

PART III: CONSUMER INFORMATION

PrRAMIPRIL
(ramipril)
Manufacturer's Standard

Read this carefully before you start taking RAMIPRIL and each time you get a refill. This leaflet is a summary and will not tell you everything about RAMIPRIL. Talk to your doctor, nurse, or pharmacist about your medical condition and treatment and ask if there is any new information about RAMIPRIL.

ABOUT THIS MEDICATION

What the medication is used for:

High Blood Pressure (Hypertension)

RAMIPRIL lowers high blood pressure. It can be used alone or together with a diuretic ("water pill").

Managing your lifestyle

Keeping your blood pressure controlled

It takes more than just medication to reduce blood pressure. Discuss the risk factors, and how they apply to your lifestyle, with your doctor. You may have to modify some of your daily habits to keep your blood pressure down.

Exercise regularly. It will help to keep your weight down, make you feel more energetic and is a good way to deal with stress. If you are not exercising regularly, be sure to discuss a fitness plan with your doctor.

Remember, hypertension is a long-term disease without symptoms. Just because you feel fine does not mean you can stop taking your medication. If you stop, serious complications of the disease may occur. Therefore, you should continue to take RAMIPRIL regularly, as prescribed by your doctor.

The "lifestyle" part of your treatment is as important as your medication. By working as a team with your doctor, you can help reduce the risk of complications to maintain the style of life you are accustomed to.

- **Alcohol:** 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.
- **Diet:** Generally, avoid fatty foods and food that is high in salt or cholesterol.
- **Smoking:** Avoid it completely.

What it does:

RAMIPRIL is an angiotensin converting enzyme (ACE) inhibitor. You can recognize ACE inhibitors because their

medicinal ingredient ends in '-PRIL'.

This medicine does not cure your disease. It helps to control it. Therefore, it is important to continue taking RAMIPRIL regularly even if you feel fine.

When it should not be used:

Do not take RAMIPRIL if you:

- Are allergic to ramipril or to any non-medicinal ingredient in the formulation.
- Have experienced an allergic reaction (angioedema) with swelling of the hands, feet, or ankles, face, lips, tongue, throat, or sudden difficulty breathing or swallowing, to any ACE inhibitor or without a known cause. Be sure to tell your doctor, nurse, or pharmacist that this has happened to you.
- Have been diagnosed with hereditary angioedema: an increased risk of getting an allergic reaction that is passed down through families. This can be triggered by different factors, such as surgery, flu, or dental procedures.
- Are pregnant or intend to become pregnant. Taking RAMIPRIL during pregnancy can cause injury and even death to your baby.
- Are breastfeeding. RAMIPRIL passes into breast milk.
- Are taking ENTRESTO® (sacubitril/valsartan), due to the increased risk of serious allergic reaction which causes swelling of the face or throat (angioedema) when taken with RAMIPRIL.
- Have narrowing of the arteries to one or both kidneys (renal artery stenosis).
- Have hypotension (low blood pressure).
- Are on dialysis or LDL apheresis (a treatment to remove LDL cholesterol from the blood).
- Are already taking a blood pressure-lowering medicine containing aliskiren (such as Rasilez) and you have one of the following conditions:
 - diabetes
 - kidney disease
 - high potassium levels
 - heart failure combined with low blood pressure
- Are taking an angiotensin receptor blocker (ARB), another medicine to treat your high blood pressure, or another ACE inhibitor **and** have one of the following conditions:
 - diabetes with end organ damage
 - kidney disease
 - high potassium levels
 - heart failure combined with low blood pressure

You can recognize an ARB because its medicinal ingredient ends in "-SARTAN".

What the medicinal ingredient is:

Ramipril

What the nonmedicinal ingredients are:

The qualitative formulation for all potencies of RAMIPRIL is: ramipril, calcium phosphate (dibasic), colloidal silicon

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dioxide, magnesium hydroxide, magnesium stearate, pregelatinized starch, talc and empty gelatin capsules.

Empty gelatin capsules for all potencies of RAMIPRIL are composed of gelatin, titanium dioxide and colouring agents specific to each potency (see below).

