

Package leaflet: Information for the patient

LONITEN® 5 mg Tablets Minoxidil

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

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

This medicine contains minoxidil, which is one of a group of medicines called ‘vasodilators’. It can be used to treat very high blood pressure (severe hypertension), and works by relaxing blood vessels so that blood passes through them more easily. This helps to lower blood pressure. Loniten should be used in combination with a diuretic (water tablet), to prevent fluid retention and oedema, and a beta-blocker or similar medicine, to stop your heart beating too fast or angina pain in the chest.

You must talk to a doctor or pharmacist if you do not feel better or if you feel worse.

2. What you need to know before you take LONITEN

Do not take LONITEN:

- If you are allergic to minoxidil, or any of the other ingredients of this medicine (listed in section 6).
- If your high blood pressure is caused by hormones from a tumour (phaeochromocytoma), usually near the kidneys.

Warnings and precautions

Talk to your doctor or pharmacist before using LONITEN:

- If you are pregnant or trying to become pregnant.
- If you have heart failure (you may feel breathless, wheezy or tired and your ankles may swell up).
- If you have ever had a heart attack.

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 stop your heart beating too fast or angina pain in the chest.

If your doctor gives you a low salt diet, follow it carefully.

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 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. Your doctor will want to monitor fluid and salt (electrolyte) levels in your body.

You may recognise increased hair growth (hypertrichosis) after starting treatment, this 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.

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.

Your doctor may monitor your blood for the very rare possibility of decreased white blood cells and platelets cells.

In some patients, inflammation of membrane around heart, fluid accumulation under the membrane around heart (cardiac tamponade) can occur. Your doctor should monitor these carefully and may try to drain the fluid or may consider stopping treatment with LONITEN.

If you have suffered from a heart attack in the past, you will be treated with LONITEN only when the doctor has ascertained that your heart has returned to a stable state.

If you suffer from severe kidney disease or are on dialysis your doctor may prescribe you smaller doses of LONITEN.

Other medicines and LONITEN

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. It is particularly important you tell your doctor about any other medicine you are taking to reduce your high blood pressure, such as guanethidine or betanidine. These medicines 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 or betanidine so you can be monitored whilst on treatment with LONITEN or your doctor may consider stopping these therapies before starting treatment with LONITEN. Your doctor will tell you when and how to stop taking this medicine.

Pregnancy and breast-feeding

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

LONITEN passes into breast milk and is not recommended if you are breast-feeding unless your doctor thinks it is necessary.

Driving and using machines

LONITEN tablets may affect your ability to drive or operate machines safely. If you feel faint or dizzy while taking LONITEN, do not drive or operate machines.

LONITEN contains lactose

This medicine contains lactose (a type of sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take LONITEN

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

You may be given other medication as well as LONITEN to treat your condition.

Swallow LONITEN tablets whole with water.

The score line is not intended for breaking the tablet.

Adults and children over the age of 12

The usual starting dose of LONITEN for adults and children aged over 12 years is 5 mg each day. The dose can be increased to 20 mg and then 40 mg as single or divided doses if required for optimum blood pressure control. It is unusual to need more than 50 mg a day in adults and children aged over 12 years. In very rare instances your doctor can decide to use up to a maximum of 100 mg. Your doctor might change your daily dose gradually to get the best results. **There should be at least three days between each change of dose.** Don't wait until your tablets are finished before seeing your doctor.

Use in children 12 years and under

For children of 12 and under, the dose depends on their weight but they should not be given more than 1 mg per kilogram of body weight each day. The starting dose is normally 0.2 mg each day for each kilogram of their weight. Your doctor might change the daily dose gradually to get the best results. **There should be at least three days between each change of dose.** The maximum dose is 50 mg per day.

During treatment with minoxidil the child should be under specialist supervision. The daily dose of minoxidil will be determined by the specialist and it may be adjusted according to the child's needs. During treatment the child will be additionally treated with other medicines as decided by the specialist to prevent rapid heartbeat and accumulation of fluid in the body.

You should contact the doctor if the child has any of the following: a very rapid heartbeat, rapid breathing, swelling of the legs, rapid weight gain, and reduced urine. While on treatment with minoxidil the child will need to be regularly seen by the doctor.

Elderly patients

For adults over 65, the usual starting dose is 2.5 mg each day.

Patients on dialysis

If you are on dialysis you may need a lower dose, even though dialysis can remove LONITEN from your blood. Do not take your tablets in the two hours before your dialysis session. Take them after the dialysis, or more than two hours before.

Patients with liver failure

If you have liver failure, you may need to start therapy on a lower dose, once daily, and gradually adjust the dose as necessary.

Rapid reduction of blood pressure

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 six hours until your blood pressure is normal.

If you take more LONITEN than you should

Taking too many tablets may make you unwell. If you take too many tablets, tell your doctor straight away. If you feel faint or dizzy, or your skin gets unusually cold and pale, you may need to go to hospital.

If you forget to take LONITEN

Do not worry. If you forget to take a tablet, miss out the forgotten dose completely and take the next dose at the normal time. Do not take a double dose to make up for a forgotten dose.

If you stop taking LONITEN

Do not stop taking your medicine or alter the dose you are currently taking without talking to your doctor first. LONITEN helps to control your blood pressure.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following events have been reported in patients with high blood pressure being treated with LONITEN:

Contact your doctor immediately if any of the following occur.

- You may feel faint or dizzy, especially when you stand up.
- Your body could hold on to more water than normal: you may notice that your ankles get puffy, or your rings get tight, or you put on weight.
- You may find that you get more wheezy, breathless and tired, especially if you already have a weak heart.
- You may notice angina (usually pains in your chest) for the first time, or if you have angina already it could get worse.

Other side effects LONITEN may cause are:**Very common: may affect more than 1 in 10 people**

Increased heart rate, inflammation of the lining that surrounds the heart, abnormal electrocardiogram (ECG), increased hair growth, hair colour changes.

Common: may affect up to 1 in 10 people

Accumulation of fluid around the heart, compression of the heart due to a build-up of fluid, fluid retention, gastrointestinal disorder.

Uncommon: may affect up to 1 in 100 people

Accumulation of fluid between the layers of tissue that line the lungs and chest cavity, breast tenderness.

Rare: may affect up to 1 in 1,000 people

Decrease in white blood cells, reduction in blood platelets, which increases risk of bleeding or bruising, serious illness with blistering of the skin, mouth, eyes and genitals (Stevens-Johnson syndrome), inflammation and blistering of the skin, rash.

Not known: frequency cannot be estimated from the available data

Chest pains (angina), swelling of the ankles, feet or fingers associated with or independent of weight gain. Reduced kidney function resulting in increased creatinine and urea levels in your blood, a rare but life threatening condition where the top layer of skin lifts from the lower layers all over the body.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRAPharmacovigilance. Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store LONITEN

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton, blister or bottle after EXP. The expiry date refers to the last day of that month.

Store below 25°C.

Store in the original package in order to protect from moisture.

Do not throw away medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information**What LONITEN contains**

The active substance is minoxidil. Each tablet contains 5 mg minoxidil.

The other ingredients are: microcrystalline cellulose, maize starch, colloidal anhydrous silica, magnesium stearate and lactose monohydrate (see Section 2 LONITEN contains lactose).

What LONITEN looks like and the contents of the pack

LONITEN are round, white to light tan, biconvex tablets, 5 imprinted on one side, scored on the reverse with a 'U' on either side of the score. The score line is not intended for breaking the tablet. They are available in blisters of 60 tablets or bottles of 100 tablets.

Not all pack sizes may be marketed.

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