

PART III: CONSUMER INFORMATION

PrRAMIPRIL

Ramipril Capsules, 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”).

Following a Recent Heart Attack

RAMIPRIL reduces the effort required by your heart to pump blood. This is to compensate for the reduced pumping power that may have resulted from your heart attack. RAMIPRIL has been shown to improve survival and reduce hospitalizations for heart failure in patients that are now clinically stable and recovering from recent heart attacks.

For the Management of Patients at Increased Risk of Cardiovascular Events

Your doctor has prescribed RAMIPRIL because:

- You have coronary heart disease (such as chest pains or angina, or have had a heart attack in the past)
- You had a stroke
- You have peripheral vascular disease (poor blood circulation)
- You have diabetes and at least one of the following physical conditions: high blood pressure, elevated total cholesterol levels, low high-density lipoprotein (HDL) levels, cigarette smoking or documented tiny amounts of albumin from your blood detected in your urine (microalbuminuria).

RAMIPRIL may lower the risk of heart attack, stroke, or death from heart disease in some patients who have a heart problem or poor blood circulation.

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’.

RAMIPRIL opens blood vessels to reduce blood pressure, just like the way opening a hose reduces water pressure.

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. You must wait at least 36 hours after your last dose of sacubitril/valsartan before taking 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 non-medicinal ingredients are:

Lactose monohydrate (spray-dried), magnesium stearate, talc, empty gelatin capsules (which are composed of gelatin, titanium dioxide and/ or iron oxide yellow and / or FD & C red no. 40 and/or D & C red no. 28 and/or FD & C blue no. 1 and/ or D & C yellow no.10 and/or iron oxide black) and black edible ink (which is composed of shellac glaze, iron oxide black, propylene glycol, and ammonium hydroxide).

What dosage forms it comes in:

Capsules: 1.25 mg, 2.5 mg, 5 mg and 10 mg

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 diabetes.
- Have liver disease. Your doctor should take blood tests to measure your liver function before you start taking RAMIPRIL and occasionally throughout your treatment.
- Have kidney disease. Your doctor should take regular blood tests to measure your kidney function and the levels of potassium in your blood.
- Have Raynaud’s phenomenon which is a condition resulting from poor circulation in the extremities (i.e., fingers and toes). It may begin or get worse.
- 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, or 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, light-headedness, or fainting can especially occur after the first dose and when the dose is increased.

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 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 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.

Following a Recent Heart Attack: The recommended initial dosage of RAMIPRIL is 2.5 mg given twice a day in the morning and in the evening for patients with clinical signs of heart failure (a condition in which the heart has difficulty pumping enough blood to the body's other organs). Treatment should be started under close medical supervision.

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

Management of Patients at Increased Risk of Cardiovascular Events: The recommended initial dosage of RAMIPRIL is 2.5 mg once daily. Your doctor will determine the appropriate dosage.

Overdose:

If you think you, or a person you are caring for, have taken too much RAMIPRIL, contact a healthcare professional, 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 to your healthcare professional		Stop taking drug and get immediate medical help
		Only if severe	In all cases	
Common	Low Blood Pressure: dizziness, fainting, light-headedness may occur when you go from lying or sitting to standing up.	✓		

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN 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	
	Increased levels of potassium in the blood: irregular heartbeat, muscle weakness and generally feeling unwell		✓	
Uncommon	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			✓

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN 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	
	Electrolyte Imbalance: weakness, drowsiness, muscle pain or cramps, irregular heartbeat		✓
Rare	Decreased Platelets: bruising, bleeding, fatigue, and weakness		✓
	Decreased White Blood Cells: infections, fatigue, 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		✓

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN 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	
	Cerebrovascular accident/Stroke: weakness, trouble speaking, trouble seeing, headaches, dizziness		✓
	Intestinal Angiodema: abdominal pain (with or without nausea or vomiting)		✓

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 at room temperature 15°C-30°C, in a well-closed container.

Keep this medication 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 **RAMIPRIL**:

- 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 Sivem Pharmaceuticals ULC at: 1-855-788-3153.
- Or at: www.sivem.ca

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