

**PART III: CONSUMER INFORMATION****Pr LONITEN®  
(minoxidil tablets)**

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

**ABOUT THIS MEDICATION****What the medication is used for:**

LONITEN is used for the treatment of severe hypertension that is difficult to control. It is taken with other medicines.

**What it does:**

LONITEN tablets contain minoxidil which is a powerful drug for lowering the blood pressure. It works by relaxing and enlarging certain small blood vessels so that blood flows through them more easily.

**Who should take LONITEN:**

There are many people with high blood pressure but most of them do not need LONITEN. LONITEN is used ONLY when your doctor decides that:

1. Your blood pressure is severe;
2. Your high blood pressure is causing symptoms or damage of vital organs and
3. Other medicines did not work well enough or had very disturbing side effects.

LONITEN should be taken only when a doctor prescribes it. Never give any of your LONITEN tablets, or any other high blood pressure medicine, to a friend or a relative.

**When it should not be used:****Do not take LONITEN:**

- If you think you might be allergic to the active ingredient minoxidil or any other nonmedicinal ingredients listed in the section below (What the nonmedicinal ingredients are).
- If your high blood pressure is caused by hormones from a tumour (phaeochromocytoma) usually near the kidneys.
- If you have pulmonary hypertension associated with a heart valve disorder (mitral stenosis).
- If you have severely reduced liver function

**What the medicinal ingredient is:**

Minoxidil

**What all the nonmedicinal ingredients are:**

Colloidal silicon dioxide, corn starch, lactose, magnesium stearate, and microcrystalline cellulose.

**What dosage forms it comes in:**

2.5 mg and 10 mg tablets

**WARNINGS AND PRECAUTIONS****SERIOUS WARNINGS AND PRECAUTIONS**

LONITEN is not recommended during pregnancy and in women of childbearing potential not using contraception. Neonatal hypertrichosis has been reported following exposure to minoxidil during pregnancy.

Temporary changes in some blood parameters may occur, including a decrease in hematocrit, hemoglobin and red blood cell count. Body weight and blood count should be monitored closely.

**BEFORE you use LONITEN talk to your doctor or pharmacist if:**

- You are taking prescription and/or non-prescription products (especially other medications for high blood pressure, diuretics (water pills), and guanethidine
- You have or have ever had heart disease, a heart attack, pheochromocytoma or kidney disease. If you are pregnant, plan to become pregnant, or are breast-feeding

LONITEN tablets encourage salt and water to remain in your body. Too much salt and water in the body can make you feel breathless, wheezy, sick and tired, and can stop LONITEN working properly. LONITEN also makes your heart beat faster.

To avoid these problems, your doctor will prescribe two other medicines for you to take with LONITEN. One will be a water tablet (diuretic) to help your body get rid of excess water, and the other a beta-blocker or similar medicine to prevent your heart from beating too fast.

You should weigh yourself daily and keep an accurate record of your weight while you are taking this medicine. Tell your doctor if you put on more than 2 to 3 pounds (1 to 1.5 kg). The cause could be extra fluid in your body. Tell your doctor if you think you have gained weight - even though it may not be due to the medicine.

You may have increased hair growth (hypertrichosis) after starting treatment; this usually emerges in the face but subsides with continued treatment. This side effect is reversible upon stopping treatment but may take 1 to 6 months.

Your doctor will want to make regular checks on your blood pressure and general health. You should also have occasional checks on your heart. If you have an ECG test (to check the electrical activity of your heart) or any blood tests, remind your doctor that you are taking Loniten, as it can change the results.

**Driving and operating machines**

Do not drive a car or operate machinery until you know how LONITEN affects you.

**Pregnancy and Breast-feeding:**

LONITEN is not recommended, if you are pregnant or trying to become pregnant. You should only take LONITEN if your doctor tells you to. LONITEN passes into the breast milk and is not recommended if you breast-feeding unless your doctor thinks it is

necessary.

If you are pregnant or breast-feeding you should ask your doctor for advice before taking any medicine.

**INTERACTIONS WITH THIS MEDICATION**

You should always tell your doctor if you are taking any other medicine including those obtained without prescription. It is particularly important you tell your doctor about any other medicine you are taking to reduce your high blood pressure. These drugs may interact with LONITEN by causing blood pressure to drop too low and/or cause a sudden drop in blood pressure when standing up. In particular, tell your doctor if you are taking guanethidine, probenecid, valproic acid or atazanavir. Your treatment of Loniten should be monitored and the dosage may need to be adjusted.

**PROPER USE OF THIS MEDICATION**

Usually, your doctor will prescribe two other medicines along with LONITEN. These will help lower blood pressure and will help prevent undesired effects of LONITEN.

Often, when a medicine like LONITEN lowers blood pressure, your body tries to return the blood pressure to the original, higher level. It does this by holding on to water and salt (so there will be more fluid to pump) and by making your heart beat faster.

To prevent this, your doctor will usually prescribe a water tablet to remove the extra salt and water from your body and another medicine to slow your heart beat.

