

PATIENT INFORMATION LEAFLET

Please read this leaflet carefully before using Lamisil tablets

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or your pharmacist.
- This medicine 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.

SCHEDULING STATUS: S4

PROPRIETARY NAME AND DOSAGE FORM:

LAMISIL® 125 mg TABLETS

LAMISIL® 250 mg TABLETS

1. COMPOSITION OF THE MEDICINE (i.e., what this medicine contains):

125 mg tablets

- The **active substance** of LAMISIL® is terbinafine hydrochloride.
- The **other ingredients** are magnesium stearate; hydroxypropylmethyl cellulose; microcrystalline cellulose; lactose; sodium carboxymethyl starch.

250 mg tablets

- The **active substance** of LAMISIL® is terbinafine hydrochloride.
- The **other ingredients** are magnesium stearate; silica colloidal anhydrous; hydroxypropylmethyl cellulose; microcrystalline cellulose; sodium carboxymethyl starch.

2. APPROVED INDICATION AND USE (i.e., what this medicine is used for):

LAMISIL® tablets are used to treat fungal infections of the fingernails and toenails.

LAMISIL® tablets are also used to treat tinea (ringworm) infections of the scalp and hair, groin and other body areas and the feet (athlete's foot), as well as yeast infections of the skin.

Terbinafine belongs to the group of medicines called antifungal agents and is used to treat fungal infections of the skin, hair and nails. When taken by mouth, it reaches the site of infection in concentrations strong enough to kill the fungus or stop it growing.

3. BEFORE TAKING THE MEDICINE:

It is important to tell your doctor if you have other medical problems or if you are taking other medicines

Do not take LAMISIL®

- If you are allergic (hypersensitive) to terbinafine or any of the other ingredients of LAMISIL® listed at the beginning of this leaflet.
- If you have or had any liver problems.
- If you have any kidney problems

If any of these apply to you, tell your doctor without taking LAMISIL®.

Take special care with LAMISIL®

- If you have any kidney problems.
- If you take other medicines.
- If you have been told by your doctor that you have an intolerance to some sugars (since LAMISIL® 125 mg tablets contain lactose).

If any of these apply to you, tell your doctor before you take LAMISIL®.

LAMISIL® and older people.

LAMISIL® tablets can be taken by people over the age of 65 years. If you are more than 65 years old, you will be given the same dose as other adults.

LAMISIL® and children

LAMISIL® tablets are not recommended for use in children under 2 years of age.

Pregnant women

If you are pregnant or think you may be pregnant, tell your doctor. LAMISIL® should not be used during pregnancy unless clearly necessary. Your doctor will discuss with you the potential risks of taking LAMISIL® during pregnancy.

Breast-feeding mothers

You should not breast-feed while taking LAMISIL® tablets because your baby would be exposed to terbinafine through your breast milk. This might harm your baby.

Driving and using machines

LAMISIL® has no known effect on the ability to drive and use machines.

Taking other medicines with LAMISIL®:

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including herbal medicines, oral contraceptives (birth control pills) and non-prescription medicines. Some other medicines may interact with LAMISIL®. These include:

- some antibiotics (e.g. rifampicin),
 - some antidepressants (e.g. desipramine),
 - some medicines used to treat heart problems (e.g. propafenone),
 - some medicines used to treat high blood pressure (e.g. metoprolol),
 - some medicines used to treat stomach ulcers (e.g. cimetidine).
- Be sure to tell your doctor about these, or any other medicines you take.

4. INSTRUCTIONS ON HOW TO TAKE THE MEDICINE:

Always follow the instructions of your doctor carefully. If you are unsure about how much LAMISIL®

to take, or when to take it, please ask your doctor or pharmacist. In order for the medication to have the full therapeutic effect, the full course of medication must be taken as indicated. Do not exceed the recommended dosage.

How much LAMISIL® to take and how often

Adults

The usual dose is one 250 mg tablet daily.

Children

No data is available for children under 2 years of age (usually less than 12 kg).

Children weighing less than 20 kg 62.5 mg (half a 125 mg tablet) once daily

Children weighing 20 to 40 kg 125 mg (one 125 mg tablet) once daily

Treatment duration: 12 weeks is sufficient in most cases.

Some patients with poor nail growth may need longer treatment. Your doctor will discuss it with you.

If you forget to take LAMISIL®

Take your tablet(s) as soon as you remember, unless it is less than 4 hours before your next dose is due. In this case, wait and take your next dose at the usual time.

If you take more LAMISIL® than you should

If you accidentally take more tablets than your doctor has prescribed, call your doctor immediately or go to the casualty department at your nearest hospital. Symptoms caused by an overdose of LAMISIL® tablets include headache, nausea, stomach pain and dizziness.

What else should you be aware of while taking LAMISIL®?

There are other measures that you can take to help clear up your infection and make sure it does not return. For example, keep the infected areas dry and cool and change clothing that is in direct contact

with the infected area(s) daily.

5. POSSIBLE SIDE EFFECTS:

Like all medicines LAMISIL® tablets may cause unwanted effects (side-effects).

Some rare or very rare side effects can be serious:

Rarely LAMISIL® tablets can cause liver problems, in very rare cases the liver problems can be serious. Very rare side effects include a decrease in certain types of blood cells, lupus (an autoimmune disease) or serious skin problems, including allergic reactions.

6. STORING AND DISPOSING OF LAMISIL:

Keep all medicines out of the reach and sight of children.

Do not use the medicine after the expiry date shown on the pack.

Store in a cool, dry place. Store at or below 30 °C. Protect from light.

Return any unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION:

LAMISIL® 125 mg tablets: Blister pack of 14.

LAMISIL® 250 mg tablets: Blister pack of 14.

8. IDENTIFICATION:

LAMISIL® 125 mg tablet (scored) for use in children: A whitish to white-tinged yellow, circular, biconvex, bevelled edged tablet, scored and coded LP on one side, with smooth or slightly rough surface.

LAMISIL® 250 mg tablet (scored): a whitish to yellow-tinged white, circular, biconvex, bevelled edged tablet, scored on one side and coded LAMISIL® 250 (circular) on the other side, with smooth or slightly rough surface.

9. REGISTRATION NUMBERS:

LAMISIL® 125 mg tablets: Z/20.2.2/184

LAMISIL® 250 mg tablets: Z/20.2.2/185

10. NAME AND ADDRESS OF REGISTRATION HOLDER:

NOVARTIS SOUTH AFRICA (Pty) Ltd
Magwa Crescent West
Waterfall City
Jukskei View
Johannesburg
2090

11. DATE OF PUBLICATION OF THIS PACKAGE INSERT:

17 April 2009

Manufacturer:

Lamisil 125 mg:

Novartis Farmaceutica SA

Ronda Santa Maria 158, 08210 Barberà del Vallès, Barcelona, Spain

Lamisil 250 mg:

Novartis Pharma Produktions GmbH

Oeflingerstrasse 44, 79664 Wehr, Germany