

MEDICATION GUIDE

LAMISIL® (lam-i-sil)
(terbinafine hydrochloride) Tablets

What is the most important information I should know about LAMISIL Tablets?

LAMISIL Tablets may cause serious side effects, including:

- **Liver problems that can lead to the need for a liver transplant or death.** This can happen in people who have liver problems and in people who have never had liver problems. Tell your doctor right away if you get any of these symptoms of liver problems:

- nausea
- poor appetite
- tiredness
- vomiting
- upper right stomach-area (abdomen) pain
- yellowing of your skin or eyes (jaundice)
- dark (tea-colored) urine
- pale or light colored stools

Your doctor should do a blood test to check you for liver problems before you start treatment with LAMISIL Tablets. Your doctor may also check you for liver problems during treatment, and tell you to stop taking LAMISIL Tablets if you develop liver problems.

What are LAMISIL Tablets?

LAMISIL Tablets is a prescription medicine used to treat fungal infections of the fingernails and toenails (onychomycosis).

Your doctor should do tests to check you for fungal infection of your nails before you start LAMISIL Tablets.

It is not known if LAMISIL Tablets are safe and effective in children for the treatment of onychomycosis.

Who should not take LAMISIL Tablets?

Do not take LAMISIL Tablets if you:

- have had a severe allergic reaction to terbinafine hydrochloride when taken by mouth.
- have had liver disease for a long time (chronic) or have active liver disease.

What should I tell my doctor before taking LAMISIL Tablets?

Before taking LAMISIL Tablets, tell your doctor about all of your medical conditions, including if you:

- have or had liver problems
- have a weakened immune system (immunocompromised)
- have lupus (an autoimmune disease)
- are pregnant or plan to become pregnant. It is not known if LAMISIL Tablets will harm your unborn baby. You should not start taking LAMISIL Tablets during pregnancy.
- are breastfeeding or plan to breastfeed. LAMISIL passes into your breast milk and may harm your baby. You should not breastfeed while taking LAMISIL Tablets. Talk to your doctor about the best way to feed your baby if you take LAMISIL Tablets.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. LAMISIL Tablets may affect the way other medicines work and other medicines may affect how LAMISIL Tablets work.

How should I take LAMISIL Tablets?

- Take LAMISIL Tablets exactly as your doctor tells you to take it.
- LAMISIL comes as a tablet that you take by mouth.
- **LAMISIL Tablets are usually taken:**
 - **1 time each day for 6 weeks to treat fungal infections of your fingernail, or**
 - **1 time each day for 12 weeks to treat fungal infections of your toenail**
- LAMISIL Tablets can be taken with or without food.
- If you miss a dose of LAMISIL Tablets, take it as soon as you remember. If it is less than 4 hours before your next dose, skip the missed dose. Just take the next dose at your regular time.
- If you take too many LAMISIL Tablets, call your doctor. You may have the following symptoms:
 - nausea
 - stomach-area (abdomen) pain
 - frequent urination
 - rash
 - headache
 - vomiting
 - dizziness

What should I avoid while taking LAMISIL Tablets?

Avoid sunlight. LAMISIL Tablets can make your skin sensitive to the sun and the light from sunlamps and tanning beds. You can get a severe sunburn. Use sunscreen and wear a hat and clothes that cover your skin if you have to be in sunlight. Talk to your doctor if you get sunburn.

What are the possible side effects of LAMISIL Tablets?

LAMISIL Tablets may cause serious side effects, including:

- See “What is the most important information I should know about LAMISIL Tablets?”
- **Change in your sense of taste or loss of taste** is common with LAMISIL Tablets, but can also be severe. This may improve within several weeks after you stop taking LAMISIL Tablets, but may last for a long time or may become permanent. Tell your doctor if you develop any of the following:
 - change in your sense of taste or loss of taste
 - poor appetite
 - change in your mood or depressive symptoms. See the list of depressive symptoms below.
 - weight loss
 - anxiousness
- **Change in your sense of smell or loss of smell** may happen with LAMISIL Tablets. This may improve after you stop taking LAMISIL Tablets, but may last for a long time or may become permanent. Tell your doctor if you have a change in your sense of smell or loss of smell.
- **Depressive symptoms. Tell your doctor right away if you develop any of these signs or symptoms:**
 - feel sad or worthless
 - change in sleep pattern
 - mood changes
 - loss of energy or interest in daily activities
 - restlessness
- **Low white blood cell count.** LAMISIL Tablets may decrease your white blood cell count, especially neutrophils. You may have a higher risk of getting an infection when your white blood cell count is low.
- **Serious skin or allergic reactions, which may include problems with some of your body organs. Tell your doctor right away or get emergency medical help** if you get any of these symptoms:
 - skin rash
 - hives
 - sores in your mouth, or your skin blisters and peels
 - swelling of your face, eyes, lips, tongue or throat
 - trouble swallowing or breathing
 - fever
 - swollen lymph glandsAlso tell your doctor about any new symptoms, such as cough, chest pain, fast heartbeat, or blood in your urine.
- **New or worsening lupus.** Stop taking LAMISIL Tablets and tell your doctor if you get any of the following:
 - a skin rash that gets worse (progresses), is scaly, red, shows scarring, or loss of skin color
 - unusual sensitivity to the sun that can cause a rash

The most common side effects of LAMISIL Tablets include:

- headache
- diarrhea
- rash
- upset stomach
- abnormal liver function tests
- itching
- nausea
- stomach-area (abdomen) pain
- gas

These are not all of the possible side effects of LAMISIL Tablets.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store LAMISIL Tablets?

- Store LAMISIL Tablets below 77°F (25°C).
- Keep LAMISIL Tablets in a tightly closed container and keep out of the light.

Keep LAMISIL Tablets and all medicines out of the reach of children.

General information about the safe and effective use of LAMISIL Tablets.

Medicines are sometimes prescribed for purposes other than those listed in Medication Guide. Do not use LAMISIL Tablets for a condition for which it was not prescribed. Do not give LAMISIL Tablets to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or doctor for information about LAMISIL Tablets that is written for health professionals.

What are the ingredients in LAMISIL Tablets?

Active ingredient: terbinafine hydrochloride

Inactive ingredients: colloidal silicon dioxide, hydroxypropyl methylcellulose, magnesium stearate, microcrystalline cellulose, sodium starch glycolate.

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This Medication Guide has been approved by the U.S. Food and Drug Administration

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