

LAMISIL® Tablets 250 mg (terbinafine)

Patient Information Leaflet

What you need to know about Lamisil Tablets

Your doctor has decided that you need this medicine to help treat your condition. Please read this leaflet carefully before you start to take your medicine. It contains important information. Keep the leaflet in a safe place because you may want to read it again.

If you have any other questions, or if there is something you don't understand, please ask your doctor or pharmacist.

This medicine has been prescribed for you. Never give it to someone else. It may not be the right medicine for them even if their symptoms seem to be the same as yours.

If any side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Lamisil Tablets are, and what they are used for
2. Things to consider before you start to take Lamisil Tablets
3. How to take Lamisil Tablets
4. Possible side effects
5. How to store Lamisil Tablets
6. Contents of the pack and other information

1. What Lamisil Tablets are and what they are used for

Terbinafine, the active ingredient in Lamisil Tablets, is an antifungal medicine.

Lamisil Tablets are used to treat a number of fungal infections of the skin and nails.

2. Things to consider before you start to take Lamisil Tablets

Some people MUST NOT take Lamisil Tablets. Talk to your doctor if:

- you think you may be allergic to terbinafine or to any of the other ingredients of Lamisil Tablets. (These are listed in Section 6.)
- you have or have had any liver problems
- you are breast-feeding

You should also ask yourself these questions before taking Lamisil Tablets. If the answer to any of these questions is YES, tell your doctor or pharmacist because Lamisil Tablets might not be the right medicine for you.

- Are you pregnant or trying to become pregnant?
- Do you have any problems with your kidneys or liver?
- Do you have psoriasis?
- Do you have systemic lupus erythematosis (SLE)?
- Do you have rash due to a high level of a specific type of white blood cells?

Children should not normally be given Lamisil Tablets.

Are you taking other medicines?

Some medicines can interfere with your treatment. Tell your doctor if you are taking any of the following:

- Rifampicin for infections
- Cimetidine for gastric problems such as indigestion or ulcer
- Antidepressants including tricyclic antidepressants, SSRIs (selective serotonin reuptake inhibitors), or MAOIs (monoamine oxidase inhibitors)
- Oral contraceptives (as irregular periods and breakthrough bleeding may occur in some female patients)
- Beta-blockers or anti-arrhythmics for heart problems
- Warfarin, a medicine used to thin your blood
- Medicines to treat heart problems (eg propafenone, amiodarone)
- Ciclosporin, a medicine used to control your body's immune system in order to prevent rejection of transplanted organs
- Medicines used to treat fungal infections (eg fluconazole, ketoconazole)
- Medicines used to treat cough (eg dextromethorphan)
- Caffeine

Always tell your doctor about all the medicines you are taking. *This means medicines you have bought yourself as well as medicines on prescription from your doctor.*

You should have blood tests before and during treatment with Lamisil Tablets to monitor your liver function.

Will there be any problems with driving or using machinery?

Some people have reported feeling dizzy or giddy while they are taking Lamisil Tablets. If you feel like this you should not drive or operate machinery.

Information about sodium content

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

3. How to take Lamisil Tablets

The doctor will decide what dose of Lamisil Tablets you should take. Always take the tablets exactly as your doctor has told you to. 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. If you are not sure, ask your doctor or pharmacist. Keep taking the tablets for as long as you have been told unless you have any problems. In that case, check with your doctor.

The usual dose for adults, including the elderly, is 250 mg once a day.

- 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, although some patients with toenail infections may need to be treated for 6 months or longer.
- If your kidneys are not working very well, your doctor may reduce the dose of Lamisil Tablets you take.
- Swallow the tablets whole with a glass of water.

What if you forget to take a dose?

If you miss taking a Lamisil Tablet, do not worry. Take it as soon as you remember. Take your next tablet at the usual time, then carry on as normal until you have finished all the tablets. It is important that you finish all the tablets you have been given unless your doctor tells you to stop taking them.

What if you take too many tablets?

All tablets can be risky if you take too many. If you take too many Lamisil Tablets at once, tell your doctor or hospital casualty department as soon as possible. Take your medicine pack with you so that people can see what you have taken.

