

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986**

The medicine is dispensed with a doctor's prescription only

## LAMISIL® Tablets 250 mg

### Active ingredient

Each tablet contains:  
Terbinafine (as hydrochloride) 250 mg

### Inactive ingredients:

See section 6 'Further information'.

**Read this leaflet carefully in its entirety before using the medicine.** This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

The medicine is not intended for children under two years of age.

### 1. WHAT IS THE MEDICINE INTENDED FOR?

For the treatment of skin and nail fungal infections.

Therapeutic group: Oral antifungal agent.

Lamisil tablets are used to treat fungal infections of the fingernails and toenails, 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.

When taken by mouth, terbinafine reaches the site of infection in concentrations strong enough to kill the fungus or stop it growing.

### 2. BEFORE USING THE MEDICINE

**❗ Do not use the medicine if:** you are allergic (hypersensitive) to the active ingredient or any of the other ingredients of the medicine that are listed in the section 'Further information'. If you think you may be allergic, consult the doctor.

### Special warnings regarding use of the medicine

**⚠ Before treatment with Lamisil tell the doctor without taking the medicine:**

- if you have or have had any liver problems
- if you have any kidney problems

If one or more of the following cases apply to you before or during treatment with Lamisil, **refer to the doctor immediately:**

- Symptoms such as unexplained persistent nausea, vomiting, stomach pain, loss of appetite, unusual tiredness, the skin or whites of the eyes look yellow, unusually dark urine or unusually light-colored stools (signs of liver problems). Before and periodically after starting treatment with Lamisil, the doctor might have blood tests performed to monitor your liver function. In case of abnormal test results he may ask you to stop taking Lamisil

- Skin problems such as rash, red skin, blistering of the lips, eyes or mouth, skin peeling, fever (possible signs of serious skin reactions), rash due to a high level of a specific type of white blood cells (eosinophilia)

- Thickened patches of red/silver skin (psoriasis) or facial rash, joint pain, muscle disorder, fever (cutaneous and systemic lupus erythematosus)

- Weakness, unusual bleeding, bruising or frequent infections (signs of blood disorders)

- If you are taking or have recently taken any other medicine, see section 'Taking other medicines'.

### ⚠ Taking other medicines

**If you are taking or have recently taken other medicines, including herbal medicines and oral contraceptives (birth control pills), non-prescription medicines and nutritional supplements, inform the doctor or pharmacist.**

Especially if you are taking:

- some medicines used to treat stomach ulcers (e.g. cimetidine)

- some medicines used to treat fungal infections (e.g. fluconazole, ketoconazole)

- some medicines used to treat infectious diseases called antibiotics (e.g. rifampicin)

- some medicines used to treat mood disorders (some antidepressants such as tricyclic antidepressants, selective serotonin reuptake inhibitors including class 1A, 1B and 1C, monoamine oxidase inhibitors Type B, desipramine)

- some medicines used to treat high blood pressure (some beta-blockers such as metoprolol)

- some medicines used to treat irregular heart rhythm (antiarrhythmics such as propafenone, amiodarone)

- some medicines used to treat cough (e.g. dextromethorphan)

- caffeine

- ciclosporin, a medicine used to control the body's immune system (e.g. in order to prevent rejection of a transplanted organ)

### ⚠ Taking Lamisil with food

Lamisil tablets can be taken on an empty stomach or after a meal.

### ⚠ Older people (aged 65 years and above)

Patients aged 65 years and over can take the same dose of Lamisil tablets as younger adult patients.

### ⚠ Children and adolescents (aged 2 years to 17 years)

Lamisil tablets can be used in adolescents and children aged 2 years and over as long as the dose is adjusted for body weight and the child weighs over 20 kg.

As the patient grows, the doctor will adjust the dosage.

Lamisil is not recommended for use in children under 2 years of age since there is no experience in this age group.

### ⚠ Pregnancy and breast-feeding

Consult the doctor or pharmacist before taking any medicine.

The doctor will discuss with you the potential risk of taking Lamisil during pregnancy.

If you are pregnant or think you may be pregnant, inform the doctor.

You should not take Lamisil during pregnancy unless specifically advised to do so by the doctor.

You should not breast-feed during treatment with Lamisil because your baby would be exposed to the active substance through the breast milk. This might harm your baby.

### ⚠ Driving and using machinery

Do not drive or use machinery if you feel dizzy while taking Lamisil tablets.

