

PART III: CONSUMER INFORMATION

- Pr **PRO-ENALAPRIL - 2.5**
- Pr **PRO-ENALAPRIL - 5,**
- Pr **PRO-ENALAPRIL - 10**
- Pr **PRO-ENALAPRIL - 20**

Enalapril Maleate Tablets USP

This leaflet is part III of a three-part "Product Monograph" published when PRO-ENALAPRIL was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about PRO-ENALAPRIL. Contact your physician or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

PRO-ENALAPRIL is available **only on prescription** from your physician.

What the medication is used for:

PRO-ENALAPRIL is used for:

- reducing high blood pressure

When **blood pressure** is high, the workload of the heart and arteries increases so that over time, these organs may not function as they should. In turn, this could lead to damage of the "vital organs": brain - heart - kidneys, and result in stroke, heart failure, heart attack, blood vessel disease or kidney disease.

PRO-ENALAPRIL is used for:

- treating patients with heart failure

PRO-ENALAPRIL may also be used to treat patients with **heart failure**. This is a condition where the heart cannot pump adequate amounts of blood to satisfy the needs of the body.

If your physician has recommended a particular diet, for instance - less salt - follow the diet carefully. This could help your medicine to better control your blood pressure. Your physician may also recommend weight loss. Do follow these suggestions.

What it does:

PRO-ENALAPRIL is part of a class of medicines known as angiotensin converting enzyme (ACE) inhibitors. They lower blood pressure by specifically blocking a naturally occurring substance called angiotensin II. Angiotensin II normally tightens your blood vessels. PRO-ENALAPRIL allows them to relax and therefore help lower high blood pressure.

This medicine does not cure high blood pressure, **but does help control it**. So, it is important to continue taking the tablets regularly to keep your blood pressure

down. You may have to take high blood pressure medicine for life.

Keep your regular appointments with your physician, even if you feel well. High blood pressure may not be easily recognized by you, because you may not "feel any symptoms"; but your physician can measure your blood pressure very easily and check how the medicine is controlling it.

Read the following information carefully. **If you need any explanations, or further information, ask your physician or pharmacist.**

When it should not be used:

Do not take PRO-ENALAPRIL if you:

- are allergic to enalapril or any other component of PRO-ENALAPRIL (see What the important non- medicinal ingredients are).
- have a history of swelling of the face, lips, tongue, throat, or sudden difficulty breathing or swallowing-
- have been diagnosed with swelling of the face, lips, tongue, throat, or sudden difficulty breathing or swallowing due to genetic factors or unknown reasons (please refer to Side Effects and What to Do About Them).
- Are already taking a blood pressure-lowering medicine that contains aliskiren (such as RASILEZ) and you have diabetes or kidney disease.
- are taking a medicine containing a neprilysin inhibitor (e.g., sacubitril). Do not take PRO-ENALAPRIL for at least 36 hours before or after you take sacubitril/valsartan, a medicine containing a neprilysin inhibitor.

What the medicinal ingredient is:

enalapril maleate.

What the important nonmedicinal ingredients are:

lactose and zinc stearate.

The tablets also contain:

10 mg tablets: red ferric oxide

20 mg tablets: red and yellow ferric oxide

What dosage forms it comes in:

Tablets: 2.5 mg (white), 5 mg (white), 10 mg (reddish-pink) and 20 mg (peach).

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

PRO-ENALAPRIL should not be used during pregnancy. If you discover that you are pregnant while taking PRO-ENALAPRIL, stop the medication and please contact your physician as soon as possible.

This medicine may not be suitable for certain people. Tell your physician or pharmacist if you think **any** of the following applies to you:

- You have previously taken PRO-ENALAPRIL or other medication of the same type - Angiotensin Converting Enzyme (ACE) inhibitors such as enalapril, lisinopril, captopril, and you were allergic or reacted badly to it, particularly if you experienced swelling of the face, lips, tongue, or throat, or had sudden difficulty breathing or swallowing. These are symptoms of conditions called hereditary angioedema or idiopathic angioedema.
- Are taking a medicine that contains aliskiren, such as RASILEZ, used to lower high blood pressure. The combination with PRO-ENALAPRIL is not recommended.
- Are taking an angiotensin receptor blocker (ARB). You can recognize an ARB because its medicinal ingredient ends in “-SARTAN”.
- Are taking anti-cancer (temsirolimus, everolimus) or anti-rejection (sirolimus) medications. Use of ACE inhibitors, such as PRO-ENALAPRIL, with these drugs may increase the chance of having an allergic reaction (angioedema).
- **You should not take this medicine if you have been diagnosed with hereditary angioedema or idiopathic angioedema (angioedema of unknown cause).**
- Dizziness or drowsiness may occasionally occur when taking medication to lower blood pressure. Therefore, before you perform tasks which may require special attention (driving a car or operating dangerous machinery), wait until you know how you respond to your medicine.
- You should be aware that black patients are at increased risk of these types of reactions to ACE inhibitors.
- **You are pregnant, breast-feeding or thinking of becoming pregnant.** Taking PRO-ENALAPRIL during pregnancy can cause injury and even death to your developing baby. This medicine should **not** be used during pregnancy.

If you become pregnant while taking PRO-ENALAPRIL, stop the medication and report to your physician as soon as possible. It is possible that PRO-ENALAPRIL passes into breast milk. You should not breast-feed while taking PRO-ENALAPRIL.

- You suffer from low blood pressure (you may notice this as faintness or dizziness, especially when standing).
- You are undergoing dialysis.
- You have any of these conditions:
 - diabetes
 - heart or blood vessel disease
 - liver disease
 - kidney disease
- You are receiving gold (sodium aurothiomalate) injections.
- You are taking "water pills", potassium supplements or other drugs that may increase serum potassium (e.g., trimethoprim containing products).
- You use potassium containing salt substitutes with your food.
- You are taking a medicine containing a neprilysin inhibitor (e.g., sacubitril).

