PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

LONITEN® 5 mg tablets

LONITEN® 10 mg tablets

Minoxidil

Contains sugar (lactose monohydrate)

Each LONITEN 5 mg tablet contains 94 mg lactose monohydrate.

Each LONITEN 10 mg tablet contains 90 mg lactose monohydrate.

Read all of this leaflet carefully before you start taking LONITEN

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- LONITEN has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What LONITEN is and what it is used for
2. What you need to know before you take LONITEN
3. How to take LONITEN
4. Possible side effects
5. How to store LONITEN
6. Contents of the pack and other information

1. What LONITEN is and what it is used for

LONITEN belongs to a group of medicines known as vasodilators, hypertensive medicines and is used to treat hypertension (high blood pressure) together with other medicines.

2. What you need to know before you take LONITEN

Viewed on: Monday, March 30, 2026 - 10:19:03 AM Eastern Time

Do not take LONITEN:

- if you are hypersensitive (allergic) to minoxidil or any of the other ingredients of LONITEN (listed in section 6)
- if you have high blood pressure of the lung blood vessels associated with heart disease of the valves
- if you have phaeochromocytoma (a tumour that secretes a hormone known as adrenaline and causes a rise in blood pressure)
- if you are pregnant, plan to become pregnant or if you are breastfeeding your baby
- if you have severe liver problems

Warnings and precautions

Take special care with LONITEN:

- as you may experience heart conditions like inflammation of the membrane surrounding the heart, abnormal accumulation of fluid in the space between the layers of the membranes that surrounds the heart or blood flow stoppage into a blood vessel. You should be periodically monitored by your doctor for signs and symptoms related to these conditions.
- if you have ever had a heart attack
- if you have kidney failure or are undergoing dialysis (artificial replacement for lost kidney function)
- as you may experience elongation, thickening or discolouration of body hair which usually emerges in the face but may subside with continued treatment. This side effect is reversible upon stopping treatment but may take one to six months.
- as it may alter tests that measure the activity of the heart (ECG tests)
- as you may experience fluid retention resulting in puffy eyes, hands or face, swollen neck veins, enlarged liver, engorgement of lung vessels and temporary decreases in red blood cell counts. You will be prescribed a medicine to aid with water loss.
- as you may experience increased rate of heartbeat or severe chest pain. You may be prescribed a medicine to protect against this.
- if you have mild or constantly changing high blood pressure, LONITEN is not recommended
- if you have high blood pressure that will become better with surgery

Viewed on: Monday, March 30, 2026 - 10:19:03 AM Eastern Time

Other medicines and LONITEN

Always tell your health care provider if you are taking other medicine. (This includes all complementary or traditional medicines.)

If you are taking other blood pressure lowering medicines, please tell your doctor as these medicines may interact with LONITEN. If taken together with LONITEN, it can result in a dizzy spell when you stand up.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

LONITEN should not be used during pregnancy and in women of childbearing potential not using contraception.

LONITEN should not be used by women who are breastfeeding. A risk to the suckling child cannot be excluded.

Driving and using machines

The ability to drive or operate machinery may be influenced by the individual response to treatment, particularly at the start of therapy.

It is not always possible to predict to what extent LONITEN may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which LONITEN affects them.

LONITEN contains lactose monohydrate

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take LONITEN

Do not share medicines prescribed for you with any other person.

Viewed on: Monday, March 30, 2026 - 10:19:03 AM Eastern Time

Always take LONITEN exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you not sure.

The usual adult dosage range of LONITEN is 5 to 40 mg/day. The maximum recommended dosage is 100 mg/day. LONITEN therapy can be initiated with a single or divided daily dosage. Your doctor will adjust your dosage to that which is best for you.

You will also be prescribed other medicines, to maintain your salt and water balance, that have to be taken together with LONITEN.

Patients over 12 years of age

Initial dosage: 5 mg as a single or divided daily dosage.

Incremental increases: 5 - 10 mg/day, at 3-day intervals, until 50 mg/day is reached; then in increments of 25 mg/day up to a maximum of 100 mg/day.

If you have kidney failure or undergo dialysis, you may require smaller doses than normal.

If you have liver problems, your doctor may prescribe a lower dose.

Your doctor will tell you how long your treatment with LONITEN will last. If you have the impression that LONITEN is too strong or too weak, tell your doctor or pharmacist.

If you take more LONITEN than you should

You may experience low blood pressure. In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take LONITEN

Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

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LONITEN can have side effects.

Not all side effects reported for LONITEN are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking LONITEN, please consult your health care provider for advice.

You may experience an extremely serious allergic skin reaction known as Stevens-Johnson syndrome which usually begins with fever, sore throat and fatigue and ulcers appear in the mouth, lips and genital areas. Seek help immediately if this occurs.

Tell your doctor if you notice any of the following:

Frequent side effects

- increased heart rate
- inflammation of the membrane surrounding the heart
- increased hair growth
- hair colour changes
- abnormal electrocardiogram (ECG)
- fluid retention
- swelling caused by fluid in your body's tissues
- puffiness of face, eyes or hands
- abnormal accumulation of fluid in the space between the layers of the membranes that surrounds the heart
- pressure on the heart muscle due to an abnormal accumulation of fluid
- gastrointestinal disorder

Less frequent side effects

- accumulation of fluid between the layers of tissue that line the lungs and chest cavity
- reduced number of white cells in your blood
- low blood platelet count which increases risk of bleeding or bruising

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- inflammation and blistering of the skin
- rash

Other side effects

- decreased haemoglobin (oxygen carrying blood cells) and red blood cells
- increased urea in your blood
- low blood pressure
- chest pain (angina)
- expanding/swelling of the veins in the neck or lungs
- abnormal enlargement of the liver
- a skin condition that causes the top layer of skin (the epidermis) to detach from the lower layers of the skin (the dermis), all over the body, leaving the body susceptible to severe infection (Toxic epidermal necrolysis (TEN))
- breast tenderness
- enlargement of breasts in males
- irregular menstruation
- temporary rise in creatinine in the blood

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting side effects

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the **"6.04 Adverse Drug Reactions Reporting Form"**, found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of LONITEN.

5. How to store LONITEN

- Store all medicines out of reach of children.
- Store at or below 25 °C. Protect from light. Protect from moisture.

Viewed on: Monday, March 30, 2026 - 10:19:03 AM Eastern Time

- Do not use LONITEN after the expiry date stated on the packaging.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What LONITEN contains

- The active substance is minoxidil. Each LONITEN tablet contains 5 mg and 10 mg minoxidil respectively.
- The other ingredients are lactose monohydrate, microcrystalline cellulose, corn starch, colloidal silicone dioxide, magnesium stearate.

What LONITEN looks like and contents of the pack

LONITEN 5 mg and 10 mg tablets are round white tablets.

LONITEN 5 mg tablets are imprinted with a "5" on one side of the tablet with a "U" with a "score" and then "U" on the other side of tablet.

LONITEN 10 mg tablets are imprinted with a "10" on one side of the tablet with a "U" with a "score" and then "137" on the other side of tablet.

Bottles of 100 tablets containing 5 mg or 10 mg.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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