



PROPERTIES/THERAPEUTIC USE

What is LAMISIL and when is it used?
LAMISIL cream is a medicine (antifungal agents) intended for treatment of skin infections caused by fungi (mycoses) such as athlete's foot or other superficial mycoses of the skin and pityriasis versicolor. **LAMISIL** cream is also effective against infections caused by yeasts (candidoses of the skin). **LAMISIL** cream rapidly suppresses symptoms such as itching, desquamation (scaling) and red blotches. **LAMISIL** cream is available without prescription.

ADDITIONAL INFORMATION

Apart from treatment what steps can be taken?
In order to prevent mycoses, observe the following rules: Change your clothes every day because it is possible that the germs remain attached to parts of the clothes which are in contact with infected regions of the skin. Avoid wearing clothes which fit too tightly or have little permeability to air. Carefully dry the affected parts after washing. Change your flannel and towel every day. If you are suffering from athlete's foot, do not walk barefoot. In addition, sprinkle or spray the inside of your socks or shoes every day with a powder or spray which is effective against fungal infections.

CONTRAINDICATIONS

When should LAMISIL not be used?
Do not use this product if you are allergic

(hypersensitive) to terbinafine hydrochloride or any of the other ingredients of this medicine. As the experience in children under 12 years of age is limited, the use of **LAMISIL** cream is not recommended in children under 12 years of age.

PRECAUTIONS AND WARNINGS

What precautionary measures should be observed when using LAMISIL?
LAMISIL cream should only be used externally. Do not use in the mouth or swallow. Avoid all contact with your eyes. If by accident the product comes into contact with the eyes, they should be carefully flushed with cold water. Consult your doctor if there is still discomfort. Consult your doctor in the case of large-scale mycoses or when the mycosis involves the nails. Please inform your doctor or pharmacist if you suffer from other illnesses, allergies or use other medicines for internal or external use (even under self-medication!). Do not apply other medicinal products on the areas being treated.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you might be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine. Should not be used during pregnancy unless clearly necessary. Do not use Lamisil Cream while breast-feeding. The ingredients can pass into your breast milk. Do not allow infants to come into contact with any treated areas, including the breasts.

Driving and using machines
Lamisil Cream has no influence on the ability to drive and use machines.

Important information about some of the ingredients of Lamisil Cream
Lamisil Cream contains cetyl alcohol and stearyl alcohol: may cause local skin reactions (e.g. contact dermatitis).

DOSAGE/METHOD OF USE

How is LAMISIL used?
Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. It is important to use Lamisil Cream correctly. Follow the instructions carefully. If you have a **fungal nail infection** (fungus inside and under the nail), with discoloration of the nails and change in nail texture (thick, flaky), you should see your doctor because Lamisil Cream is NOT appropriate for this type of infection. Be aware that in rare cases the underlying fungal infection may be aggravated. Lamisil tablets, available on prescription only, should be used to treat nail fungus. For use on the skin. For adults and children above 12 years: Direction for use:

- Clean and dry the affected skin and surrounding areas, and wash your hands.
- Unscrew the cap, and if using for the first time, use the point in the cap to pierce the top of the tube, then gently squeeze the tube.
- Apply enough gel to put a thin layer on the affected skin and surrounding areas.
- Rub in gently.
- Replace the cap on the tube.
- Wash your hands so that you do not spread the infection on to yourself or on to others.



If you are treating an infection in folded areas of your body you can cover the treated area with a gauze strip, especially at night. If you do, use a fresh, clean gauze strip each time you apply the cream.

Duration of normal treatment

Do not use in children below 12 years of age.

For adults and children above 12 years:

Cream:

Athlete's foot, superficial skin mycoses: apply once a day for 1 week.

Skin candidiasis (intertrigo or sweat rash): apply 1-2 times a day for 1 week.

Pityriasis versicolor: apply 1-2 times a day for 2 weeks.

Use the cream for the recommended treatment period even if the infection seems to be better after a few days. Infections usually appear to improve within a few days, but may reappear if the cream is not applied regularly or is stopped too early.

The cream should start to improve your skin condition in a few days. The cream will continue to work even after you have completed the treatment.

If you have not noticed any signs of improvement within 2 weeks of first starting treatment, please see your doctor or pharmacist who will advise you.

UNDESIRABLE SIDE EFFECTS

What undesirable side effects can LAMISIL have?

Like all medicines, Lamisil Cream can cause side effects, although not everybody gets them.

STOP using Lamisil Cream and seek medical help immediately if you have any of the following which may be signs of an allergic reaction:

- difficulty in breathing or swallowing
- swelling of the face, lips, tongue or throat
- severe itching of the skin, with a red rash or raised bumps

When using this product you may experience:

- Skin peeling, itching.
- Skin lesion, scab, skin disorder, skin color changes, redness, burning, pain, application site pain, application site irritation.

Other side effects include:

- Dry skin, eczema.
- Contact dermatitis which is a type of inflammation of the skin.
- Skin rash.
- Worsening of disease symptoms.
- Allergic reactions.

If Lamisil Cream is accidentally applied to the eyes, eye irritation may occur.

If you get other any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

SPECIAL REMARKS

What should also be taken into consideration?

Medicines must be kept out of the sight and reach of children. If Lamisil is accidentally swallowed, tell your doctor or pharmacist immediately. Do not store above 30 °C. The medicine may not be used beyond the date printed on the package with the indication <EXP>. Keep the tube closed and in the carton. Store in the original package. For more comprehensive information, consult your doctor or pharmacist who have more detailed information intended for representatives of the medical professions.

If you forget to use Lamisil Cream

If you forget an application of the cream, apply it as soon as possible and then carry on as normal. If you only remember at the time of the next application, just apply the usual amount and then carry on as normal. Do not take a double dose to make up for a forgotten dose. Should a larger amount of Lamisil Cream be inadvertently ingested, adverse effects similar to those observed with an overdosage of Lamisil tablets are to be expected. These include headache, nausea, epigastric pain and dizziness.

COMPOSITION

Cream: One gram of Lamisil 1% Cream contains 10 mg terbinafine hydrochloride (active ingredient), equivalent to 8.8 mg of terbinafine base, benzyl alcohol and other excipients.

PRESENTATION

Cream 1%: 7.5 g, 10 g and 15 g tube. (Not all pack sizes may be marketed)

INFORMATION UPDATED

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