Consumer Medicine Information (CMI) summary

The <u>full CMI</u> on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Loniten?

Loniten contains the active ingredient minoxidil. Loniten is used to lower high blood pressure, also called hypertension. For more information, see Section <u>1. Why am I using Loniten?</u> in the full CMI.

2. What should I know before I use Loniten?

Do not take if you have ever had an allergic reaction to minoxidil or any of the ingredients listed at the end of the CMI.

Do not take if you have had phaeochromocytoma (rare tumour of the adrenal gland) or pulmonary hypertension (high blood pressure in the vessels of the lung).

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use Loniten? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Loniten and affect how it works. A list of these medicines is in Section <u>3. What if I am taking other medicines?</u> in the full CMI.

4. How do I use Loniten?

• The usual adult dosage range of Loniten is between 5 mg and 40 mg per day. The maximum recommended dosage is 100 mg per day.

More instructions can be found in Section 4. How do I use Loniten? in the full CMI.

5. What should I know while using Loniten?

Things you should do	Remind any doctor, pharmacist or dentist you visit that you are using Loniten.
Things you should not do	 Do not stop taking this medicine or lower the dosage, without checking with your doctor. Do not give Loniten to anyone else, even if they have the same condition as you. Do not take Loniten to treat any other complaints unless your doctor tells you to.
Driving or using machines	Be careful driving or operating machinery until you know how Loniten affects you.
Looking after your medicine	• Keep your tablets in a cool dry place where the temperature stays below 25°C.

For more information, see Section 5. What should I know while using Loniten? in the full CMI.

6. Are there any side effects?

Common side effects include unusual growth, thickening and darkening of fine body hair or changes in hair colour. Serious side effects include puffiness or swelling of your face, eyes, ankles, hands or feet; weight gain; increase in heart rate; dizziness or light headedness (particularly when standing up from a sitting position); tiredness; muscle aches; constipation, diarrhoea, nausea or vomiting; stomach pain or signs of indigestion; rash; breast tenderness; frequent infections such as fever, severe chills, sore throat or mouth ulcers as a result of a decrease in white blood cell levels; bleeding or bruising more easily. Tell your doctor or go to the hospital immediately if you notice onset or worsening of angina (chest pain, or a feeling of tightness or pressure in the chest); pain behind the breast bone, sometimes spreading to the neck and shoulders and sometimes accompanied by fever; shortness of breath; difficulty breathing; peeling skin or skin redness; severe blisters and bleeding in lips, mouth, nose and genitals.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

Consumer Medicine Information (CMI)

This leaflet provides important information about using Loniten. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Loniten.

Where to find information in this leaflet:

- 1. Why am I using Loniten?
- 2. What should I know before I use Loniten?
- 3. What if I am taking other medicines?
- 4. How do I use Loniten?
- 5. What should I know while using Loniten?
- 6. Are there any side effects?
- 7. Product details

1. Why am I using Loniten?

Loniten contains the active ingredient minoxidil.

Loniten lowers high blood pressure. High blood pressure is also called hypertension.

Loniten works by relaxing the muscles of your blood vessels. This makes it easier for your blood to flow around your body and results in a decrease in your blood pressure.

Loniten is reserved for use in severe cases of high blood pressure where it is used in combination with other blood pressure lowering medicines.

Ask your doctor if you have any questions about why Loniten has been prescribed for you.

Your doctor may have prescribed Loniten for another purpose.

2. What should I know before I use Loniten?

Warnings

Do not take Loniten if:

1. you are allergic to minoxidil, or any of the ingredients listed at the end of this leaflet.

Some of the symptoms of any allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Always check the ingredients to make sure you can use this medicine.

- 2. you have or have had any of the following medical conditions:
- phaeochromocytoma (a rare tumour of the adrenal gland, which sits near the kidney)

- pulmonary hypertension (high blood pressure in the vessels of the lung) due to a narrowing of the valve between the main blood vessels from the lung and the heart.
- 3. you are pregnant.
- 4. you are not using any form of contraception and could fall pregnant.

Check with your doctor if you:

- have allergies to:
 - o any other medicines, foods, preservatives or dyes.
- have or have had any other medical conditions especially:
 - o unstable or mild hypertension
 - symptoms of heart failure
 - o a heart attack
 - fast heart rate
 - o chest pain
 - o renal failure
 - regular dialysis
 - o liver disease.
- take any medicines for any other condition

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking Loniten.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section <u>6. Are there any side effects</u>?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. Loniten is not recommended for use during pregnancy.

Talk to your doctor if you are breastfeeding or intend to breastfeed. Loniten is not recommended while you are breast feeding. Loniten passes into breast milk. It is not known whether this will have any effect on the baby.

If you have not told your doctor about any of the above, tell them before you start taking Loniten.

