

# LAMISILAT

## 1% GEL

### Terbinafine

**Read all of this leaflet carefully because it contains important information for you.**

This medicine is available without prescription. However, you still need to use Lamisil AT 1% Gel carefully to get the best results from it.

- Please keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve after 7 days.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

#### **In this leaflet:**

1. What Lamisil AT 1% Gel is and what it is used for
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### **1. WHAT LAMISIL AT 1% GEL IS AND WHAT IT IS USED FOR**

Lamisil AT 1% Gel contains the active ingredient terbinafine which is an antifungal used to treat skin problems caused by fungi in:

- Athlete's foot (tinea pedis) – athlete's foot appears only on the feet (usually both, but not always), where it often appears in-between the toes. It can also appear on the instep, soles, or other areas of the feet. The most common type of athlete's foot causes cracking or scaling of the skin, but you may also have mild swelling, blisters, or weeping ulcers. Lamisil AT 1% Gel is recommended for athlete's foot when it occurs between the toes. If you have a fungal nail infection (fungus inside and under the nail) with discolouration of the nails and changes in nail texture (thick or flaky), you should consult your doctor because Lamisil AT 1% Gel is not appropriate for this type of infection.
- Dhobie itch/jock itch (tinea cruris) – dhobie itch appears in the groin and inner thigh area, usually on both sides but often with one side more than the other, where it can spread further between the legs to the buttocks, or up towards the stomach. Dhobie itch looks like a clearly bordered rash, which may have blisters.
- Ringworm (tinea corporis) – ringworm usually appears as circular, sharp-edged areas of red rash, with dry, scaly or

crusty patches towards the edges. Lamisil AT 1% Gel is suitable for ringworm occurring on the trunk of the body, legs, arm, neck or head, but not face.

### **2. BEFORE YOU USE LAMISIL AT 1% GEL**

**DO NOT use Lamisil AT 1% Gel if you have:**

- an allergy (hypersensitivity) to any of the ingredients in the product (see Section 6 and end of Section 2).

The gel is NOT recommended for children under 16 years of age.

**Take special care with Lamisil AT 1% Gel**

The gel is for application on the skin only.

- Avoid inhaling the product.
- Eyes, mouth or face – avoid contact of the gel. In case of accidental contact with eyes, rinse thoroughly with running water.

#### **Taking other medicines**

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including those obtained without a prescription.

Do not apply other medicines on the areas you are treating with Lamisil AT 1% Gel.

#### **Pregnancy and breast-feeding**

If you are pregnant ask your doctor before using this medicine.

Do not use the gel if you are breast-feeding.

#### **Driving and using machines**

Lamisil AT 1% Gel is not expected to affect your ability to drive or operate machinery.

#### **Important information about some of the ingredients of Lamisil AT 1% Gel**

**Butylated hydroxytoluene (E321)** – may cause local skin reactions (e.g. contact dermatitis), or irritation to the eyes and membrane linings.

**Benzyl alcohol** - contains 10.8 mg benzyl alcohol in each daily dosage which is equivalent to 5 mg/g. Benzyl alcohol may cause allergic reactions.

**Ethanol** - contains 207.36 mg alcohol (ethanol) in each daily dose which is equivalent to 100 mg/g of 96% ethanol. It may cause burning sensation on damaged skin.

### **3. HOW TO USE LAMISIL AT 1% GEL**

**Always use this medicine exactly as described in this leaflet or as advised by your doctor or pharmacist.**

#### **Adults**

Lamisil AT 1% Gel is applied once a day, for one week only, for all fungal infections.

- Cleanse and dry the affected areas thoroughly and wash your hands. Treatment can be helped by keeping the affected areas clean by regular washing and careful drying with your own clean towels and clothes, and not rubbing or scratching the skin.
- Unscrew the cap – if using the medicine for the first time, use the point in the cap to pierce the top of the tube then gently squeeze out the gel.

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- Rub the gel in lightly to the affected skin and surrounding areas (avoid application to where alcohol could cause stinging or irritation). When used between the toes, buttocks or on the groin, the treated area may be covered with a light, fresh gauze strip, especially at night.
- Replace the cap on the tube and wash your hands.

Even though you will not be using Lamisil AT 1% Gel during the second week, full skin healing after the infection has cleared will continue for up to 4 weeks. If you have not noticed any signs of improvement within 2 weeks of first starting treatment, please seek advice from your doctor or pharmacist.

**Children under 16 years**

NOT recommended.

**If you accidentally swallow Lamisil AT 1% Gel**

Contact your doctor or nearest hospital emergency department if you, or someone else, has swallowed some gel. Take any remaining medicine and this leaflet with you if possible.

Symptoms of accidental ingestion include headache, nausea (feeling sick), dizziness and stomach pain.

**If you forget to use Lamisil AT 1% Gel**

If you miss an application, apply the gel as soon as possible then carry on as before. If you only remember at the time of your next application, just apply the gel and carry on as normal. It is important to try to use the gel at the correct times as forgotten applications could risk the infection returning.

**If you stop using Lamisil AT 1% Gel**

You should not stop using the gel before the recommended time as this may reduce the effectiveness of treatment or the infection may return. If you have any further questions on the use of this product, ask your doctor or pharmacist.

**4. POSSIBLE SIDE EFFECTS**

Like all medicines, Lamisil AT 1% Gel can cause side effects, although not everybody gets them.

**STOP using** the gel and **seek medical help immediately** if you have any of the following very rare allergic reactions:

- Difficulty breathing or swallowing, swelling of the mouth, face, lips, tongue or throat (**severe allergic reaction**).
- Severe itching of the skin, with red rash or raised lumps, hives or blisters.

**Common** (*may affect up to 1 in 10 people*): skin peeling, itching.

**Uncommon** (*may affect up to 1 in 100 people*): skin lesions, scab, skin colour changes, redness, burning, pain and irritation at the site of application.

These common and uncommon side effects are usually harmless and you can carry on using the gel.

**Rare** (*may affect up to 1 in 1000 people*): eye irritation, dry skin, contact dermatitis, eczema, worsening of symptoms.

**If any of these side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.**

**Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow

Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

**5. HOW TO STORE LAMISIL AT 1% GEL**

Keep out of the sight and reach of children. Do not store above 30°C. Use this medicine within 1 month of opening. Do not use or keep this medicine after the expiry (EXP) date shown on the box and tube. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

**6. FURTHER INFORMATION**

**What Lamisil AT 1% Gel contains**

The **active** ingredient is terbinafine, 1% w/w.

The **other** ingredients are purified water, ethanol, isopropyl myristate, polysorbate 20, carbomer 974P, sorbitan laurate, benzyl alcohol, sodium hydroxide and butylated hydroxytoluene (see also Section 2 'Important information about some of the ingredients of Lamisil AT 1% Gel').

**What Lamisil AT 1% Gel looks like and contents of the pack**

The gel is available in a 15g aluminium or laminated screw cap tube.

**Marketing Authorisation Holder**

Karo Healthcare AB, Box 16184, 103 24 Stockholm, Sweden.

**Manufacturer**

Karo Healthcare AB, Klara Norra Kyrkogata 33, 111 22 Stockholm, Sweden.

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