4. Possible side effects

Lamisil Tablets are suitable for most people, but, like all medicines, they can sometimes cause side effects. Any side effects are usually mild or moderate and don't last for too long.

Some side effects can be serious

Stop taking the tablets and tell your doctor immediately if you notice any of the following rare symptoms:

- Yellowing of your skin or eyes. Unusually dark urine or pale faeces, unexplained persistent nausea, stomach problems, loss of appetite or unusual tiredness or weakness (this may indicate liver problems), increase in liver enzymes which may be noted on a blood test result
- Severe skin reactions including rash, light sensitivity, blistering or wheals
- Weakness, unusual bleeding, bruising, abnormal pale skin, unusual tiredness, or weakness or breathlessness on exertion or frequent infections (this may be a sign of blood disorders)
- Difficulty breathing, dizziness, swelling mainly of the face and throat, flushing, crampy abdominal pain, stiffness, rash, fever or swollen/enlarged lymph nodes (possible signs of severe allergic reactions)
- Symptoms such as rash, fever, itching, tiredness or if you notice appearance of purplish spots under the skin surface (signs of blood vessel inflammation)
- Severe upper stomach pain which spreads to the back (possible signs of pancreas inflammation)
- Unexplained muscle weakness or pain, or dark (red-brown) urine (possible signs of muscle breakdown)

The most common side effects are :-

- Headache
- Stomach problems such as loss of appetite, ache, indigestion, feeling bloated or sick
- Diarrhoea
- Itching, rash or swelling
- Pains in the muscles and joints

The side effects listed below have also been reported.

Up to 1 in 100 people have experienced:

Taste loss and taste disturbance. This usually disappears within several weeks after you stop taking the medicine. However, a very small number of people, (less than 1 in 10,000), have reported that the taste disturbance lasts for some time and, as a result, they go off their food and lose weight. There have also been reports of some people experiencing anxiety or symptoms of depression as a result of these taste disturbances.

Up to 1 in 1,000 people have experienced:

- Feeling unwell, dizzy
- Numbness or tingling

Up to 1 in 10,000 people have experienced:

- Feeling tired
- Decrease in the number of some blood cells. You may notice that you seem to bleed or bruise more easily than normal, or you may catch infections easily and these might be more severe than usual
- Psoriasis like skin eruptions, or worsening of any psoriasis including a rash or eruption of small pus containing blisters
- Vertigo
- Hair loss
- Onset or worsening of a condition called lupus (a long-term illness with symptoms including skin rash and pain in the muscles and joints)

The following have also been reported: Signs of blood disorders: weakness, unusual bleeding, bruising or frequent infections.

Disorders of sense of smell which may be permanent, impaired hearing, hissing and/or ringing in the ears, flu like symptoms, increase in blood of a muscle enzyme called creatine phosphokinase (may be found on a blood test), reduced or blurred vision.

If any of the symptoms become troublesome, or if you notice anything else not mentioned here, please go and see your doctor. He/she may want to give you a different medicine.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. By reporting side effects you can provide more information on the safety of this medicine.

5. How to store Lamisil Tablets

Store the tablets in their original pack away from direct light. Store below 25°C.

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

Do not take the tablets after their expiry date which is printed on the outside of the pack.

If your doctor tells you to stop taking Lamisil Tablets, please take any unused tablets back to your pharmacist to be destroyed. Only keep the tablets if the doctor tells you to. Do not throw them away with your normal household water or waste. This will help to protect the environment.

6. Contents of the pack and other information

What Lamisil Tablets contain

- Each tablet contains 250 mg of the active ingredient terbinafine.
- The other excipients are magnesium stearate, colloidal anhydrous silica, hydroxypropylmethylcellulose, sodium carboxymethyl starch and microcrystalline cellulose.

What Lamisil Tablets look like and contents of the pack

Lamisil Tablets are round, whitish or very pale yellow tablets marked with a score line on one side and 'LAMISIL 250' on the other.

They come in blister packs of 7, 14 or 28 tablets. Not all pack sizes are marketed.

Marketing Authorisation Holder

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This leaflet was last revised in September 2020.

If you would like any more information, or would like the leaflet in a different format, please contact Medical Information at Novartis Pharmaceuticals UK Ltd, telephone number 01276 698370.

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