

PATIENT MEDICATION INFORMATION**READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE****PRO-CETIRIZINE****Cetirizine Hydrochloride Tablets**

Read this carefully before you start taking PRO-CETIRIZINE and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about PRO-CETIRIZINE.

What is PRO-CETIRIZINE used for?

PRO-CETIRIZINE 20 mg tablet is used in adults and children 12 years of age and older for the fast relief of nasal and non-nasal seasonal (e.g., trees, 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.

How does PRO-CETIRIZINE work?

Your allergy symptoms are simply your body's overreaction 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. PRO-CETIRIZINE helps relieve your allergy symptoms by blocking these receptor sites before histamine binds there, preventing or reducing many of the symptoms of an allergic reaction. The anti-inflammatory properties of PRO-CETIRIZINE also help by reducing swelling and related symptoms, including redness and hives (red, itchy bumps or welts on your skin).

What are the ingredients in PRO-CETIRIZINE?

Medicinal ingredient: Cetirizine Hydrochloride

Non-medicinal ingredients: Corn Starch, Hypromellose, Lactose Monohydrate, Magnesium Stearate, Polyethylene Glycol, Povidone and Titanium Dioxide.

PRO-CETIRIZINE comes in the following dosage forms:

Tablets: 20 mg

Do not use PRO-CETIRIZINE if:

- you are allergic (hypersensitive) to cetirizine hydrochloride, hydroxyzine, piperazine derivatives or any of the other ingredients in PRO-CETIRIZINE (see **What are the ingredients in PRO-CETIRIZINE?**)
- you have serious kidney problems

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take PRO-CETIRIZINE 20 mg tablet. Talk about any health conditions or problems you may have, including if you:

- have kidney or liver problems
- are pregnant or planning to become pregnant are breastfeeding or planning to breastfeed
- are 65 years of age or older.

Other warnings you should know about:

- **Serious skin reactions:** Serious skin reactions, such as acute generalized exanthematous pustulosis (AGEP), have been reported in patients taking products that contain cetirizine, the medicinal ingredient found in PRO-CETIRIZINE. This reaction can happen soon after taking PRO-CETIRIZINE or it can be delayed. See the **Serious side effects and what to do about them** table, below, for more information on this and other serious side effects.
- **Driving and using machines:** PRO-CETIRIZINE can cause drowsiness. Give yourself time after taking PRO-CETIRIZINE to see how you feel before driving a vehicle or using machinery. If drowsiness occurs, do not drive or operate machinery.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with PRO-CETIRIZINE:

- Alcohol
- Other substances that cause sedation such as anti-anxiety medications, sleep aids, antihistamines, antidepressants, muscle relaxants and pain medication.

How to take PRO-CETIRIZINE:

PRO-CETIRIZINE 20 mg tablet can be taken with or without food.

Usual dose:

Children 12 years of age and over and adults: One tablet once per day.

Overdose:

Symptoms of an overdose include: confusion, diarrhea, dizziness, sleepiness, headache, fatigue, feeling of bodily discomfort, large pupils, itching, restlessness, sedation, lowered level of consciousness, rapid heartbeat, high blood pressure, tremor and inability to urinate. Extreme activity and extreme lack of energy have been seen in children.

If you think you, or a person you are caring for, have taken too much PRO-CETIRIZINE, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

Missed Dose:

If you missed a dose of this medication, you do not need to make up the missed dose. Skip the missed dose and continue with your next scheduled dose. Do not take two doses at the same time. Do not exceed the maximum daily dose.

What are possible side effects from using PRO-CETIRIZINE?

These are not all the possible side effects you may have when taking PRO-CETIRIZINE. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- Headache
- Sleepiness, fatigue
- Dry mouth
- Loss of taste
- Nausea
- Dizziness
- Trouble sleeping (insomnia)
- Eye pain or swelling
- Blurred vision
- Erectile dysfunction

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
VERY RARE			
Agitation, aggressiveness		✓	
Allergic Reaction: rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing			✓
Difficulty urinating		✓	
Hallucinations: seeing or hearing things that are not really there			✓
Liver Problems: yellowing of the skin or eyes (jaundice), right upper stomach area pain or swelling, nausea or vomiting, unusual dark urine, unusual tiredness		✓	
Memory problems, partial or total memory loss		✓	
New rash or itching after stopping drug		✓	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
Restlessness with increased body movement		✓	
Severe Skin Reaction: rash with small pimples and redness on the skin folds, trunk and arms, with or without fever			✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (canada.ca/drug-device-reporting) for information on how to report online by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store between 15°C and 30°C.

Keep out of the reach and sight of children.

If you want more information about PRO-CETIRIZINE:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Consumer Information by visiting the Health Canada website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>) or by contacting Pro Doc Ltée at 1-800-361-8559, www.prodoc.qc.ca or info@prodoc.qc.ca.

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