### 3. HOW SHOULD YOU USE THE MEDICINE?

Always use according to the doctor's instructions. You should check with the doctor or pharmacist if you are not sure.

If you are under the impression that the effect of Lamisil is too strong or too weak, refer to the doctor or pharmacist.

### Tests and follow-up

**A laboratory test must be performed to determine the causative pathogen before starting treatment.**

### Dosage

The dosage and manner of treatment will be determined by the doctor only.

The usual dosage is generally:

#### Adults

The usual dose is one 250 mg tablet daily.

#### Children

There is no experience with Lamisil in children under 2 years of age (usually less than 12 kg).

The dosage in children above 2 years of age depends on the body weight. Lamisil tablets are only meant for children weighing more than 20 kg:

Children weighing	20 to 40 kg	125 mg	once daily
Children weighing	more than 40 kg	250 mg	once daily

**Do not exceed the recommended dose.**

### When to take Lamisil

Taking Lamisil at the same time each day will help you remember when to take your medicine. Lamisil tablets can be taken on an empty stomach or after a meal.

### How to take

Do not chew! The tablets should be swallowed with water.

Lamisil 250 mg tablets can be divided into two equal parts (i.e. 125 mg strength).

The scored tablets cannot be crushed due to a bitter taste.

### Duration of treatment

The duration of treatment depends on the type of infection, its degree of severity, and what part of the body it affects. The doctor will tell you for exactly how long you will need to use the medicine.

The normal duration of treatment is:

**For tinea (ringworm) infections of the feet (athlete's foot),** Lamisil tablets are usually taken for 2 to 6 weeks.

**For tinea (ringworm) and yeast infections of the groin and other body areas,** Lamisil tablets are usually taken for 2 to 4 weeks.

It is important to take the tablet/tablets every day and to continue the treatment for as long as the doctor tells you to. This will ensure that the infection is completely cured and lessen the chance of its return after you stop taking the tablets.

**Hair and scalp infections:** The normal duration of treatment is 4 weeks.

### Nail infections

Fungal nail infections usually take longer to cure than fungal skin infections. For most nail infections, Lamisil tablets have to be taken for 6 to 12 weeks.

**Fingernail infection:** Treatment duration of 6 weeks is sufficient in most cases.

**Toenail infection:** Treatment duration of 12 weeks is sufficient in most cases.

Some patients with poor nail growth may need longer treatment. The doctor will discuss this with you.

### If you have accidentally taken a higher dosage

If you have taken an overdose or if a child has accidentally swallowed the medicine, refer immediately to the doctor or to a hospital emergency room and bring the package of the medicine with you.

Medical supervision may be required.

This is also relevant if another person has accidentally taken your medicine. Symptoms of Lamisil overdose include headache, nausea, stomach pain and dizziness.

### If you forget to take the medicine

If you forget to take this medicine at the specified time, take the dose as soon as you remember, unless less than 4 hours remain until the next scheduled dose. In this case wait and take the next dose at the scheduled time. Do not take a double dose to make up for the one that you missed.

Adhere to the treatment as recommended by the doctor.

Even if there is an improvement in your health do not stop treatment with the medicine without consulting the doctor.

### How can you contribute to the success of the treatment?

There are other measures that can be taken to help clear up the infection and make sure it does not return.

Moisture encourages the fungi growth; therefore you should keep the infected areas dry and cool and change clothing that is in direct contact with these areas daily.

If the feet are treated - you should be sure to wash and dry thoroughly, especially between the toes. It is advisable to use cotton socks; you should avoid wearing wool or synthetic socks. It is advisable to change them several times a day (according to the amount of sweat).

In the appropriate seasons it is recommended to wear sandals without socks.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.

If you have further questions regarding the use of the medicine, consult the doctor or pharmacist.

### 4. SIDE EFFECTS

As with any medicine, use of Lamisil may cause side effects in some users. Do not be alarmed by the list of side effects. You may not suffer from any of them.

### Some side effects could be serious:

In rare cases Lamisil can cause liver problems, and in very rare cases the liver problems can be serious. Serious side effects also include a decrease in certain types of blood cells, lupus (an autoimmune disease), serious skin reactions, severe allergic reactions, inflammation of blood vessels, inflammation of the pancreas or muscle necrosis.

