

Package Leaflet: Information for the user

Lamisil® 250mg Tablets

(terbinafine)

Basic Patient Leaflet

Read all of this leaflet carefully before you start taking LAMISIL

Keep this leaflet. You may need to read it again. This medicine has been prescribed only for you. Do not give it to anybody else or use it for any other illnesses. If you have any further questions, please ask your doctor or pharmacist.

The name of your medicine is Lamisil 250mg Tablets but it will be referred to as Lamisil throughout this leaflet.

In this leaflet

1. What Lamisil is and what it is used for
2. Before you take Lamisil
3. How to take Lamisil
4. Possible side effects
5. Storing Lamisil
6. Further information

Lamisil 250mg tablets

- The **active substance** of Lamisil is terbinafine hydrochloride
- Each tablet contains 250mg terbinafine (as hydrochloride)
- The **other ingredients** are magnesium stearate, colloidal silica anhydrous, hypromellose, microcrystalline cellulose and sodium carboxymethyl starch (potato without gluten).

Lamisil are Circular, biconvex, bevelled-edge, white or off-white tablets about 11mm in diameter. One face is scored and the reverse is marked 'LAMISIL 250'. Lamisil is available in calendar blister packs containing 28 tablets.

Manufactured by: Novartis Farmaceutica, S.A., Gran Via de les Corts Catalanes, 764, 08013, Barcelona, Spain.

Procured from within the EU and repackaged by the PPA holder: B&S Healthcare, Unit 4, Bradfield Road, Ruislip, Middlesex, HA4 ONU, UK.

Lamisil® 250mg tablets, PPA No: 1328/120/002

POM

1. What Lamisil is and what it is used for

Lamisil is used to treat fungal infections of the fingernails and toenails. Lamisil is 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.

2. Before you take Lamisil

Lamisil will only be prescribed for you by a doctor. Follow all your doctor's instructions carefully, even if they differ from the general information contained in this leaflet.

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.

If you think you may be allergic, ask your doctor for advice.

Take special care with Lamisil:

- If you take other medicines.
- If you experience symptoms such as unexplained persistent nausea, vomiting, stomach pain, loss of appetite, unusual tiredness, if your skin or the whites of your eyes look yellow, that your urine is unusually dark or your bowel motions are unusually light in colour (signs of liver problems).

- If you experience any skin problems such as rash, red skin, blistering of the lips, eyes or mouth, skin peeling (signs of serious skin reactions).
- If you have or experience thickened patches of red/silver skin (psoriasis) or facial rash, joint pain, muscle disorder, fever (cutaneous and systemic lupus erythematosus).
- If you experience weakness, unusual bleeding, bruising or frequent infections (signs of blood disorders).

If you get any of these symptoms, **tell your doctor straight away.**

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

Lamisil and older people

Lamisil 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 is not recommended for children.

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 because your baby would be exposed to terbinafine through your breast milk. This might harm your baby.

Driving and using machines

If you feel dizzy while taking Lamisil, do not drive or use machines.

Taking other medicines

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),
- Caffeine
- some antidepressants (e.g. desipramine),
- some medicines used to treat heart problems (e.g. propafenone, amiodarone),
- some medicines used to treat high blood pressure (e.g. metoprolol),
- 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 cough (e.g. dextrometorphan)
- ciclosporin, a medicine used to control your body's immune system in order to prevent rejection of transplanted organs

Be sure to tell your doctor about these, or any other medicines you take.

3. How to take Lamisil

Follow your doctor's instructions carefully. Do not exceed the recommended dose. If you have the impression that the effect of Lamisil is too strong or too weak, talk to your doctor or pharmacist.

How much Lamisil to take and how often Adults

The usual dose is one 250mg tablet daily.

Children

Lamisil is not recommended for use in children.

How long to take Lamisil

This will depend on the type of infection you have, how severe it is, and what part of your body is affected. Your doctor will tell you exactly for how long you will need to take the tablets.

The normal duration of treatment is as follows:

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

For tinea (ringworm) and yeast infections of the groin and other body areas, Lamisil is usually taken for 2 to 4 weeks. It is important to take your tablet(s) every day and to continue to take it/them for as long as your 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.

You can take Lamisil tablets with or without food.

Hair and scalp infections

The normal duration of treatment for tinea (ringworm) infections of the scalp and hair is 4 weeks.

Nail infections

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

Fingernail infection

Treatment duration of less than 12 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. 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 have accidentally taken too many tablets, talk to your doctor straight away. You may require medical attention.

Symptoms caused by an overdose of Lamisil 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.

4. Possible side effects

In general, Lamisil is well tolerated. Like all medicines, Lamisil may cause some unwanted effects (side effects) in some people.

Some side effects can be serious:

Rarely Lamisil can cause liver problems, in very rare cases the liver problems can be 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. Tell your doctor immediately:

- If you experience symptoms such as unexplained persistent nausea, stomach problems, loss of appetite or unusual tiredness or weakness or if you notice that your skin or the whites of your eyes look yellow, that your urine is unusually dark or your bowel motions are unusually light in colour (possible signs of liver problems).
- If you develop a sore throat with fever and shivering or if you experience unusual bleeding or bruising (possible signs of diseases that affect the level of certain types of blood cells).
- If you notice abnormal 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).
- If you experience difficulty 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
- If you experience severe upper stomach pain with radiation 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).

The following side effects have been reported with Lamisil:

Very common (*likely to affect more than 1 in every 10 patients*): Nausea, mild stomach pain, heartburn, diarrhoea, a feeling of fullness in the stomach, loss of appetite, skin rashes, aching joints and muscles.

Common (*likely to affect 1 to 10 in every 100 patients*): Headache.

Uncommon (*likely to affect 1 to 10 in every 1,000 patients*): Loss of or altered sense of taste. This is uncommon and usually recovers within several weeks after stopping treatment with Lamisil. It may lead to a reduction of appetite and significant weight loss in very few patients. You should tell your doctor if the altered sense of taste lasts for several days.

Rare (*likely to affect 1 to 10 in every 10,000 patients*): Liver problems.

Very rare (*likely to affect less than 1 in every 10,000 patients*): Decrease in certain types of blood cells, lupus (an autoimmune disease), serious skin reactions, allergic reactions, hair loss, fatigue, psoriasis-like skin eruptions, worsening of psoriasis, dizziness, decreased physical sensitivity, numbness and tingling.

The following side effects have also been reported:

Low level of red blood cells, severe allergic reactions, inflammation of blood vessels, smell disorders including permanent loss of smell, anxiety (with symptoms such as sleep disturbances, fatigue, loss of energy or diminished ability to think or concentrate) and depressive symptoms (e.g. depressed mood) due to taste disturbances, inflammation of the pancreas, muscle necrosis, flu-like symptoms (e.g. tiredness, chills, sore throat, joint or muscles aching), fever, increase in blood of a muscle enzyme (creatine phosphokinase), increased sensitivity of skin to sun, decreased hearing, impaired hearing and/or perception of noises in the absence of sound (e.g. hissing, ringing) in ears.

If you are concerned about any of these side effects or experience any side effects not mentioned in this leaflet, inform your doctor or pharmacist.

5. Storing Lamisil

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

Do not use the medicine after the expiry date stated on the carton/ blister label after 'Exp'. The expiry date refers to the last day of that month.

Do not store above 30°C.

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

6. Further information

If you have any further questions about this medicinal product, please contact your doctor or pharmacist.

Leaflet date: 05.09.2013

Lamisil is a registered trademark of Novartis group of companies.