

IMPORTANT: PLEASE READ

PART III: CONSUMER INFORMATION

^{Pr} RAMIPRIL-HCTZ
(ramipril and hydrochlorothiazide Tablets)

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

ABOUT THIS MEDICATION

What the medication is used for

RAMIPRIL-HCTZ was prescribed to you by your doctor to lower your blood pressure.

What it does

RAMIPRIL-HCTZ contains ramipril, which is one of a group of medicines called ACE (angiotensin converting enzyme) inhibitors which acts on the heart and blood vessel. Ramipril blocks an enzyme in the body that is necessary to produce a substance that causes blood vessels to tighten.

RAMIPRIL-HCTZ contains also hydrochlorothiazide which is one of a group of medicines called diuretics. Diuretics are sometimes called water pills. They lower the amount of salt and water in your body, which helps to lower your blood pressure.

When it should not be used

You must not take RAMIPRIL-HCTZ if:

- You have had an allergic reaction to ramipril, any other ACE inhibitor, hydrochlorothiazide, thiazide diuretics, any of the ingredients in this medicine or sulfonamide-derived drugs
- You have a history of angioedema (swelling around your face, throat or tongue)
- You are pregnant or breast feeding

What the medicinal ingredients are

RAMIPRIL-HCTZ contains ramipril and hydrochlorothiazide.

What the important nonmedicinal ingredients are
RAMIPRIL-HCTZ 5mg/12.5 mg, 10 mg/12.5mg, and 10 mg/25 mg tablets contain the following non medicinal ingredients: Colloidal Silicon Dioxide, Crospovidone (XL), Hypromellose, Microcrystalline cellulose (Vivapur 12), Lactose Monohydrate and Sodium Stearyl Fumarate. The 5 mg/12.5 mg and 10 mg/25 mg contain also Red Iron Oxide and the 10 mg/12.5 mg strength contain also Iron Oxide IC07434 (Yellow #10) and Red Iron Oxide.

What dosage forms it comes in

RAMIPRIL-HCTZ is available in tablets of the following strengths.

- 5 mg ramipril/12.5 mg hydrochlorothiazide
- 10 mg ramipril/12.5 mg hydrochlorothiazide
- 10 mg ramipril/25 mg hydrochlorothiazide

WARNINGS AND PRECAUTIONS

Serious Warning and Precautions RAMIPRIL-HCTZ *should not be used during pregnancy. If you discover that you are pregnant while taking RAMIPRIL-HCTZ, stop the medication and please contact your physician.*

Have you told your doctor everything about your condition and of any problems you may have had with taking medicines in the past?

BEFORE you use RAMIPRIL-HCTZ talk to your doctor or pharmacist if:

- You have to perform tasks that require special attention (for example, operating a vehicle or machinery);
- You have heart problems or if you have any kidney or liver diseases
- You are on haemodialysis;
- You are allergic to RAMIPRIL-HCTZ or any of its ingredients;
- You have a history of angioedema (swelling around your face, throat or tongue);
- You have lupus erythematosus (disorders of the immune system) or scleroderma (disease that can cause thickening, hardening, or tightening of the skin, blood vessels and internal organs);
- **You are pregnant, breast-feeding or thinking of becoming pregnant**

Taking RAMIPRIL-HCTZ during pregnancy can cause injury and even death to the foetus. This medicine should not be used during pregnancy. If you become pregnant while taking RAMIPRIL-HCTZ, stop the medication and report promptly to your doctor. It is not known if RAMIPRIL-HCTZ passes into breast milk. You should not breast-feed while taking RAMIPRIL-HCTZ.

INTERACTIONS WITH THIS MEDICATION

Some drugs may have negative effect on RAMIPRIL-HCTZ, or RAMIPRIL-HCTZ may have negative effect on other drugs. If you are currently taking a medication, whether on prescription or otherwise, inform your doctor or pharmacist.

Drugs that may interact with RAMIPRIL-HCTZ include:

- Diuretics (water pills), potassium retaining diuretics;
- Medicines for high blood pressure, heart disease;
- Lithium salts;
- Antidiabetic agents
- Digitalis preparation (Digoxin)
- Non steroidal anti-inflammatory drugs
- Corticosteroids;
- Sympathomimetics which may be found in some decongestants, cough/cold medicines;
- Anaesthetics.

Avoid alcoholic beverages until you have discussed their use with your doctor. Alcohol consumption may alter your blood pressure and/or increase the possibility of dizziness or fainting.

PROPER USE OF THIS MEDICATION

It is important to take RAMIPRIL-HCTZ at the same time every day as prescribed by your doctor. Generally, it is recommended that the daily dose be administered in the morning.

Swallow your tablet whole with sufficient amount of water (approximately half a glass), before, during or after meal. Do not chew or crush the tablets.

Usual dose

Your starting dose will be determined by your doctor

taking into account pre-existing blood pressure treatment. The maximum daily dose of RAMIPRIL-HCTZ is 10 mg/50 mg.

Overdose

In case of overdosage, contact your doctor, nearest hospital emergency department or regional poison control center.”

Missed Dose

If a dose of this medication has been missed, it should be taken as soon as possible. However, if it is almost time for the next dose, skip the missed dose and go back to the regular dosing schedule. Do not double doses.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Along with its intended action, RAMIPRIL-HCTZ may cause side effects. After you have started taking RAMIPRIL-HCTZ, it is important that you tell your doctor at once about any unexplained symptom you might experience. Examples of occasional side effects include:

- Dizziness
- Headache
- Flu-like symptoms such as sore throat, fever, malaise, muscle pain, rash, nausea, vomiting, diarrhea
- Dry cough, mouth ulcer, tongue pain
- Chest pain
- Unusual tiredness and/or weakness
- Palpitations and tachycardia
- Mood changes, nervousness, restlessness, confusion
- Problems with sleeping
- Sexual difficulties in men
- Very small number of people find that this medicine affects their sense of taste and smell.

If you feel ill after you have started taking RAMIPRIL-HCTZ tablets, or notice anything unusual or unexpected, tell your doctor or seek medical assistance.

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 call your doctor or pharmacist*
		Only If Severe	In all cases	
Common	<i>Hypersensitivity Reactions</i> Skin rash, skin eruption or other effect on the skin or eyes, itching or fever			√
Uncommon	Abdominal pain		√	
	<i>Hypotension</i> Fainting when the Blood Pressure is Too low			√
	<i>Allergic reactions</i> Swelling of the lips, face or neck, accompanied by difficulty in breathing, speaking or swallowing (signs of angioedema). Intestinal angioedema may also occur and is characterized by abdominal pain (with or without nausea or vomiting)			√
	<i>Liver disorder</i> Symptoms include nausea, loss of appetite, vomiting combined with itching, upper abdominal pain, yellowing of the skin or eyes (sign of jaundice or hepatitis)			

*** If you think you have these side effects, it is important that you seek medical advice from your doctor immediately.**

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

HOW TO STORE IT

Store RAMIPRIL-HCTZ in original container at room temperature, between 15°C - 25°C and not beyond the date indicated on the container. Protect from heat and humidity.

Keep out of reach of children.

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, ON 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 the side effect, 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 Pro Doc Ltée at 1-800-361-8559, www.prodoc.qc.ca or info@prodoc.qc.ca.

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