Lamisil®

125 mg and 250 mg

Terbinafine hydrochloride

Consumer Medicine Information (CMI) summary

The full CMI 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 Lamisil?

Lamisil contains active ingredient Terbinafine hydrochloride. Lamisil is used to treat ringworm (tinea) infections occurring in groin, body, feet and soles. It is also used to treat fungal infection of finger and toenails.

For more information, see Section 1. Why am I using Lamisil? in the full CMI.

2. What should I know before I use Lamisil?

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

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 Lamisil? in the full CMI.

3. What if I am taking other medicines?

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

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use Lamisil?

- Your doctor will advise you on the appropriate dose.
- For skin infections: take 250 mg Lamisil once a day
- For fungal infection of finger and toenails: take 250 mg Lamisil once a day
- If your fungal infection does not improve. Your doctor will review and determine if an alternative antifungal therapy is needed.

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

5. What should I know while using Lamisil?

Things you should do	• Remind any doctor, dentist, pharmacist or specialist you visit that you are using Lamisil. • Tell your doctor immediately if you develop any signs of an allergic reaction.
Things you should not do	• Do not stop using this medicine suddenly. • Do not use Lamisil in children.
Driving or using machines	• Lamisil may cause dizziness in some people. Avoid driving vehicles or using machines if you are dizzy. • Be careful before you drive or use any machines or tools until you know how Lamisil affects you.
Looking after your medicine	• Store below 30°C. • Protect from light.

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

6. Are there any side effects?

Common side effects include low appetite, headache, dizziness, weakness, vomiting, rash, hives, feeling sick, yellowing of the skin and eyes, light-coloured stools, dark coloured urine, indigestion.

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.

Lamisil®

125 mg and 250 mg

Active ingredient: *Terbinafine hydrochloride*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Lamisil. **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 Lamisil.**

Where to find information in this leaflet:

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

1. Why am I using Lamisil?

Lamisil contains active ingredient Terbinafine hydrochloride. Lamisil belongs to a group of medications called antifungals.

Lamisil is used to treat ringworm (tinea) infections occurring in groin, body, feet (athlete's foot) and soles. It is also used to treat fungal infection of finger and toenails (Onychomycosis). These infections are caused by a group of fungi called dermatophytes. Lamisil help to kill these dermatophytes.

2. What should I know before I use Lamisil?

Warnings

Do not use Lamisil:

- If you are allergic to Terbinafine hydrochloride, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine. Symptoms of allergic reaction include swelling of the face, lips, tongue or other parts of the body, difficulty in breathing, redness, itching or rash on the skin, rash, fever.

Check with your doctor if you:

- have any other medical conditions such as liver problems or any symptoms such as feeling sick, loss of appetite, weakness, vomiting, pain in right upper part of tummy or yellowing of skin or eyes, dark urine or pale stools.
- suffer from any kidney diseases.
- take any medicines for any other condition.
- have any skin diseases like Psoriasis (skin problem that causes a rash with itchy, scaly patches), rash or any other serious skin reactions (e.g. Stevens-Johnson syndrome, a serious disorder of the skin with symptoms such as blisters, weakness, fever or toxic epidermal necrolysis, severe skin problem having symptoms of blistering and peeling of skin)
- have any problems related to your blood (e.g. unusual bleeding, bruising or frequent infections)
- have or develop unexplained bleeding or blood clots

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 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Lamisil is not recommended during pregnancy. Your doctor will advise you regarding the possible risks and benefits of using Lamisil during pregnancy.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Do not use Lamisil during breast feeding as Terbinafine hydrochloride passes in breast milk.

Laboratory tests

- Your doctor might do routine blood tests, liver function test before and during treatment with Lamisil.

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 Lamisil and affect how it works.

Tell your doctor or pharmacist if you take any of the following:

- Warfarin, a drug used to prevent blood clots
- Oral contraceptives (birth control pills)
- Medicines used to treat heart problems (e.g. metoprolol)
- Caffeine
- Drugs used to treat depression and other mental problems (e.g. tricyclic antidepressants: desipramine, selective serotonin reuptake inhibitors (SSRIs), antiarrhythmics Class 1A, 1B, and IC, and monoamine oxidase inhibitors (MAOIs) Type B)
- Cyclosporin, a medicine used to treat certain problems with the immune system
- Drugs used for treatment of cough e.g. dextromethorphan

Medicines that may <u>increase</u> the effect of Lamisil:

- Cimetidine or other similar medicines used to treat stomach problems
- Other antifungal medicines such as Fluconazole, ketoconazole

Medicines that may <u>reduce</u> the effect of Lamisil:

- Rifampicin or other similar antibiotics used to treat infections.

