

Package leaflet: Information for the patient

Lamisil® 250 mg Tablets

terbinafine

Read all of this leaflet carefully before you start taking this medicine - because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- This medicine will be referred to as Lamisil in this leaflet.

What is in this leaflet

1. What Lamisil is and what it is used for
2. What you need to know before you take Lamisil
3. How to take Lamisil
4. Possible side effects
5. How to store Lamisil
6. Contents of the pack and other information

1. What Lamisil is and what it is used for

Lamisil contains a medicine called terbinafine. It is an "anti-fungal" medicine.

Lamisil is used in adults and older people to treat a number of fungal infections of the skin and nails. It kills the fungus or stops it growing.

2. What you need to know before you take Lamisil

Do not take Lamisil if:

- you are allergic to terbinafine or any of the other ingredients of this medicine (listed in section 6)
- you have or had any liver problems
- you are breast-feeding
- you are pregnant or trying to become pregnant.

Do not take Lamisil if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Lamisil.

Warnings and precautions

Talk to your doctor or pharmacist before taking Lamisil if:

- you have ever had liver or kidney problems
- you have or experienced thickened patches of red/silver skin (psoriasis) or facial rash, joint pain, muscle disorder, fever (cutaneous and systemic lupus erythematosus). Lamisil can make these problems worse.

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking Lamisil.

Look out for side effects

Lamisil can cause some side effects that may require urgent medical treatment. They include problems with your liver, skin, muscles or blood. See "Stop taking Lamisil and see a doctor or go to a hospital straight away, if you notice any of the following serious side effects" at the beginning of Section 4 for more information.

Children and adolescents

Lamisil tablets can be used in adolescents and children aged 2 years and over. As the patient grows, the doctor will adjust the dose.

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

Other medicines and Lamisil

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription, oral contraceptives or herbal medicines. This is because Lamisil can affect the way some other medicines work. Also some other medicines can affect the way Lamisil works.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

- rifampicin - used to treat infections
- cimetidine – used to treat stomach problems such as indigestion or stomach ulcers
- ciclosporin – used to control your body's immune system after a transplant
- anti-depressants – including tricyclic anti-depressants such as desipramine, SSRIs (selective serotonin reuptake inhibitors), or MAOIs (monoamine oxidase inhibitors)
- oral contraceptives (as irregular periods and breakthrough bleeding may occur in some females)

- anti-fungals – used to treat fungal infections such as fluconazole or ketoconazole
- beta-blockers or anti-arrhythmics – used to treat heart problems such as metoprolol, propafenone or amiodarone
- dextromethorphan – used in some cough medicines
- caffeine – used in some pain killers or cold remedies.

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking Lamisil.

Lamisil with food and drink

Lamisil may increase the effects of caffeine in your drinks.

Lamisil and Sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

Pregnancy and breast-feeding

- Do not take Lamisil if you are pregnant or trying to become pregnant.
- Do not breast-feed if you are taking Lamisil. This is because small amounts may pass into the mother's milk.

Driving and using machines

Lamisil can cause dizziness. If you feel dizzy after taking this medicine, do not drive or use any tools or machines.

3. How to take Lamisil

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

How much to take

Adults

Your doctor will decide what dose of Lamisil you should take. The dose will be on the pharmacist's label. Check the label carefully. It should tell you how many tablets to take, and how often.

The recommended dose for adults and older people is 250 mg once a day. If your liver or kidneys are not working very well, your doctor may reduce the dose.

The length of your treatment with Lamisil will depend on the type of infection you have, how severe it is and what part of your body is affected.

- For skin infections continue taking the tablets for **2 to 6 weeks**.
- For nail infections treatment usually lasts for between **6 weeks and 3 months**. Some patients with toenail infections may need to be treated for **6 months or longer**.

Children and adolescents

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:

Children weighing 20 to 40 kg	125 mg (half a 250 mg tablet) once daily
Children weighing more than 40 kg	250 mg (one 250 mg tablet) once daily

Taking this medicine

- You should take Lamisil by mouth.
- Swallow the tablets whole with a glass of water.
- Lamisil can be taken with or without food.
- The tablet can be divided into equal doses.

Other ways to clear up your infection

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

If you take more Lamisil than you should

If you take too much Lamisil, tell your doctor or go to the hospital straight away. Take your medicine pack with you so that people can see what you have taken. You may get a headache, stomach pain, feel sick or dizzy.

If you forget to take Lamisil

If you miss taking a Lamisil tablet, do not worry. Take it 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 tablet at the usual time. Then carry on as normal until you have finished all the tablets. Do not take a double dose to make up for a forgotten dose.

