

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrPRO-LISINOPRIL-5

PrPRO-LISINOPRIL-10

PrPRO-LISINOPRIL-20

Lisinopril Tablets

Read this carefully before you start taking **PRO-LISINOPRIL** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **PRO-LISINOPRIL**.

Serious Warnings and Precautions

- PRO-LISINOPRIL should not be used during pregnancy. Taking it during pregnancy can cause injury or even death to your baby. If you discover that you are pregnant while taking PRO-LISINOPRIL, stop the medication and contact your healthcare professional as soon as possible.

What is PRO-LISINOPRIL used for?

PRO-LISINOPRIL is used in adults:

- To treat high blood pressure (hypertension);
- With other medications to treat heart failure, where the heart does not pump your blood around your body as well as it should;
- To lower the risk of having a heart attack (myocardial infarction) in patients who have already had a heart attack.

PRO-LISINOPRIL is used in children (6 to 16 years of age) to treat high blood pressure.

How does PRO-LISINOPRIL work?

PRO-LISINOPRIL belongs to a group of medicines called angiotensin converting enzyme (ACE) inhibitors. You can recognize ACE inhibitors because their medicinal ingredient ends in '-PRIL'.

PRO-LISINOPRIL works by widening your blood vessels, which makes it easier for your heart to pump blood to all parts of your body. This helps to lower blood pressure.

This medicine does not cure your disease, but helps to control it. Therefore, it is important to

continue taking PRO-LISINOPRIL regularly even if you feel fine.

What are the ingredients in PRO-LISINOPRIL?

Medicinal ingredients: Lisinopril

Non-medicinal ingredients: Anhydrous lactose, red ferric oxide, and zinc stearate.

PRO-LISINOPRIL comes in the following dosage forms:

Tablets: 5 mg, 10 mg and 20 mg.

Do not use PRO-LISINOPRIL if:

- You are allergic to lisinopril or to any non-medicinal ingredient in the formulation.
- You have a family history of angioedema (allergic reaction), or have ever had an allergic reaction to any other ACE inhibitor. Be sure to tell your healthcare professional that this has happened to you.
- You are taking sacubitril/valsartan (Entresto®), due to the increased risk of serious allergic reaction which causes swelling of the face or throat (angioedema) when taken with PRO-LISINOPRIL.
- You are pregnant or intend to become pregnant. Taking PRO-LISINOPRIL during pregnancy can cause injury or even death to your baby.
- You are breastfeeding. PRO-LISINOPRIL passes into breast milk.
- You 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
- You 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 ARBs because their medicinal ingredient ends in “-**SARTAN**”.

- You are 6 to 16 years old with severe kidney problems.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take PRO-LISINOPRIL. Talk about any health conditions or problems you may have, including 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.
- Are dehydrated or suffer from excessive vomiting, diarrhea, or sweating.
- Are taking a salt substitute that contains potassium, potassium supplements, or a potassium-sparing diuretic (a specific kind of “water pill”).
- Are on a low-salt diet.
- Are taking a medicine that contains aliskiren, such as Rasilez, used to lower high blood pressure. The combination with PRO-LISINOPRIL is not recommended.
- Are taking an angiotensin receptor blocker (ARB). You can recognize an ARB because its medicinal ingredient ends in “-**SARTAN**”.
- Are receiving gold (sodium aurothiomalate) injections.

Other warnings you should know about:

Monitoring: During your treatment with PRO-LISINOPRIL, your healthcare professional may check your kidney and liver function, blood pressure, and the amount of electrolytes (e.g. potassium) in your blood at regular intervals.

Exposure to sunlight: You may become sensitive to the sun while taking PRO-LISINOPRIL. Limit your exposure to sunlight until you know how you respond.

Use of anesthesia: If you are going to have surgery and will be given an anesthetic, be sure to tell your healthcare professional that you are taking PRO-LISINOPRIL.

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

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

Serious Drug Interactions

- Sacubitril/valsartan.
- Medicines containing aliskiren, ARBs or other ACE inhibitors if you also have:
 - Diabetes (with or without end organ damage),
 - Kidney disease,
 - High potassium levels, or
 - Heart failure with low blood pressure.

