

**READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE**  
**PATIENT MEDICATION INFORMATION**

 **PRINIVIL**<sup>®</sup>

(lisinopril tablets, Merck Standard)

Read this carefully before you start taking **PRINIVIL**<sup>®</sup> 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 **PRINIVIL**<sup>®</sup>.

**Serious Warnings and Precautions**

- You should not take **PRINIVIL**<sup>®</sup> while you are pregnant. Taking it while you are pregnant can cause injury and even death to your baby. If you become pregnant while taking this drug, **stop** taking it and get in touch with your doctor as soon as possible.

**What is **PRINIVIL**<sup>®</sup> used for?**

**PRINIVIL**<sup>®</sup> is used to:

- treat high blood pressure
- treat heart failure
- reduce the risk of having another heart attack.

It can be used alone or along with other medications to treat your condition.

**How does **PRINIVIL**<sup>®</sup> work?**

**PRINIVIL**<sup>®</sup> belongs to a group of drugs called Angiotensin Converting Enzymes (ACE) inhibitors.

These types of drugs block your body from making a chemical called angiotensin II. When this chemical enters your blood:

- your blood vessels become narrower. When this happens your blood has less space to move in.
- it also triggers a hormone that makes your body hold on to water.

Having more fluid in your body, in a narrow space will cause your blood pressure to go up.

ACE inhibitors help to lower your blood pressure by:

- reducing the amount of angiotensin II in your body. This allows your blood vessels to relax and become wider. It makes it easier for your blood to flow through your blood vessels.
- lowering the amount of water your body retains.

The lowering of your blood pressure makes it easier for your heart to pump blood. It can also help your heart work better if you have heart failure.

This drug does not cure high blood pressure or congestive heart failure but it helps control these conditions.

### **What are the ingredients in PRINIVIL®?**

Medicinal ingredients: Lisinopril

Non-medicinal ingredients: calcium phosphate, corn starch, magnesium stearate, mannitol, pregelatinized starch, and yellow and/or red iron oxides.

### **PRINIVIL® comes in the following dosage forms:**

Tablets: 10 mg (light yellow) and 20 mg (peach).

PRINIVIL® 5 mg tablets are no longer available, but this strength, as lisinopril, is available at the pharmacy.

### **Do not use PRINIVIL® if you:**

- are allergic to lisinopril or to any of the other ingredients in PRINIVIL®.
- have had an allergic reaction (angioedema):
  - a) to any other ACE inhibitor. You can tell you are taking or have taken an ACE inhibitor because these types of drugs have ingredients that end with –‘PRIL’ (such as enalapril and captopril) or
  - b) have been diagnosed with hereditary angioedema. This is an increased risk of getting an allergic reaction that is passed down through your family, or
  - c) where the reason for it is not known

Signs of an allergic reaction include:

- swelling of the hands, feet, ankles, face, lips, tongue and throat
- suddenly having trouble breathing or swallowing

Make sure that you tell your doctor, nurse or pharmacist that this has happened to you before.

- have diabetes or kidney disease and are already taking:
  - a blood pressure-lowering medicine that contains aliskiren (such as Rasilez) or
  - an angiotensin receptor blocker (drugs that have ingredients that end in “-SARTAN”).Taking these drugs at the same time as PRINIVIL<sup>®</sup> is not recommended.
- are taking a medicine containing a neprilysin inhibitor (e.g., sacubitril). Do not take PRINIVIL<sup>®</sup> for at least 36 hours before or after you take sacubitril/valsartan, a medicine containing a neprilysin inhibitor.

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take PRINIVIL<sup>®</sup>. Talk about any health conditions or problems you may have, including if you:**

- are breastfeeding. It is possible that PRINIVIL<sup>®</sup> passes into breast milk. You should not breast-feed while you are taking it.
- have liver disease
- have low blood pressure
- have heart and blood vessel disease
- are at risk for developing high levels of potassium in your blood. This can be serious and can happen if you:
  - are taking:
    - a salt substitute that contains potassium
    - potassium supplements
    - a potassium-sparing diuretic (a specific kind of “water pill” that makes your body hold onto potassium such as spironolactone, triamterene or amiloride).
    - other drugs that may increase serum potassium (e.g., trimethoprim-containing products).
  - have diabetes or any kidney problems.
- have diabetes and are taking oral medications or insulin. You should closely monitor yourself for low blood glucose levels especially during the first month of taking PRINIVIL<sup>®</sup>.
- have recently suffered from excessive vomiting or severe diarrhea

- are planning to have dental or any other type of surgery and will be given anesthesia. Tell your doctor or dentist that you are taking this drug.
- if you are taking a medicine containing a neprilysin inhibitor (e.g., sacubitril).

**Other warnings you should know about:**

**Low Blood Pressure:** You may feel dizzy or light headed:

- particularly in the first few days after you start taking PRINIVIL<sup>®</sup>. You should lie down if this happens. You should avoid driving or doing any tasks that require special attention.
- when you exercise or when the weather is hot.

If you faint, **stop** taking the drug and talk to your doctor.

**Blood tests:** While you are taking PRINIVIL<sup>®</sup> your doctor may do blood tests to check:

- the level of white blood cells in your blood
- the potassium levels in your blood.
- that your kidneys are working properly

**Cough:** You may develop a cough while taking PRINIVIL<sup>®</sup>. This usually goes away once you stop taking it or when the dose is lowered.