2.5 mg: Empty gelatin capsules colouring agents: D&C Yellow No.10 and FD&C Red No.40.

5.0 mg: Empty gelatin capsules colouring agents: D&C Red No. 33, FD&C Blue No. 1 and FD&C Red No. 40.

10.0 mg: Empty gelatin capsules colouring agents: D&C Red No. 28, FD&C Blue No. 1 and FDA/E172 Black Iron Oxide.

What dosage forms it comes in:

RAMIPRIL (ramipril) is available as a 2.5 mg, 5 mg and 10 mg capsule.

Capsules should be swallowed whole. DO NOT open, crush or chew the capsules.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions - Pregnancy

RAMIPRIL should not be used during pregnancy. If you discover that you are pregnant while taking RAMIPRIL, stop the medication and please contact your doctor, nurse, or pharmacist as soon as possible.

BEFORE you use RAMIPRIL, talk to your doctor, nurse, or pharmacist if you:

- Are allergic to any drug used to lower blood pressure.
- Have recently received or are planning to get allergy shots for bee or wasp stings.
- Have narrowing of an artery or a heart valve.
- Have had a heart attack or stroke.
- Have heart failure.
- Have diabetes, liver or kidney disease.
- Are on dialysis or LDL apheresis (a treatment to remove LDL cholesterol from the blood).
- Are dehydrated or suffer from excessive vomiting, diarrhea, or sweating.
- Are taking a salt substitute that contains potassium, potassium supplements, a potassium-sparing diuretic (a specific kind of “water pill”), or other medicinal products that may increase potassium. Use of RAMIPRIL with these medicines is not recommended.
- Are on a low-salt diet.
- Are receiving gold (sodium aurothiomalate) injections.
- Are less than 18 years old.
- Are taking a medicine that contains aliskiren, such as Rasilez, used to lower high blood pressure. The combination with RAMIPRIL is not recommended.
- Are taking an angiotensin receptor blocker (ARB). You can recognize an ARB because its medicinal ingredient ends in “-SARTAN”. The combination with RAMIPRIL is not recommended.

- Are taking drugs such as:
 - Temsirolimus and everolimus (used to treat cancer),
 - Sirolimus (used to prevent organ rejection after a transplant),
 - Sitagliptin or other gliptins (used to treat Type II diabetes)
 - A neutral endopeptidase inhibitor

Taking ACE inhibitors, such as RAMIPRIL, with these types of drugs may increase your chances of having an allergic reaction (angioedema). You may become sensitive to the sun while taking RAMIPRIL. Exposure to sunlight should be minimized until you know how you respond.

If you are going to have surgery and will be given an anesthetic, be sure to tell your doctor or dentist that you are taking RAMIPRIL.

Driving and using machines: Before you perform tasks which may require special attention, wait until you know how you respond to RAMIPRIL. Dizziness, lightheadedness, or fainting can especially occur after the first dose and when the dose is increased.

Raynaud’s phenomenon is a condition resulting from poor circulation in the extremities (i.e., fingers and toes). It may begin or get worse.

INTERACTIONS WITH THIS MEDICATION

As with most medicines, interactions with other drugs are possible. Tell your doctor, nurse, or pharmacist about all the medicines you take, including drugs prescribed by other doctors, vitamins, minerals, natural supplements, or alternative medicines.

The following may interact with RAMIPRIL:

- Agents increasing serum potassium, such as a salt substitute that contains potassium, potassium supplements, a potassium-sparing diuretic (a specific kind of “water pill”), or other medicinal products that may increase potassium. Use of RAMIPRIL with these medicines is not recommended.
- Alcohol
- Allopurinol used to treat gout.
- Antidiabetic drugs, including insulin and oral medicines, such as gliptins (e.g. sitagliptin).
- Lithium used to treat bipolar disease.
- Gold for the treatment of rheumatoid arthritis.
- Nonsteroidal anti-inflammatory drugs (NSAIDs), used to reduce pain and swelling. Examples include ibuprofen, naproxen, and celecoxib.
- Blood pressure lowering drugs, including diuretics (“water pills”), aliskiren-containing products (e.g. Rasilez), or angiotensin receptor blockers (ARBs).
- Nitrates used to treat angina (chest pain)
- Acetylsalicylic acid (aspirin)
- Heparin used to prevent and treat blood clots
- Immunosuppressants used to lower the body’s ability to