The following may also interact with PRO-LISINOPRIL:

- Agents increasing serum potassium, such as a salt substitute that contains potassium, potassium supplements, or a potassium-sparing diuretic (a specific kind of “water pill”).
- Allopurinol used to treat gout.
- Drugs to treat diabetes such as:
 - Insulin,
 - Medicines known as dipeptidyl peptidase IV (DPP-IV) inhibitors, these include alogliptin, linagliptin, saxagliptin and sitagliptin,
 - Other oral medications (such as sulphonylureas).Your dose of these types of drugs may need to be changed when taking them in combination with PRO-LISINOPRIL.
- Drugs used to treat cancer such as, temsirolimus and everolimus.
- Gold for the treatment of rheumatoid arthritis.
- Lithium used to treat bipolar disease.
- Non-steroidal anti-inflammatory medicines (NSAIDs), used to reduce pain and swelling. These include ibuprofen, naproxen, and celecoxib.
- Blood pressure-lowering drugs, including diuretics (“water pills”), aliskiren-containing products (such as Rasilez), or angiotensin receptor blockers (ARBs).
- Medicines known as mammalian target of rapamycin (mTOR) inhibitors such as sirolimus, a drug used to prevent the organ rejection after a transplant.
- Medicines known as tissue plasminogen activators (tPA), these are used to dissolve blood clots that have formed in blood vessels.
- Medicines known as neutral endopeptidase (NEP) inhibitors.

How to take PRO-LISINOPRIL:

- Take PRO-LISINOPRIL exactly as prescribed.
- It is recommended to take your dose at about the same time every day.
- Swallow the tablet with a drink of water. It does not matter if you take PRO-LISINOPRIL before or after food.
- Do NOT stop taking PRO-LISINOPRIL unless your healthcare professional tells you to, even if you are feeling better.

Usual dose:

Your healthcare professional has decided the best dose for you. Take your dose once daily, exactly as your healthcare professional has told you to.

Overdose:

If you think you, or a person you are caring for, have taken too much PRO-LISINOPRIL, 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 take a double dose.

What are possible side effects from using PRO-LISINOPRIL?

These are not all the possible side effects you may have when taking PRO-LISINOPRIL. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- dizziness (or light-headedness), drowsiness, fatigue, headache, tiredness, weakness (loss of strength)
- cough, running nose
- itching, psoriasis, sinus pain, skin rash, wheezing
- abdominal pain, diarrhea, nausea, stomach pain and indigestion, vomiting
- confusion, feeling sleepy or difficulty in going to sleep, mood changes (including signs of depression), seen and/or heard hallucinations, strange dreams
- changes in the way things smell or taste, dry mouth, numbness or tingling in the fingers or toes
- rapid heartbeat
- impotence
- hair loss

In patients with high blood pressure, fainting is uncommon. However, fainting may become common in patients with heart failure.

In patients with coronary heart disease, an excessive drop in blood pressure may be experienced.

PRO-LISINOPRIL can cause abnormal blood test results. Your healthcare professional will decide when to perform blood tests and will interpret the results.

Serious side effects 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	√		
Increased levels of potassium in the blood: irregular heartbeats, muscle weakness and generally feeling unwell		√	
UNCOMMON			
Allergic Reaction: rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing			√
Kidney Disorder: change in frequency of urination, nausea, vomiting, swelling of extremities, fatigue		√	
Liver and Pancreas 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			
Anemia (decreased number of red blood cells): fatigue, loss of energy, weakness, shortness of breath.		√	
Decreased Platelets: bruising, bleeding, fatigue and weakness, small purple or red dots under the skin		√	
Decreased White Blood Cells: infections, fatigue, fever, aches, pains, and flu-like symptoms		√	
VERY RARE			
Serious Skin Reactions (Stevens- Johnson Syndrome, Toxic Epidermal Necrolysis): any combination of itchy skin, rash, redness, blistering and peeling of the skin and/or of the lips, eyes, mouth, nasal passages or			√

Serious side effects 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	
genitals, accompanied by fever, chills, headache, cough, body aches or joint pain.			

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

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.

Storage:

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

Do not take your medicine after the expiry date shown on the bottle.

Keep out of reach and sight of children.

If you want more information about PRO-LISINOPRIL:

- 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 by contacting Pro Doc Ltée at 1-800-361-8559, www.prodoc.qc.ca or medinfo@prodoc.qc.ca.

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