

DermGel

#### **PROPERTIES / THERAPEUTIC USE**

# What is LAMISIL and when is it used?

Lamisil dermgel is a medicine (antifungal agent) intended for treatment of skin infections caused by fungi (mycoses) such as ring worm, jock-itch, athlete's foot or other superficial mycoses of the skin and pityriasis versicolor.

Lamisil dermgel is available without prescription for you to treat the following skin infections without a doctor's help (nevertheless you need to use it carefully to get the best results from it).

*LAMISIL* dermgel rapidly suppresses symptoms such as itching, desquamation (scaling) and red blotches.

#### 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 base or any of the other ingredients of *LAMISIL* dermgel. *LAMISIL* dermgel is not recommended for use in children and adolescents below 18 years of age due to insufficient data on safety and efficacy.

#### **PRECAUTIONS AND WARNINGS**

# What precautionary measures should be observed when using LAMISIL?

Talk to your doctor or pharmacist before using *LAMISIL* dermgel. *LAMISIL* dermgel should only be used externally. Do not use it in the mouth or swallow it. 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 taking or have recently taken or might take any other medicines. Do not apply any other medicinal products on the areas being treated.

# Avoid contact with your eyes.

If by accident the product comes into contact with your eyes, they should be carefully flushed with cold water. Consult your doctor if there is still discomfort.

**LAMISIL** dermgel must be used with care on open wounds because these products contain alcohol which can cause irritation. It must not be used on the face.

# PREGNANCY AND BREAST-FEEDING

**Can LAMISIL be used during pregnancy or lactation?** 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* dermgel 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* dermgel has no influence on the ability to drive and use machines.

# Important information about some of the ingredients of LAMISIL dermgel

LAMISIL dermgel contains:

 butylhydroxytoluene, which may cause local skin reactions (e.g. contact dermatitis), or irritation to the eyes and mucous membranes.

# 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* dermgel correctly. Follow the instructions carefully. If you have a fungal nail infection (fungus inside and

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** dermgel is NOT appropriate for this type of infection. Be aware that in rare case 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.

# Directions 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 dermgel.

#### Duration of normal treatment Adults:

Ring worm, jock-itch, athlete's foot or other superficial skin mycoses: Apply once a day for 1 week. Pityriasis vesicolor: apply once a day for 1 week.

Use the gel 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 gel should start to improve your skin condition in a few days. The gel 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.

# If you use more LAMISIL dermgel than you should

If you or someone else accidentally swallows some LAMISIL dermgel, please tell your doctor who will advise you on what to do. Should a larger amount of Lamisil Dermgel 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.

# If you forget to use LAMISIL dermgel

If you forget an application of the gel, 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.

# **UNDESIRABLE SIDE EFFECTS**

# What undesirable side effects can LAMISIL have?

Like all medicines, *LAMISIL* dermgel can cause side effects, although not everybody gets them. STOP using LAMISIL dermgel and seek medical help immediately if you have any of the following which may be signs of an allegic 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. ٠
- Contact dermatitis which is a type of inflammation of the skin.
- Skin rash.
- Worsening of disease symptoms.
- Allergic reactions.

If LAMISIL dermgel 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 reach and sight 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>. For more comprehensive information, consult your doctor or pharmacist who have more detailed information intended for representatives of the medical professions.

#### COMPOSITION

Dermgel: 1g gel contains 10mg terbinafine (active ingredient), benzyl alcohol, alcohol, butylhydroxytoluene (E321) and other excipients.

# PRESENTATION

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Dermgel: 5g, 15g, 30g (Not all pack sizes may be marketed) **INFORMATION UPDATED** 

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