Patient Information

Lamisil (Lam-i-sil)

(terbinafine hydrochloride)

Tablets

Read this Patient Information before you start taking Lamisil and each time you get a refill. There may be new information. This information does not take the place of talking to your doctor about your medical condition or your treatment.

What is Lamisil?

Lamisil is a prescription antifungal 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.

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

Who should not take Lamisil?

Do not take Lamisil if you are allergic to terbinafine hydrochloride when taken by mouth.

What should I tell my doctor before taking Lamisil?

Before you take Lamisil, tell your doctor if you:

- have or had liver problems
- have a weakened immune system (immunocompromised)
- have lupus (an autoimmune disease)
- have kidney problems
- have any other medical conditions
- are pregnant or plan to become pregnant. It is not known if Lamisil will harm your unborn baby. You should not start using Lamisil during pregnancy without talking with your doctor.
- are breast-feeding or plan to breast-feed. Some Lamisil passes into your milk and may harm your baby. Talk to your doctor about the best way to feed your baby if you take Lamisil.

Tell your doctor about all the medicines you take, including prescription and nonprescription medicines, vitamins, and herbal supplements. Lamisil may affect the way other medicines work and other medicines may affect how Lamisil works. Especially tell your doctor if you take:

- a medicine for depression
- a medicine for high blood pressure
- a medicine for heart problems
- desipramine (Norpramin)
- caffeine
- cyclosporine (Gengraf, Neoral, Sandimmune)
- fluconazole (Diflucan)
- rifampin (Rifater, Rifamate, Rimactane, Rifadine)
- cimetidine (Tagamet)

If you are not sure if your medicine is one listed above, ask your doctor or pharmacist.

Know the medicines you take. Keep a list of them to show your doctor and pharmacist when you get a new medicine.

How should I take Lamisil?

- Take Lamisil exactly as your doctor tells you to take it.
- Lamisil comes as a tablet that you take by mouth.
- Lamisil is 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
- You can take Lamisil with or without food.
- If you forget to take Lamisil, take your tablets 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 dose at the usual time.
- If you take too much Lamisil call your doctor. You may have the following symptoms:
 - nausea

rash

- vomitingdizziness
- stomach (abdominal) pain
- frequent urination

• headache

What are the possible side effects of Lamisil?

Lamisil may cause serious side effects, including:

- **liver problems that can lead to the need for liver transplant, or death**. Tell your doctor right away if you get any of these symptoms of a liver problem:
 - nausea
 - poor appetite

- upper right stomach (abdominal) painyellowing of your skin or eyes (jaundice)
- dark (tea-colored) urine

tirednessvomiting

pale or light colored stools

Your doctor should do a blood test to check you for liver problems before you take Lamisil.

- **change in taste or loss of taste** may happen with Lamisil. This usually improves within several weeks after stopping Lamisil, but may last for a long time or may become permanent. Tell your doctor if you have:
 - change in taste or loss of taste
 - poor appetite
 - unwanted weight loss, or
 - change in mood or depressive symptoms
- **change in smell or loss of smell** may happen with Lamisil. This may improve after stopping Lamisil, but may last for a long time or may become permanent.
- depressive symptoms. Tell your doctor right away if you have any of these signs or symptoms:
 - feel sad or worthless
 - change in sleep pattern
 - loss of energy or interest in daily activities

- restlessness
- mood changes
- serious skin or allergic reactions. Tell your doctor right away or get emergency 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

- **new or worsening lupus (an autoimmune disease).** Stop taking Lamisil and tell your doctor if you experience any of the following:
 - progressive skin rash that is scaly, red, shows scarring, or loss of pigment
 - unusual sensitivity to the sun that can lead to a rash

The most common side effects of Lamisil include: headache, diarrhea, rash, dyspepsia, liver enzyme abnormalities, pruritus, taste disturbance, nausea, abdominal pain, and flatulence.

Tell your doctor if you have any side effect that bothers you or that does not go away.

These are not all of the possible side effects of Lamisil. For information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects.

You may report side effects to FDA at 1-800-FDA-1088.

How do I Store Lamisil?

- Store Lamisil at a temperature below 77° F (25° C).
- Keep Lamisil in a tightly closed container and away from light.

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

General information about the safe and effective use of Lamisil.

Medicines are sometimes prescribed for purposes other than those listed in Patient Information. Do not use Lamisil for a condition for which it was not prescribed. Do not give Lamisil to other people, even if they have the same symptoms that you have. It may harm them.

This Patient Information summarizes the most important information about Lamisil. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for information about Lamisil that is written for health professionals.

What are the ingredients in Lamisil?

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

This Patient Information has been approved by the U.S. Food and Drug Administration.

Distributed by: Novartis Pharmaceuticals Corporation East Hanover, New Jersey 07936

© Novartis

T2012-143/T2011-62 April 2012/March 2011