You should also inform your physician or pharmacist if you have recently suffered from excessive vomiting or have diarrhea.

If you have diabetes and are taking oral medicines to treat diabetes or insulin, you should closely monitor for low blood glucose levels, especially during the first month of treatment with PRO-ENALAPRIL.

If you have to undergo any dental or other surgery, inform the dentist or the physician in charge that you are taking this medicine.

Remember - This medicine is prescribed for the particular condition that you have. **Do not give this medicine to other people, nor use it for any other condition.**

Do not use outdated medicine.

INTERACTIONS WITH THIS MEDICATION

Do not take any other medicines unless you have discussed the matter with your physician or pharmacist. Certain medications tend to increase your blood pressure, for example, non-prescription preparations for appetite control, asthma, colds, coughs, hay fever and sinus problems, or may also react badly with PRO-ENALAPRIL.

Your physician or pharmacist also needs to know if you are taking any other medication, whether on prescription or otherwise. It is particularly important to inform your physician or pharmacist if you are taking:

- Diuretics or "water pills"; any other medicines to reduce blood pressure.
- Diabetes medicine and/or insulin.
- Blood pressure-lowering drugs, including diuretics ("water pills"), aliskiren-containing products (e.g. RASILEZ), or angiotensin receptor blockers (ARBs).
- Potassium-containing medicines, potassium supplements or other drugs that may increase serum potassium (e.g., trimethoprim-containing products).
- Salt substitutes that contain potassium, as these may lead to increased levels of potassium in the blood which can be serious. In these cases, your physician may need to adjust the dosage of PRO-ENALAPRIL or monitor your blood level of potassium.
- Lithium (a drug used to treat a certain kind of depression).
- Certain pain and arthritis medicines, including gold therapy and non-steroidal anti-inflammatory drugs.
- mTOR inhibitor (e.g., temsirolimus, sirolimus, everolimus) therapy or a medicine containing a neprilysin inhibitor (e.g., sacubitril). Taking these drugs together with PRO-ENALAPRIL could increase the risk for an allergic reaction called angioedema.

PROPER USE OF THIS MEDICATION

Usual Dose:

- Take this medicine exactly as your physician ordered.
- The absorption of this medicine is not affected by food; so it can be taken with or without a meal.
- Try to take your medicine every day at the same time. This way it becomes easy to remember your doses.
- The splitting of PRO-ENALAPRIL tablets is not advised.

For patients with high blood pressure:

Adults:

Your physician may adjust the dose according to your blood pressure response. The usual dose range is 10 mg to 40 mg per day given in a single dose or two divided doses. The maximum daily dose for PRO-ENALAPRIL oral administration is 40 mg.

Children (less than 16 years):

The usual starting dose is up to 5 mg once daily. Doses above 40 mg have not been studied.

For patients with congestive heart failure:

The initial dose is 2.5 mg taken once a day. Your physician will closely monitor you to determine the initial effect on your blood pressure. The usual daily dose is 5 mg to 20 mg given in a single dose or two divided doses. The maximum daily dose is 40 mg.

Overdose:

If you think you have taken too much PRO-ENALAPRIL contact your doctor, nurse, pharmacist, hospital emergency department or regional Poison control Centre immediately, even if there are no symptoms. The most likely symptom would be a feeling of lightheadedness or dizziness due to a sudden or excessive drop in blood pressure.

Missed Dose:

- If you miss a dose of this medicine, take it as soon as possible. However, if no more than six hours have elapsed since the missed dose, you may take that day's dose of medication and then go back to your regular dosing schedule. **Do not take a double dose.**

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Along with its intended action, any medication, including PRO-ENALAPRIL, may cause side effects. Most people do not experience any problem when taking these medicines; but if you notice any of the following, have other side effects or if the condition persists or worsens, seek medical attention.

- Dry cough, sore throat.
- The initial dose may cause a greater fall in blood pressure than will occur following continued treatment. You may notice this as faintness or dizziness and it may help to lie down. If concerned, please consult your physician or pharmacist.

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

Symptom / effect		Talk with your physician or pharmacist		Stop taking drug and call your physician or pharmacist
		Only if severe	In all cases	
Common	Fatigue	√		
	Dizziness/Fainting/Lightheadedness, especially following exercise, and/or when it is hot and you have lost a lot of water by sweating			√
	Low blood pressure		√	
	Headache	√		
	Rash/Itching		√	
	Nausea/Vomiting/Diarrhea	√		
	Lasting cough		√	
	Chest pain		√	
	Shortness of breath		√	
Uncommon	Allergic reactions/Angioedema (sudden difficulty in breathing or swallowing, swelling of face, eyes, lips, tongue and/or throat, hands or feet)			√
	Flu-like symptoms (fever, malaise, muscle pain, rash, itching, abdominal pain, nausea, vomiting, diarrhea, jaundice, loss of appetite)			√

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

Symptom / effect		Talk doctor or pharmacist		Stop taking drug and seek immediate medical help
		Only if severe	In all cases	
	Liver impairment such as jaundice, dark/brown urine		√	
	Abdominal pain	√		
	Low blood sugars in diabetic patients	√		
	Loss of appetite	√		

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

HOW TO STORE IT

Store your tablets at 15°C to 30°C, in a tightly closed container, away from heat and direct light, and out of damp places, such as the bathroom or kitchen.

Keep all medicines 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

PRO-ENALAPRIL:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this patient medication 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 it 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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