

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr LAMISIL®

Terbinafine Tablets

Terbinafine Hydrochloride topical cream

Terbinafine Hydrochloride topical spray solution

Read this carefully before you start taking **LAMISIL®** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **LAMISIL**.

Serious Warnings and Precautions

Do not take LAMISIL tablets if you have pre-existing chronic or active liver disease. Serious and life-threatening cases of liver failure, including death, or requiring liver transplant, have been reported in patients with or without pre-existing chronic or active liver disease taking LAMISIL Tablets.

Stop taking LAMISIL tablets and consult your doctor immediately if you develop jaundice (yellowness of skin and/or eyes). See Table of Serious Side Effects and what to do about them.

Your doctor may order blood tests before you start LAMISIL and during LAMISIL treatment.

What is LAMISIL used for?

LAMISIL is used to treat fungal infections of skin, fingernails and toenails:

- LAMISIL tablets are used to treat fungal infections of the nail (toes, fingers) and may be used for certain fungal skin infections that do not respond to topical treatment.
- LAMISIL cream and spray are used to treat certain fungal infections of the skin.

The treatment should only be taken as prescribed by your doctor. Some evidence of infection may still be present at the end of treatment. This will gradually diminish.

How does LAMISIL work?

LAMISIL interferes in the production of a substance (ergosterol) that the fungus needs to grow and causes a build-up of another substance in the cells (squalene). Both actions cause the death of the fungus and elimination of the infection.

What are the ingredients in LAMISIL?

Medicinal ingredient: terbinafine

Non-medicinal ingredients:

- **Tablets:** cellulose microcrystalline; magnesium stearate; methylhydroxypropylcellulose; silica, colloidal anhydrous; sodium carboxymethyl starch.
- **Cream:** benzyl alcohol; cetyl alcohol; cetyl palmitate; isopropyl myristate; polysorbate 60; purified water; sodium hydroxide; sorbitan monostearate; stearyl alcohol.
- **Spray:** cetomacrogol 1000; ethanol (28.8% v/v); propylene glycol; water

LAMISIL comes in the following dosage forms:

- Tablets: 250 mg
- Topical cream: 1 % w/w (10 mg/g)
- Topical spray solution: 1% w/w (10mg/g)

Do not use LAMISIL if:

- you are allergic to terbinafine (the active antifungal ingredient) or any of the ingredients in the formulation (See What the nonmedicinal ingredients are). If you think you may be allergic, ask your doctor for advice.
- you have chronic or active liver disease.

Important information about some of the ingredients

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

- LAMISIL cream contains benzyl alcohol, cetyl alcohol and stearyl alcohol which may cause local skin reactions (e.g contact dermatitis).
- LAMISIL spray contains propylene glycol and ethanol which may cause skin irritation.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take LAMISIL. Talk about any health conditions or problems you may have, including if you:

- have or have a history of liver or kidney problems, blood diseases (e.g. anemia), serious skin reactions, or alcohol abuse
- if you have or have had liver problems, your doctor may require blood tests before and during LAMISIL treatment to test liver function
- are pregnant or plan to become pregnant while using LAMISIL.
- are breast-feeding or plan to breast-feed; oral LAMISIL is excreted in breast milk. Nursing mothers should avoid topical applications of LAMISIL to the breast and infants should not come into contact with areas treated with topical LAMISIL.

Other warnings you should know about:

Contact your doctor immediately, while taking LAMISIL, if you develop conditions such as:

- liver problems with symptoms such as persistent nausea, vomiting, abdominal pain, dark urine, pale stools, fatigue, loss of appetite, yellowing of the skin and eyes
- serious skin reactions such as blistering or peeling skin, blistering of the lips, eye or mouth, red/inflamed skin, hives, fever (due to skin reactions), rash (due to high white blood cell count-eosinophilia)

- experience symptoms of lupus erythematosus such as thickened patches of red/silver skin (psoriasis), joint pain, muscle disorder/pain and fever
- blood disorder with symptoms such as weakness, unusual bleeding, bruising, sore throat or frequent infections

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

- **Tablets:**

- Tell your doctor or pharmacist if you are taking or have recently oral contraceptives or birth control pills.

The following medicines may interact with LAMISIL:

- 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 irregular heart rhythm (antiarrhythmics (e.g. propafenone, amiodarone),
- some medicines used to treat high blood pressure (e.g. beta-blockers such as metoprolol),
- theophylline, a medicine used to relieve bronchospasm in asthma,
- some medicines used to treat cough (e.g. dextromethorphan),
- cyclosporine, a medicine used to control your body's immune system (e.g. in order to prevent rejection of transplanted organs),
- St John's wort [*Hypericum perforatum*]), a herbal medicine used to treat depression.

- **Cream and spray:**

- No drug interactions are known to date.

How to take LAMISIL:

To help clear up your infection completely, it is very important that you keep taking this medicine for the prescribed treatment period, even if your symptoms begin to clear up or you begin to feel better after a few days. Since fungal infections may be very slow to clear up, stopping your medication too soon can cause the symptoms and the fungal infection to flare up again.

Usual Dose:

Follow your doctor's instructions carefully. Do not exceed the recommended dosage. If you feel that the effect of LAMISIL is too strong or too weak, talk to your healthcare professional.

ORAL:

- **LAMISIL tablets**

Adults: 250 mg once daily

- 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.
- You can take LAMISIL tablets if you are aged 65 years and over at the same dose as younger adults.

TOPICAL:

If the cream accidentally gets into your eyes, wipe it away and rinse the eye thoroughly with running water. Consult your doctor if symptoms persist.