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- reject a transplanted organ
- Corticosteroids used to treat joint pain and swelling or for other conditions.
- Procainamide used to treat irregular heartbeat
- Cytostatic medicines used to treat certain types of cancer
- mTOR inhibitors (e.g. temsirolimus) used to lower the body's ability to reject a transplant (e.g. sirolimus) or to treat certain types of cancer (e.g. temsirolimus, everolimus)
- Neutral endopeptidase (NEP) inhibitors.

PROPER USE OF THIS MEDICATION

Take RAMIPRIL exactly as prescribed. It is recommended to take your dose at about the same time every day.

Usual adult dose:

High Blood Pressure: The recommended initial dosage of RAMIPRIL is 2.5 mg once daily. Your doctor will determine the appropriate dosage.

For patients taking diuretics (“water pills”) or with impaired kidney function: The recommended initial dosage of ramipril is 1.25 mg daily

Overdose:

If you think you have taken too much RAMPRIL, contact your doctor, nurse, pharmacist, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

If you have forgotten to take your dose during the day, carry on with the next one at the usual time. Do not double dose.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Side effects may include:

- Dizziness, difficulty in maintaining your balance while standing
- drowsiness, fatigue, weakness
- cough, nasal or sinus congestion, swollen lymph nodes, bronchitis, aggravated asthma
- rash, itching, flushing, inflammation of the eye (pink eye), skin inflammation or red skin, burning sensation, inflammation of the mouth or tongue
- headache
- abdominal pain
- sad mood, difficulty with sleep, restlessness, attention disturbances
- loss of hair
- taste modifications or loss of taste, vision or hearing modifications
- impotence/reduced libido, breast enlargement in males

If any of these affects you severely, tell your doctor, nurse

or pharmacist.

RAMIPRIL can cause abnormal blood test results. Your doctor will decide when to perform blood tests and will interpret the results.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom/Effect	Talk with your doctor, nurse, or pharmacist		Stop taking drug and seek immediate medical help	
	Only if severe	In all cases		
Common	Low Blood Pressure: dizziness, fainting, lightheadedness May occur when you go from lying or sitting to standing up.	√		
	Increased levels of potassium in the blood: irregular heartbeat, muscle weakness and generally feeling unwell		√	
Un-common	Allergic Reaction: rash, hives, swelling of the face, arms and legs, lips, tongue or throat, difficulty swallowing or breathing			√
	Kidney Disorder: change in frequency of urination, nausea, vomiting, swelling of extremities, fatigue		√	
	Liver Disorder: yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite		√	
	Electrolyte Imbalance: weakness, drowsiness, muscle pain or cramps, irregular heartbeat		√	
Rare	Decreased Platelets: bruising, bleeding, fatigue and weakness		√	
	Decreased White Blood Cells: infections, fatigue,		√	

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SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom/Effect	Talk with your doctor, nurse, or pharmacist		Stop taking drug and seek immediate medical help
	Only if severe	In all cases	
fever, aches, pains, and flu-like symptoms			
Heart Attack: chest pain and/or discomfort, pain in the jaw, shoulders, arm and/or back, shortness of breath, sweating, lightheadedness, nausea			√
Cerebro-vascular accident/stroke: weakness, trouble speaking, trouble seeing, headache, dizziness			√
Intestinal Angioedema: abdominal pain (with or without nausea or vomiting)			√

- 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

This document plus the full Product Monograph prepared for health professionals can be found by contacting:

Sanis Health Inc. at 1-866-236-4076;
or via email at quality@sanis.com

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

HOW TO STORE IT

Store in original container: bottles between 15°C to 30°C, and not beyond the date indicated on the container. Keep out of 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 (<http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>) for information on how to report online, by mail or by fax; or