### Notify the doctor immediately:

- if you experience symptoms such as unexplained persistent nausea, stomach problems, loss of appetite, unusual weakness or tiredness or if you notice that your skin or the whites of your eyes are yellow, your urine is unusually dark or your stools are unusually light in color (possible signs of liver problems)
- if you develop fever, shivering, a sore throat or mouth ulcers due to infections and weakness or if you get infections more frequently or in case of unusual bleeding or bruising (possible signs of diseases that affect the amount of certain types of blood cells)
- if you experience difficulty in breathing, dizziness, swelling mainly of the face and throat, flushing, crampy abdominal pain and loss of consciousness or if you experience symptoms such as joint pain, stiffness, rash, fever or swollen/enlarged lymph nodes (possible signs of severe allergic reactions)
- if you experience symptoms such as rash, fever, itching, tiredness or if you notice the appearance of purplish-red spots under the skin surface (possible signs of blood vessel inflammation)
- if you develop any skin problems such as rash, red skin, blistering of the lips, eyes or mouth, skin peeling, fever
- if you experience severe upper stomach pain radiating to the back (possible signs of pancreas inflammation)

- if you experience unexplained muscle weakness and pain or dark (red-brown) urine (possible signs of muscle necrosis)

#### **Additional side effects**

#### **The following side effects have been reported with Lamisil:**

If any of these effects affects you severely, **consult the doctor:**

#### **Very common side effects (likely to affect more than 1 in 10 patients):**

Headache, nausea, mild abdominal pain, stomach discomfort after a meal (heartburn), diarrhea, bloating (a feeling of fullness) of the stomach, loss of appetite, skin rashes (itchy), joint pain and muscle pain.

#### **Common side effects (likely to affect 1 to 10 in 100 patients):**

Mood disorder (depression), disturbance or loss of sense of taste, dizziness, eye disorder and tiredness.

#### **Uncommon side effects (likely to affect 1 to 10 in 1,000 patients):**

If you notice abnormally pale skin, mucosal lining or nail beds, unusual tiredness or weakness or breathlessness on exertion (possible signs of a disease that affects the level of red blood cells), anxiety, tingling or numbness and decreased skin sensitivity, increased sensitivity of the skin to sun, noises (hissing) in ears, fever and weight loss.

#### **Rare side effects (likely to affect 1 to 10 in 10,000 patients):**

Yellow eyes or skin (liver problems) and abnormal liver function test results.

#### **Very rare side effects (likely to affect less than 1 in 10,000 patients):**

Decrease in certain types of blood cells, lupus (an autoimmune disease), serious skin reactions, allergic reactions, psoriasis-like skin eruptions (silver colored rash), worsening of psoriasis, skin rash with flaking or peeling and hair loss.

#### **The following side effects have also been reported:**

If any of these effects affects you severely, **contact the doctor:**

Severe allergic reactions or infections, inflammation of the blood vessels, smell disorders including permanent loss of sense of smell, reduced ability to smell, blurred vision, decreased sharpness of vision, inflammation of the pancreas, skin rash due to high level of a specific type of white blood cells, muscle necrosis, flu-like

symptoms (e.g. tiredness, chills, sore throat, aching joints or muscles) and increase of the muscle enzyme (creatine phosphokinase) level in the blood.

If a side effect appears, if any of the side effects worsens or if you suffer from a side effect not mentioned in the leaflet, consult the doctor.

#### **5. HOW SHOULD THE MEDICINE BE STORED?**

Avoid poisoning! This medicine and any other medicine must be kept in a safe place out of the reach and sight of children and/ or infants, to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.

Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.

Store below 30°C and protect from light.

Store in the original package.

#### **6. FURTHER INFORMATION**

In addition to the active ingredient, the medicine also contains:

Cellulose microcrystalline, Sodium starch glycolate, Hypromellose, Magnesium stearate, Silica colloidal anhydrous.

The tablet contains approximately 16 mg sodium.

#### **What the medicine looks like and contents of the pack**

A circular, biconvex, beveled edge tablet, scored on one side and the circular mark LAMISIL 250 on the other side. Whitish to yellow-tinged white color. The surface is smooth or slightly rough.

Package size: 14 tablets.

**Registration holder and address:** Novartis Israel Ltd., 36 Shacham St., P.O.B. 7759, Petach-Tikva.

**Manufacturer and address:** Novartis Pharma Productions GmbH, Öflinger Strasse 44, D-79664 Wehr, Germany

For: Novartis Pharma AG, Basel, Switzerland.

This leaflet was checked and approved by the Ministry of Health in September 2014.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 065 17 27564.