Your doctor will discuss the risks and benefits of taking Loniten during pregnancy or while you are breast-feeding.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Loniten and affect how it works.

These include:

 guanethidine (a type of medicine used to treat high blood pressure).

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Loniten.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking Loniten.

4. How do I use Loniten?

How much to take

- The usual adult dosage range of Loniten is between 5 mg and 40 mg per day.
- The maximum recommended dosage is 100 mg per day.

Your doctor will adjust the dose to suit your individual needs. Dosage adjustments are usually made at intervals of 3 days or longer.

Your doctor or pharmacist will tell you how many tablets you will need to take each day. This depends on your condition and whether or not you are taking any other medicines.

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the bottle, ask your doctor or pharmacist for help.

How to take Loniten

Swallow Loniten tablets with a glass of water.

How long to take Loniten

Loniten helps control your high blood pressure, but does not cure it. Therefore, you must take Loniten every day.

Continue taking the tablets for as long as your doctor or pharmacist tells you.

Do not stop taking it unless your doctor or pharmacist tells you to.

If you forget to take Loniten

Loniten should be taken regularly at the same time each day.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much Loniten

If you think that you have taken too much Loniten, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 0800 POISON or 0800 764 766), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Loniten?

Things you should do

Tell any other doctors, dentists, and pharmacists who are treating you that you are taking Loniten.

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are taking Loniten.

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking Loniten.

If you become pregnant while taking Loniten, tell you doctor.

While you are taking Loniten your doctor may recommend that you reduce the amount of salt in your diet.

If you feel that you are gaining weight due to the retention of water, tell your doctor. Your doctor may need to adjust the medicines you are taking.

Things you should not do

- Do not give Loniten to anyone else, even if they have the same condition as you.
- Do not take Loniten to treat any other complaints unless your doctor or pharmacist tells you to.
- Do not stop taking Loniten, or lower the dosage, without checking with your doctor or pharmacist.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Loniten affects you.

As with some other blood pressure lowering medicines, Loniten may cause dizziness or light-headedness in some people.

Make sure you know how you react to Loniten before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or light-headed.

Looking after your medicine

• Keep your tablets in a cool dry place where the temperature stays below 25°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Do not use this medicine after the expiry date.

Keep it where young children cannot reach it.

When to discard your medicine

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
 unusual growth, thickening and darkening of fine body hair. This is usually first noticed on or around your face about 3 to 6 weeks after you start to take Loniten. This effect may slow after long-term use and will be reversed approximately 1 to 3 months after stopping Loniten therapy. changes in hair colour. 	Speak to your doctor if you have any of these side effects and they worry you.

Serious side effects

ious side effects	What to do
puffiness or swelling of your face, eyes, ankles, hands or feet weight gain increase in heart rate dizziness or light headedness (particularly when standing up from a sitting position) tiredness muscle aches constipation, diarrhoea, nausea or vomiting stomach pain or signs of indigestion rash breast tenderness frequent infections such as fever, severe chills, sore throat or mouth ulcers as a result of a decrease in white blood cell levels	Tell your doctor as soon as possible if you notice any of these serious side effects.
bleeding or bruising more easily.	
onset or worsening of angina (chest pain, or a feeling of tightness or pressure in the chest)	Call your doctor straight away, or go straight to the Emergency
pain behind the breast bone, sometimes spreading to the neck and shoulders and sometimes accompanied by fever shortness of breath difficulty breathing peeling skin or skin redness severe blisters and bleeding in	Department at your nearest hospital if you notice any of these more serious side effects.
	face, eyes, ankles, hands or feet weight gain increase in heart rate dizziness or light headedness (particularly when standing up from a sitting position) tiredness muscle aches constipation, diarrhoea, nausea or vomiting stomach pain or signs of indigestion rash breast tenderness frequent infections such as fever, severe chills, sore throat or mouth ulcers as a result of a decrease in white blood cell levels bleeding or bruising more easily. onset or worsening of angina (chest pain, or a feeling of tightness or pressure in the chest) pain behind the breast bone, sometimes spreading to the neck and shoulders and sometimes accompanied by fever shortness of breath difficulty breathing peeling skin or skin redness

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Reporting side effects

By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Loniten contains

Active ingredient	10 mg minoxidil
(main ingredient)	
Other ingredients	microcrystalline cellulose
(inactive	colloidal anhydrous silica
ingredients)	lactose monohydrate
	maize starch
	magnesium stearate

Do not take this medicine if you are allergic to any of these ingredients.

What Loniten looks like

Loniten tablets are white in colour and have a circular, half oval shape.

One side of the tablet is scored and marked with U and 137; the other side is marked with the number 10.

Who distributes Loniten

Pfizer New Zealand Limited Auckland Toll Free number: 0800 736 363 www.pfizermedinfo.com.au

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