NOVARTIS

LAMISIL®

(Terbinafine)

250 mg, Tablet

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SCHEDULING STATUS S4

LAMISIL® 250 mg tablets

Terbinafine

Sugar free

Read all of this leaflet carefully before you start taking LAMISIL®

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- LAMISIL® has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet:

1. What LAMISIL® is and what it is used for

What LAMISIL® is:

Each LAMISIL® tablet contains 250 mg terbinafine as terbinafine hydrochloride.

LAMISIL® belongs to a group of medicines called “Antimicrobial (Chemotherapeutic) agents.

Fungicides", which are used to treat fungal infections of the skin and treatment of ringworms.

What LAMISIL® is used for:

LAMISIL® tablets are used to treat fungal infections of the fingernails and toenails.

LAMISIL® tablets are also used to treat tinea (ringworm) infections of the scalp and hair, groin and other body areas and the feet (athlete's foot), as well as yeast infections of the skin.

Terbinafine belongs to the group of medicines called antifungal agents and is used to treat fungal infections of the skin, hair and nails. When taken by mouth, it reaches the site of infection in concentrations strong enough to kill the fungus or stop it growing.

2.What you need to know before you take LAMISIL®:

Do not take LAMISIL®:

- If you are allergic (hypersensitive) to terbinafine or any of the other ingredients of LAMISIL® listed in section 6.
- If you have or had any liver problems.
- If you have any kidney problems.
- If you are breastfeeding.

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

Warnings and precautions

Take special care with LAMISIL®

- If you experience any skin problem such as rash, red skin, blistering of the lips, eyes or mouth, skin peeling, fever (possible signs of serious skin reactions), rash due to high level

of a specific type of white blood cells (eosinophilia).

- If you have or experience thickened patches of red/silver skin (psoriasis) or facial rash, joint pain, muscle disorder, fever (cutaneous and systemic lupus erythematosus).
- If you experience weakness, unusual bleeding, bruising or frequent infections (signs of blood disorders).
- If you take other medicines refer to “Other medicines and LAMISIL®” section of this leaflet.

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

LAMISIL® and older people.

LAMISIL® tablets can be taken by people over the age of 65 years. If you are more than 65 years old, you will be given the same dose as other adults.

LAMISIL® and children

LAMISIL® tablets are not recommended for use in children under 2 years of age.

Other medicines and LAMISIL®

Always tell your healthcare provider if you are taking any other medicine (This includes complementary or traditional medicines).

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 antibiotics (e.g. rifampicin),
- some antidepressants (e.g. desipramine),
- some medicines used to treat heart problems (e.g. propafenone and amiodarone),

- some medicines used to treat high blood pressure (e.g. metoprolol),
- some medicines used to treat stomach ulcers (e.g. cimetidine),
- Some medicines used to treat fungal infections (e.g. fluconazole, ketoconazole),
- some medicines used to treat cough (e.g. dextromorphan),
- ciclosporin, a medicine used to control your body's immune system in order to prevent rejection of transplanted organs,
- caffeine.

Be sure to tell your doctor about these, or any other medicines you take.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

You may use LAMISIL during pregnancy only if advised by your doctor.

If you are taking LAMISIL, you should not breastfeed your baby.

Driving and using machines

LAMISIL has no known effect on the ability to drive and use machines.

3. How to take LAMISIL®

Do not share medicines prescribed for you with any other person.

Always follow the instructions of your doctor carefully. If you are unsure about how much LAMISIL to take, or when to take it, please ask your doctor or pharmacist. In order for the medicine to have the

full therapeutic effect, the full course of LAMISIL must be taken as indicated. Do not exceed the recommended dosage.

How much LAMISIL® to take and how often

Adults

The usual dose is one 250 mg tablet daily.

Children

No data is available for children under 2 years of age (usually less than 12 kg).

