

IMPORTANT: PLEASE READ

PART III: CONSUMER INFORMATION

PrCETIRIZINE
20 mg Tablet
(Cetirizine hydrochloride tablets)
Manufacturer's Standard

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:

CETIRIZINE (cetirizine hydrochloride) is used in adults and children 12 years of age and older for the fast, 24-hour 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.

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 (cetirizine hydrochloride) 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 CETIRIZINE also help by reducing swelling and related symptoms, including redness and hives (red, itchy bumps or welts on your skin).

When it should not be used:

Do not take CETIRIZINE (cetirizine hydrochloride) if you:

- are allergic (hypersensitivity) to cetirizine hydrochloride, hydroxyzine, piperazine derivatives or any of the other ingredient in CETIRIZINE.
- have serious kidney problems.

What the medicinal ingredient is:

Cetirizine hydrochloride

What the nonmedicinal ingredients are:

carnauba wax, cornstarch, hydroxypropyl methylcellulose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polydextrose, polyethylene glycol, titanium dioxide.

What dosage form it comes in:

Tablets: 20 mg

WARNINGS AND PRECAUTIONS

BEFORE you use CETIRIZINE tablets, talk to your doctor or pharmacist 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.

Driving and using machines: CETIRIZINE can cause drowsiness. If drowsiness occur do not drive or operate machinery.

INTERACTIONS WITH THIS MEDICATION

The following may interact with CETIRIZINE tablet:

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

PROPER USE OF THIS MEDICATION

CETIRIZINE Tablets can be taken with or without food.

Usual dose:

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

CETIRIZINE should not be taken by:

- *Adults 65 years of age and over*
- *Patients with liver or kidney problems*

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- *Children less than 12 years of age*

Overdose:

If you think you have taken too much CETIRIZINE contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

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.

Missed Dose:

If you miss taking your dose on time, do not worry; take your dose when you remember. Do not take more than one dose in 24 hours.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

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, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom/effect	Talk with your doctor or pharmacist		Stop taking drug and seek 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		√	
Memory problems, partial or total memory loss		√	
New rash or itching after stopping drug		√	
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			√

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

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HOW TO STORE IT

Store at room temperatures 15°C to 30°C.

Keep out of the reach and sight of children.

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 (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) 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.

MORE INFORMATION

If you want more information about 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://health-products.canada.ca/dpd-bdpp/index-eng.jsp>). Find the Consumer Information on the manufacturer's website www.sivem.ca, or by calling 1 855-788-3153.

This leaflet was prepared by Sivem Pharmaceuticals ULC.

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