If you stop taking Lamisil

It is important that you finish all the tablets you have been given unless your doctor tells you to stop taking them.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking Lamisil and see a doctor or go to hospital straight away, if you notice any of the following serious side effects – you may need urgent medical treatment:

- severe allergic reaction – the signs may include difficulty breathing, swelling of your lips, face, throat or tongue, flushing, stomach cramps or joint pain, stiffness, rash or swollen lymph glands. You may also become unconscious
- yellowing of your skin or eyes. Unusually dark urine or pale faeces, unexplained feeling of sickness, being sick, stomach problems, loss of appetite or unusual tiredness or weakness – these may be signs of liver problems
- a sore throat with fever and shivering – signs that the medicine has affected your blood cells
- a sore throat, with fever, tiredness and ulcers appearing on your mouth or lips – signs of a problem with your immune system
- unusual bleeding or bruising – signs that the medicine has affected your blood cells.
- stomach pain which spreads to your back – signs of “pancreatitis”
- unexplained muscle weakness and pain or having dark red-brown urine – signs of “muscle necrosis”.
- feeling unusually tired, weak or breathless and looking pale – signs of “anaemia”
- onset or worsening of a condition called psoriasis (a long-term illness with symptoms including thickened patches of red and silver skin)
- onset or worsening of a condition called Lupus (a long-term illness with symptoms including fever, facial skin rash and pain in the muscles and joints)
- severe skin rash (including light sensitivity, swelling, blistering, scales or wheals).
- skin rash, fever, itching, feeling tired or if you notice purplish-reddish spots under your skin – signs that your blood vessels have become inflamed

If you get any of the serious side effects listed above, stop taking Lamisil and see a doctor or go to hospital straight away.

Other side effects include:

Talk to your doctor or pharmacist if you notice any of the following side effects.

Very common: may affect more than 1 in 10 people

- stomach problems such as loss of appetite, stomach ache, indigestion, feeling bloated or sick
- diarrhoea.
- headache.
- skin rashes (itchy).
- joint pain and muscle pain.

Common: may affect up to 1 in 10 people

- feeling tired or dizzy.
- depression.
- disturbance or loss of sense of taste.
- eye disorder.

Uncommon: may affect up to 1 in 100 people

- If you notice unusually pale skin, nail beds or when you pull down your eyelids, feeling unusually tired, weak or breathless during physical activity (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 (e.g. hissing) in ears, fever and weight loss.

Rare: may affect up to 1 in 1,000 people

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

Very rare: may affect up to 1 in 10,000 people

- numbness, tingling or loss of sensitivity to touch
- hair loss.

Not known: frequency cannot be estimated from the available data

- loss of sense of smell or reduced ability to smell
- blurred vision, decreased sharpness of vision
- feeling anxious – signs include trouble sleeping, feeling tired, lack of energy, finding it difficult to think or concentrate
- feeling low in mood
- increase in blood level of a muscle enzyme – shown in blood tests
- skin rash due to high level of a specific type of white blood cells

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via HPRA Pharmacovigilance, Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Lamisil

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

Do not use this medicine after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

Do not store above 25 °C.

Keep the blisters in the outer carton in order to protect from light.

Do not throw away any medicines via wastewater or household waste.

Ask your pharmacist how to throw away medicines you no longer use.

These measures will help protect the environment.

6. Contents of the pack and other information

What Lamisil contains

- The active substance is terbinafine. Each tablet contains terbinafine hydrochloride equivalent to 250 mg terbinafine.
- The other ingredients are magnesium stearate, hypromellose, microcrystalline cellulose, sodium starch glycolate colloidal and anhydrous silica.

What Lamisil looks like and contents of the pack

Lamisil 250 mg tablets are circular, biconvex, white tablets with 'LAMISIL 250' on one side and a breakline on the other. The tablet can be divided into equal doses.

They come in blisters of 14 or 28 tablets.

Not all pack sizes may be marketed.

Product procured from within the EU, repackaged and distributed by the Parallel Product Authorisation Holder:

PCO Manufacturing Ltd., Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath, Ireland.

Manufacturer

Lamisil 250 mg Tablets are manufactured by Novartis Pharmaceuticals UK Ltd., Horsham, UK or Novartis Farmacéutica, S.A. Gran Via de les Corts Catalanes, 764, 08013 Barcelona, Spain or Novartis s.r.o., Na Pankraci 1724/129, 140 00 Prague 4, Czech Republic or Novartis Pharma Produktions GmbH, Wehr, Germany or Novartis (Hellas) A.E.B.E., 14451, Metamorfoosi, Greece or Lek d.d., PE PROIZVODNJA LENDAVA Trimlini 2D, Lendava, 9220, Slovenia.

Parallel Product Authorisation number: PPA0465/096/001

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This leaflet was last revised in September 2023.