- Children weighing less than 20 kg: 62.5 mg once daily (the use of Lamisil 250 mg tablets is not recommended).
- Children weighing 20 to 40 kg: 125 mg (half 250 mg tablet) once daily.
- Children weighing more than 40 kg: 250 mg once daily

Treatment duration: 12 weeks is sufficient in most cases.

Some patients with poor nail growth may need longer treatment. Your doctor will discuss it with you.

If you take more LAMISIL® than you should

If you accidentally take more tablets than your doctor has prescribed, call your doctor immediately or go to the casualty department at your nearest hospital. Symptoms caused by an overdose of LAMISIL® tablets include headache, nausea, stomach pain and dizziness.

If you forget to take LAMISIL®

Take your tablet(s) 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.

4. Possible side effects

LAMISIL® can have side effects.

Not all side effects reported for LAMISIL® are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking LAMISIL®, please consult your healthcare provider for advice.

Some side effects can be serious:

Rarely LAMISIL® tablets can cause liver problems; in some cases the liver problems can be serious. Serious side effects include a decrease in certain types of blood cells, lupus (an autoimmune disease), serious skin problems, including severe allergic reactions, inflammation of blood vessels, inflammation of the pancreas or muscle necrosis.

Tell your doctor immediately:

- if you experience symptoms such as unexplained persistent nausea, stomach problems, loss of appetite or unusual tiredness or weakness
- if you notice that your skin or the white of your eyes look yellow, that your urine is unusually dark or your bowel motions are unusually light in colour (possible signs of liver problems)
- if you develop a sore throat with fever and shivering
- If you experience unusual bleeding or bruising (possible signs of diseases that affect the level of certain types of blood cells).
- 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)
- if you experience difficulty in breathing, dizziness , swelling mainly of the face and throat, flushing, crampy abdominal pain and loss of consciousness

- if you experience symptoms such as joint pain, stiffness, rash, fever or swollen/enlarged lymph nodes (possible signs of severe allergic reactions)
- if you experience symptoms such as rash, fever, itching, tiredness or if you notice appearance of purplish-red spots under the skin surface (possible signs of blood vessel inflammation)
- if you develop any skin problems
- 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)

The following side effects have been reported with LAMISIL:

***Frequent*:**

Headache, nausea, mild stomach pain, heartburn, diarrhea, a feeling of fullness in the stomach, loss of appetite, skin rashes, aching joints and muscles, mood disorder (depression), disturbance or loss of sense of taste, dizziness, eye disorder and tiredness.

Less frequent:

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, yellow eyes or skin (liver problems) and abnormal liver function test results, 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.

The following side effects have also been reported:

Severe allergic reactions or infections, inflammation of blood vessels, smell disorders including permanent loss of smell, reduced ability to smell, blurred vision, decreased sharpness of vision, inflammation of the pancreas, skin rash due to high level of a specific type of white blood cells, muscle necrosis, flu-like symptoms (e.g. tiredness, chills, sore throat, joint or muscles aching), and increase in blood of a muscle enzyme (creatine phosphokinase).

If any of these affects you severely, tell your doctor.

If you notice any other side effects not mentioned in this leaflet, inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of LAMISIL.

5. How to store LAMISIL®

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

Do not use the medicine after the expiry date shown on the pack.

Store in a cool, dry place below 30 °C. Protect from light.

Return any unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Content of the pack and other information

What LAMISIL® contains:

LAMISIL® tablets contain 250 mg terbinafine hydrochloride.

The other ingredients are: magnesium stearate; silica colloidal anhydrous; hydroxypropylmethyl cellulose; microcrystalline cellulose; sodium carboxymethyl starch.

What LAMISIL® looks like and contents of the pack

Identification of LAMISIL®:

A whitish to yellow-tinged white, circular, biconvex, bevelled edged tablet, scored on one side and coded LAMISIL® 250 (circular) on the other side, with smooth or slightly rough surface.

Presentation of LAMISIL®:

Blister pack of 14.

Holder of the certificate of registration:

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