Avoid applying the spray to your face.

LAMISIL Cream and Spray contain alcohol (ethanol) which could be irritating to certain skin lesions.

Because fungal and yeast infections can be passed to other people, remember to keep your own towel and do not share them with others. To protect yourself from re-infection, your towels and clothes should be washed frequently.

• **LAMISIL cream**

- LAMISIL cream can be applied once or twice daily.
- The affected areas should be cleansed and dried thoroughly before application of LAMISIL.
- The cream should be applied to the affected skin and surrounding area in a thin layer and rubbed in lightly.
- In the case of skin-fold infections (under breasts, between toes, around the groin, between the buttocks) the application may be covered with a gauze strip, especially at night.
- If there are no signs of improvement after two weeks you should talk to your doctor.

• **LAMISIL spray**

- LAMISIL spray is applied once or twice daily, depending on the indication.
- The affected areas should be cleansed and dried thoroughly before application of LAMISIL. Avoid contact with cuts, wounds or other skin lesions as the alcohol in the spray may irritate or sting the skin.
- A sufficient amount of solution should be applied to wet the treatment area(s) thoroughly, and to cover the affected skin and surrounding area.
- In case of accidental inhalation, contact your doctor if any symptoms develop and persist.

- Relief of clinical symptoms usually occurs within a few days. Improper use or stopping the treatment early may cause a re-infection. If there are no signs of improvement after two weeks you should talk to your doctor.

- 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.

Overdose:

- LAMISIL tablets: Symptoms caused by an overdose include headache, nausea, stomach pain and dizziness.
- LAMISIL cream or spray: No case of overdosage has been reported. If ingested by accident, symptoms similar to the LAMISIL tablets (listed above) are to be expected.

If you think you, or a person you are caring for, have taken too much LAMISIL, contact a healthcare professional, hospital emergency department, or regional Poison Control Center immediately, even if there are no symptoms.

Missed Dose:

Try not to miss any doses. If you do miss a dose, take it as soon as possible. However, if it is almost time for your next dose (up to 4 hours), skip the missed dose and go back to your regular schedule. Do not double the doses and never make dose changes on your own. Take as prescribed by your doctor.

What are possible side effects from using LAMISIL?

LAMISIL tablets

The following side effects have been reported with LAMISIL tablets:

- Very common (*likely to affect more than 1 in every 10 patients*): headache, nausea, mild abdominal pain, stomach discomfort after meal (heartburn), diarrhea, swelling or bloating (a feeling of fullness) of the abdomen, loss of appetite, skin rashes (itchy), joint pain and muscle pain.
- Common (*likely to affect 1 to 10 in every 100 patients*): Mood disorder (depression), disturbance or loss of sense of taste, dizziness, eye disorder and tiredness. If you suffer dizziness, do not drive or operate machinery.
- Uncommon (*likely to affect 1 to 10 in every 1,000 patients*): 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), 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 (*likely to affect less than 1 to 10 in every 10,000 patients*): abnormal liver function test results.
- Very rare (*likely to affect less than 1 in every 10,000 patients*): Decrease in certain types of blood cells, psoriasis-like skin eruptions (rash with silver coloured appearance), worsening of psoriasis, skin rash with flaking or peeling and hair loss.

Serious side effects and what to do about them

Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
RARE			
Liver problems: sometimes fatal such as persistent nausea and vomiting, abdominal pain, fatigue, loss of appetite, dark urine, pale stools or jaundice (yellowing of the skin and eyes).			✓
VERY RARE			
Blood abnormalities: sore throat, shivering, fever, mouth sore, weakness, unusual bleeding or bruising or getting infections frequently			✓
Serious allergic reactions (anaphylactic or serum sickness reactions) or infections: 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			✓
Skin reactions: rash, red skin, blistering of lips, eyes or mouth, peeling skin			✓
UNKNOWN/ NOT KNOWN			
Inflammation of the blood vessels (vasculitis) rash, fever, or appearance of purplish-red spots under the skin surface			✓
Inflammation of pancreas (pancreatitis): severe upper stomach pain with radiation to the back			✓
Muscle breakdown (rhabdomyolysis): severe muscle cramps, aches and pain,			✓

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
or dark (red-brown) urine, feeling unusually tired			
Immune system disorders (lupus): facial rash, swollen joints or joint pain, muscle disorder, tiredness, fever			✓
Smell, taste, visual or hearing disorders or symptoms of depression			✓

These are not all the possible side effects you may have when taking LAMISIL. If you experience any side effects not listed here, tell your healthcare professional.

LAMISIL cream and spray

- The following side effects have been reported with LAMISIL cream and spray: Common (*likely to affect 1 to 10 in every 100 patients*): Flaking or peeling of the skin (skin exfoliation), itching (pruritus).
- Uncommon (*likely to affect 1 to 10 in every 1,000 patients*): Skin lesion, scab, skin disorder, change in the color of the skin (pigmentation disorder), redness of the skin (erythema), skin burning sensation, pain, application site pain, application site irritation.

TELL your doctor if you notice any of these possible side effects.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
UNKNOWN			
Allergic reaction (hypersensitivity): difficulty in breathing or swallowing, dizziness, swelling of the mouth, face, lips, tongue or throat	✓		

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

- Store at temperatures between 15°C and 30°C.
- Protect tablets from light.
- Keep out of the reach and sight of children.

If you want more information about LAMISIL:

- Talk to your healthcare professional
- Find the full Product Monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website www.novartis.ca, or by calling 1-800-363-8883.

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