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

4. How do I use Lamisil

How much to take

- Follow the instructions provided and use Lamisil until your doctor tells you to stop.
- For Skin infections: take 250 mg Lamisil once a day
- For fungal infection of finger and toenails (Onychomycosis): take 250 mg Lamisil once a day

Duration of Treatment:

- Your doctor will advise you regarding the duration of treatment.
- Generally, for skin infections of toes: 2 to 6 weeks
- For fungal infection of body or the groin: 2 to 4 weeks
- For fungal infection of finger and toenails (Onychomycosis): 6 weeks - 3 months.
- For infection in the big toe, treatment may take up to 6 months.
- **If you do not understand your dose, consult your doctor or pharmacist.**

If your fungal infection does not improve. Your doctor will review and determine if an alternative antifungal therapy is needed.

When to take Lamisil

- Take Lamisil orally at about the same time each day.

How to take Lamisil

- Take Lamisil orally with a full glass of water. If you notice that the Lamisil upsets your stomach, try taking it immediately after a light meal.

If you forget to use Lamisil

Lamisil should be used regularly at the same time each day. If you miss your dose at the usual time, take it as soon as you remember, and then go back to taking it as you would normally.

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

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

If you use too much Lamisil

If you think that you have used too much Lamisil, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), 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 Lamisil?

Things you should do

Keep the infected areas dry and cool and change clothing which is in direct contact with the infected areas every day.

Call your doctor straight away if you:

- develop any signs of allergic reaction.
- become pregnant or if you are breast feeding while using Lamisil.
- have any problems with your liver, kidney or blood.
- experience multiple blood clots.

Remind any doctor, dentist, pharmacist or specialist you visit that you are using Lamisil.

Things you should not do

- Do not stop using this medicine suddenly.
- Do not use Lamisil in children.
- Do not give Lamisil to anyone else, even if they have the same condition as you.

Driving or using machines

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

Lamisil may cause dizziness in some people. Avoid driving vehicles or using machines if you are dizzy.

Looking after your medicine

- Store below 30°C.
- Protect from light.

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.

Keep it where young children cannot reach it.

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.

Do not use this medicine after the expiry date.

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
General problems: • Low appetite • Joint pain • Muscle pain or weakness, not caused by exercise • Headache • Dizziness • Tiredness • Blurred vision • Vision problems • Fever, chills, body pain, dry cough **Skin problems:** • Hives • Rash • Itching • Redness of the skin **Tummy problems:** • Feeling sick • Vomiting • Uncomfortable feeling in tummy • Excessive feeling of gas in the tummy • Cramps or pain in tummy • Diarrhoea • Indigestion • Excessive burping • Swelling of your belly. **Other problems:** • Anxiety • Depression	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
General problems: • Allergic reaction such as swelling of the face, lips, tongue or other parts of the body, difficulty in breathing, redness, itching or rash on the skin, rash, fever. • Problems with your blood vessels having symptoms like fever, weight loss, tiredness, rash. **Tummy problems:** • Pain in tummy, vomiting, blood in the stools (swelling of the stomach lining) • Yellowing of the skin and eyes, feeling sick, light-coloured stools, dark colour urine **Skin problems:** • Itchy rash, fever, joint pains • Fever, red rash, painful red areas, blisters, peeling of layers of skin (may indicate serious skin reaction) **Abnormal blood tests:** • Dark-coloured urine, weakness • Weakness, feeling sick, swelling on arms, legs, or face • Yellowing of skin or eyes, loss of appetite, vomiting • Unexplained weakness, tummy problems, • Weakness, shortness of breath dizziness or lightheadedness pale skin, headaches • Fever and chills, mouth sores, sore throat • Chest pain, weakness, fever, muscle stiffness **Other problems:** • Hearing problems • Partial loss of hearing • Taste disturbance • Loss of taste • Decreased ability to smell or detect odours • Loss of the sense of smell	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

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.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the

Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. 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 Lamisil contains

Active ingredient (main ingredient)	Terbinafine hydrochloride
Other ingredients (inactive ingredients)	magnesium stearate, hypromellose, sodium starch glycollate, and cellulose - microcrystalline. Lamisil 250 mg tablet also contain silica-colloidal anhydrous.
Potential allergens	Lamisil 125 mg tablet contain lactose

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

What Lamisil looks like

Lamisil 250 mg tablet: 11 mm, white to yellow tinged, circular, biconvex, bevelled edges, scored on one side and coded “LAMISIL 250” (circular) on the other side.

Lamisil 125 mg tablet: 9 mm, white to white-tinged yellow, circular, biconvex, bevelled edges, scored and coded LP on one side.

Lamisil 250 mg tablet is available in blister packs of 42, 14*, and 28*

Lamisil 125 mg tablet is available in blister packs of 28*.

* Not all presentations or pack sizes may be marketed.

Australian Registration Number:

Lamisil 250mg tablet AUST R 43523

Who distributes Lamisil

Lamisil is supplied in Australia by:

NOVARTIS Pharmaceuticals Australia Pty Limited

ABN 18 004 244 160

Level 25, Victoria Cross Tower

155 Miller Street

North Sydney NSW 2060

Telephone 1 800 671 203

Web site: www.novartis.com.au

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