects do not go away, call your doctor or pharmacist.

This is not a complete list of side effects. For any unexpected effects while taking CETIRIZINE, contact your doctor or pharmacist.

HOW TO STORE IT

Store between 15°C and 30°C.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701E
Ottawa, Ontario
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be obtained by contacting the sponsor, Pro Doc Ltée, at: 1-800-361-8559

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