

PART III: CONSUMER INFORMATION

PrLAMISIL®

Terbinafine tablets 250 mg (as terbinafine hydrochloride)

Terbinafine hydrochloride topical cream 1% w/w (10 mg/g)

Terbinafine hydrochloride topical spray solution 1% w/w (10 mg/g)

This leaflet is part III of a three-part "Product Monograph" published when LAMISIL was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about LAMISIL. Contact your doctor or pharmacist if you have any questions about the drug.

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 other illnesses. Read all of this leaflet carefully before you start treatment. Follow all your doctor's instructions carefully, even if they differ from the general information contained in this leaflet.

ABOUT THIS MEDICATION

What the medication is 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.

Consult your doctor to confirm which type of fungal skin infection you have. Your doctor can determine if LAMISIL is the right treatment for you.

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.

What it does

Terbinafine 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.

When it should not be used:

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.

Do not use LAMISIL if 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.

What the medicinal ingredient is:

terbinafine hydrochloride

What the non-medicinal ingredients are:

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.

What dosage forms it comes in:

- Oral: 250 mg Tablets
- Topical: 1% topical cream 10 mg/g
- 1% topical spray solution 10 mg/g

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

LAMISIL (terbinafine hydrochloride) tablets must not be used 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 receiving LAMISIL Tablets.

Stop taking LAMISIL tablets and consult your doctor immediately should you develop jaundice (yellowness of skin and/or eyes or other symptoms). See *Table of Serious Side Effects*.

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

Before you use LAMISIL, talk to your doctor if you:

- have or have a history of any other medical problems such as 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 allergic to any other medicines (either prescription or non-prescription) or foods
- are pregnant or intend to become pregnant while using LAMISIL.
- are breast-feeding; 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.

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

INTERACTIONS WITH THIS MEDICATION

Tablets:

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 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

Some cases of menstrual irregularities and pregnancies have been reported in patients taking LAMISIL concomitantly with oral contraceptives; however, the rate of occurrence appears to be within the background incidence for patients taking oral contraceptives alone.

Cream and spray:

No drug interactions are known to date.

PROPER USE OF THIS MEDICATION

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.

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.

Usual Adult Dose

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

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.

The duration of treatment varies according to the indication and the severity of infection:

TABLE I

Indication	Duration of Treatment
Onychomycosis (of fingers and toes)	6 weeks to 3 months
Skin Infections Tinea pedis (interdigital & plantar/moccasin type)	2-6 weeks
Tinea corporis, cruris	2-4 weeks

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 tinea 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.

The duration of treatment varies with the indication and is dependent on the severity of the infection:

TABLE II

Indication	Duration of Treatment
Tinea pedis	1 week, once a day
Tinea corporis/cruris	1 week, once a day
Cutaneous Candidiasis	1 to 2 weeks, once or twice a day
Pityriasis versicolor	2 weeks, once or twice a day

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.

The duration of treatment varies with the indication and is dependent on the severity of the infection:

TABLE III

Indication	Duration of Treatment
Tinea pedis	1 week once a day
Tinea corporis/cruris	1 week once a day
Pityriasis versicolor	1 week twice a day

Relief of clinical symptoms usually occurs within a few days. Irregular use or premature discontinuation of treatment carries the risk of recurrence. 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:

Symptoms caused by an overdose of LAMISIL tablets include headache, nausea, stomach pain and dizziness.

No case of overdosage has been reported with LAMISIL cream or spray. Should, however, LAMISIL cream, or spray, be inadvertently ingested, adverse effects similar to those observed with an overdosage of LAMISIL tablets are to be expected. The alcohol content of the spray (28.8% v/v) has to be taken into account. Ask your doctor if you do not understand these instructions or want more information.

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

LAMISIL tablets

As with all medicines, some patients taking LAMISIL tablets may experience some unwanted effects (side effects), although not everybody gets them.

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*): Yellow eyes or skin (liver problems) and 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, lupus (an autoimmune disease), serious skin reactions, allergic reactions, psoriasis-like skin eruptions (rash with silver coloured appearance), worsening of psoriasis, skin rash with flaking or peeling and hair loss.

If you experience smell, taste, visual or hearing disorders or symptoms of depression, then stop using LAMISIL and call your doctor.

If any of the listed side effects affect-you severely, discuss this with your doctor.

Other side effects not listed above may also occur in some patients. If you notice any other side effects not mentioned in this leaflet, inform your doctor or pharmacist.

Some side effects could be serious:

- if you develop fever, shivering, a sore throat or mouth ulcers due to infections and weakness or if you get infections more frequently or
- 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 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 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).

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Rare	Liver problems, sometimes fatal with symptoms 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 with symptoms of sore throat, fever, mouth sore, unusual bleeding or bruising,			√
	Inflammation of the blood vessels (vasculitis) or the pancreas (pancreatitis)			√

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Serious allergic reactions (anaphylactic or serum sickness reactions) or infections				√
Muscle breakdown (rhabdomyolysis)				√
Immune system disorders (lupus)				√
Serious skin reactions (blistering, peeling skin)				√

LAMISIL cream and spray

The following side effects have been reported with LAMISIL cream and spray; however, treatment rarely has to be discontinued for this reason.

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, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Unknown	Allergic reaction (hypersensitivity)	√		

HOW TO STORE IT

Store at temperatures between 15°C and 30°C.

Protect tablets from light.

Keep out of reach and sight of children.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701E
Ottawa, Ontario
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at: <http://www.Novartis.ca>

or by contacting the sponsor, Novartis Pharmaceuticals Canada Inc., at: 1-800-363-8883

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