**Black patients:** you are at a higher risk for having an allergic reaction (angioedema).

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

**The following may interact with PRINIVIL<sup>®</sup>:**

- Drugs that lower your blood pressure. These include:
  - diuretics (“water pills”)
  - aliskiren-containing drugs (such as Rasilez)
  - angiotensin receptor blockers (ARBs)
  - other drugs that are used to lower blood pressure
- Drugs that can increase the levels of potassium in your blood. These include:

- potassium-sparing drugs (such as spironolactone, triamterene or amiloride)
- potassium supplements
- salt substitutes that contain potassium
- other drugs that may increase serum potassium (e.g., trimethoprim-containing products)
- Drugs used to treat diabetes (including oral drugs and insulin)
- Lithium (used to treat a certain kind of depression)
- Injectable gold (in the form of gold sodium aurothiomalate) used to treat arthritis
- Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) used to reduce pain and swelling (such as naproxen, ibuprofen and celecoxib)
- Drugs used for mTOR inhibitor therapy (such as temsirolimus, sirolimus, everolimus). These drugs are used to lower the body's ability to reject a transplant or to treat certain cancers. Taking these drugs together with PRINIVIL<sup>®</sup> could increase the risk for an allergic reaction called angioedema.
- A medicine containing a neprilysin inhibitor (e.g., sacubitril). Taking these drugs together with PRINIVIL<sup>®</sup> could increase the risk for an allergic reaction called angioedema.
- Indomethacin (used to treat pain and swelling)
- Certain drugs that you can buy without a prescription are known to cause your blood pressure to go up. These include drugs:
  - to control your hunger
  - for asthma
  - to treat colds and coughs
  - to treat allergies (such as hayfever)
  - to treat sinus problems

You should not take these types of medicines unless you have talked it over with your doctor first.

### **How to take PRINIVIL<sup>®</sup>:**

Swallow the tablet **whole**. **You should not split or break the tablets.**

If your doctor has given you specific instructions to follow, for example to eat a low salt diet or to lose weight, you should follow them.

Take PRINIVIL®:

- exactly as your doctor has told you how to take it
- once a day at about the same time every day
- with or without food

**Usual Dose:**

Your doctor has decided on the best dose for you based on your needs.

Even if you feel better, you should not stop taking this medicine unless your doctor tells you to.

**Overdose:**

If you think you have taken too much PRINIVIL®, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Symptoms of an overdose include:

- feeling light headed or dizzy. This can happen because of a sudden or extreme drop in blood pressure.

**Missed Dose:**

- If it has been **less** than 6 hours since you missed taking it, take your dose as soon as possible and then go back to your regular schedule.
- If it has been **more** than 6 hours since you missed taking it, skip the missed dose. Take the next dose at your usual time.

**Do not** take two doses at the same time.

**What are possible side effects from using PRINIVIL®?**

These are not all the possible side effects you may feel when taking PRINIVIL®. If you experience any side effects not listed here, contact your healthcare professional.

- Dry cough
- Sore throat
- Stuffy or runny nose

- Unusual tiredness and/or weakness
- Headache
- Pain in the abdomen
- Hair loss
- Changes in your mood or confusion
- Changes in taste
- Impotence (not able to have an erection)

<b>Serious side effects and what to do about them</b>			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>COMMON</b>			
<b>Low Blood Pressure:</b> Dizziness, light-headedness or fainting especially during the first few days of starting PRINIVIL <sup>®</sup> , following exercise, and/or when it is hot and you have lost a lot of water by sweating.	X		
<b>Increased Levels of Potassium in the Blood:</b> irregular heartbeat, muscle weakness and generally feeling unwell		X	
Diarrhea	X		
<b>UNCOMMON</b>			
<b>Allergic Reaction (angioedema):</b> swelling of face,			X

<b>Serious side effects and what to do about them</b>			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
eyes, lips, tongue and/ or throat, hands or feet.			
<b>Kidney Disorder:</b> change in the frequency of urination, nausea, vomiting, swelling of the extremities (hands and feet), fatigue		X	
<b>Liver Disorder (jaundice):</b> yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of weight		X	
<b>Electrolyte Imbalance:</b> weakness, drowsiness, muscle pain or cramps, irregular heartbeat		X	
Rash		X	
<b>RARE</b>			
<b>Decreased Platelets:</b> bruising, bleeding, fatigue and weakness		X	
<b>Decreased White Blood Cells:</b> infections, fatigue, aches, pains and flu –like symptoms		X	
<b>Heart Attack:</b> chest pain and/or discomfort, pain in the jaw, shoulders, arm and/or back,			X



<b>Serious side effects and what to do about them</b>			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
shortness of breath, sweating, light-headedness, nausea			
<b>Cerebro-vascular accident/ Stroke:</b> weakness, trouble speaking, trouble seeing, headache, dizziness			X
<b>Skin Disorders:</b> Steven Johnson syndrome (SJS), Toxic Epidermal Necrolysis (TEN), pemphigus			X
<b>UNKNOWN</b>			
Fever, loss of appetite and itching		X	

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

**Reporting Side Effects**

You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

**3 ways to report:**

- Online at [MedEffect](#);
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
  - Fax to 1-866-678-6789 (toll-free), or
  - Mail to: Canada Vigilance Program

Health Canada, Postal Locator 1908C  
Ottawa, ON  
K1A 0K9

Postage paid labels and the Consumer Side Effect Reporting Form are available at [MedEffect](#).

*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 your tablets:

- between 15°C - 30°C
- in the original packaging
- away from heat, direct sunlight, and damp places

Keep out of reach and sight of children.

Do not take PRINIVIL<sup>®</sup> after the expiry date on the package.

**If you want more information about PRINIVIL®:**

- 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](#) or the Merck Canada website [www.merck.ca](http://www.merck.ca) or by calling Merck Canada at 1-800-567-2594.

To report an adverse event related to PRINIVIL®, please contact 1-800-567-2594.

This leaflet was prepared by Merck Canada Inc.

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