LONITEN tablets come in two strengths (2.5 mg and 10 mg) that are marked on each tablet. Pay close attention to the tablet markings to be sure you are taking the correct strength. Your doctor may prescribe half a tablet; the tablets are scored (partly cut on one side) so that you can easily break them.

When you first start taking LONITEN, your doctor may need to see you often in order to adjust your dosage. Take all your medicine according to the schedule prescribed by your doctor. Do not skip any doses.

Remember, do not stop taking LONITEN, or any of your other high blood pressure medicines, without checking with your doctor. Make sure that any doctor treating or examining you knows that you are taking high blood pressure medicines, including LONITEN.

**Usual dose:**

Always take the tablets exactly as your doctor tells you to. Your doctor will prescribe a suitable dose for you. The dose prescribed will depend on how you respond to the medicine. Your doctor might change your daily dose gradually to get the best results.

The table below shows the usual starting dose for adults and children over the age of 12 and for children under the age of 12.

	<b>Usual Daily Dose</b>
<b>Adults and children over the age of 12</b>	Usual starting daily dose is 2.5 mg, two times per day.  Your doctor may increase the dose to 10, 20 and then to 40 mg per day in divided doses, at 3 day intervals or longer.
<b>Children 12 years and under</b> Dose depends on body weight	Usual starting daily dose is 0.2 mg per each kilogram of body weight per day, taken in 2 divided doses.  Your doctor may increase the dose by 0.1 to 0.2 mg/kg/day increments, at 3 day intervals or longer,

There should be at least three days between each change of dose.

LONITEN may also be given to you in hospital to reduce your blood pressure very quickly. It would be given by a doctor or nurse under strictly monitored conditions at increasing doses of 5 mg every 6 hours until your blood pressure is normal.

You may take LONITEN with water or with other liquids, either with or between meals.

You must follow your doctor's instructions exactly, taking all the prescribed medicines, in the right amounts, each day. These medicines will decrease the side effects you might otherwise have and will also help keep your blood pressure down.

**Overdose:**

Taking too many tablets may make you unwell. If you take too many tablets, tell your doctor straight away.

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

**Missed Dose:**

If you should forget a dose of LONITEN, wait until it is time for your next dose, then continue with your regular schedule. Do not take a double dose to make up for a missed dose.

**SIDE EFFECTS AND WHAT TO DO ABOUT THEM**

LONITEN can cause side effects and the following have been reported in patients with high blood pressure being treated with LONITEN:

hair color changes, gastrointestinal intolerance, breast tenderness, rash,

**Hair Growth:**

About 8 out of 10 patients who have taken LONITEN noticed that fine body hair grew darker or longer on certain parts of the body. This happened about three to six weeks after beginning treatment. The hair may first be noticed on the forehead and temples, between the eyebrows, or on the upper part of the cheeks. Later, hair may grow on the back, arms, legs, or scalp. Although hair

growth may not be noticeable to some patients, it often is bothersome in women and children. Unwanted hair can be controlled with a hair remover or by shaving. The extra hair is not permanent it disappears within 1 to 6 months of stopping LONITEN. Nevertheless, you should not stop taking LONITEN without first talking to your doctor.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and seek immediate emergency medical help
		Only if severe	In all cases	
Very Common	Increase in heart rate (fast heartbeat) 20 beats or more per minute over your normal pulse while at rest,		√	
	Abnormal electrocardiogram (ECG),		√	
	Difficulty in breathing, especially when lying down		√	
Common	Weight Gain If you gain quickly 5 or more pounds (two or more kg) or if there is any swelling or puffiness in the face, hands, ankles, or stomach area, this could be a sign that you are retaining body fluids,		√	
	Shortness of breath, difficulty breathing, dizziness, lightheadedness or fainting.		√	

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and seek immediate emergency medical help
		Only if severe	In all cases	
Uncommon	Chest pain, shortness of breath, palpitations light-headedness, passing out		√	
	Flu-like symptoms (headache, malaise, fever, sore throat, joint pain), rash, serious skin reaction with blistering of the skin, mouth, eyes and genitals)			√
Rare	Inflammation and blistering of the skin			√
	Increase risk of bleeding or bruising		√	
	New or worsening of pain in the chest, arm or shoulder or signs of severe indigestion (angina), reduce kidney function resulting in increased creatinine and urea levels in your blood			√
Not known	swelling of the ankles, feet or fingers associated with or without weight gain,		√	

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

**HOW TO STORE IT**

Store at controlled room temperature (15° – 30°C)  
Keep out of reach and sight of children.

**REPORTING SUSPECTED SIDE EFFECTS**

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at [www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect)
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
  - Fax toll-free to 1-866-678-6789, or
  - Mail to: Canada Vigilance Program  
Health Canada  
Postal Locator 0701E  
Ottawa, Ontario  
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at [www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect).

*NOTE: Should you require information related to the management of side effects, contact your health professional. 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 at:

<http://www.Pfizer.ca>

or by contacting the sponsor, Pfizer Canada Inc., at:  
1-800-463-6001

This leaflet was prepared by Pfizer Canada Inc.

Last revised: November 14, 2013