Lamisil® 1% w/w Cream

terbinafine hydrochloride

Read all of this leaflet carefully before you start taking this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious or you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Lamisil 1% Cream is and what it is used for

Lamisil 1% Cream is used to treat Athlete's foot (Tinea pedis), Dhobie itch (Tinea cruris), a fungal infection of the skin known as Pityriasis versicolour and certain yeast infections of the skin (those caused by the genus Candida). It attacks and kills the fungus or yeast which is causing your infection.

2. Before you use Lamisil 1% Cream

Do NOT use Lamisil 1% Cream if you:
- Are allergic (hypersensitive) to any of the ingredients in the product (see Section 6)

The cream is NOT recommended for use on children.

Take special care with Lamisil 1% cream
The cream is for external use only. Do not use on the face. Avoid contact with the eyes. In case of accidental contact with the 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.

Pregnancy and breast-feeding
Do not use the cream if you are pregnant or breastfeeding, unless advised to by your doctor. Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines
Lamisil 1% Cream is not expected to affect your ability to drive or operate machinery.

Important information about some of the ingredients of Lamisil 1% Cream
The cream contains some ingredients which you may need to be aware of:
- **Cetyl alcohol** and **stearyl alcohol:** may cause local skin reactions (e.g. contact dermatitis).

For other ingredients see Section 6.

3. How to use Lamisil 1% Cream

Always use Lamisil 1% Cream exactly as your doctor or pharmacist has told you; you should check with him/her if you are not sure.
This medicine is for external use only.

Usual dose for adults
Your doctor will decide the right amount of Lamisil 1% Cream for you to use and will tell you for how long to use your medication.
Apply the cream once or twice a day, for one to two weeks, but this will depend upon the type and area of infection.

The likely durations of treatment are as follows:

Athlete's foot:	Once a day for 1 week
Ringworm, Dhobie itch:	Once a day for 1 week
Cutaneous candidiasis:	Once or twice a day for 1 to 2 weeks
Pityriasis versicolour:	Once or twice a day for 2 weeks

Infections usually appear to improve within a few days of starting to use Lamisil 1% Cream, but may reappear if the cream is not applied regularly or is stopped too early.

Directions for use:
- 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 then gently squeeze out a small amount of the cream onto your finger
- Apply just enough cream to form a thin layer on the affected skin and surrounding areas
- Rub in gently. When used between the toes, under the breasts, 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.

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
The cream is NOT recommended for use on children.

If you use more Lamisil 1% Cream than you should
Contact your doctor or nearest hospital emergency department if you, or someone else, has swallowed some cream. Take any remaining medicine and this leaflet with you if possible.

If you forget to use Lamisil 1% Cream
If you miss an application, apply the cream as soon as possible then continue your treatment as before. If you only remember at the time of your next application, just apply the cream and carry on as normal. It is important to try to use the cream at the correct times as forgotten applications could carry a risk of the infection recurring.

If you stop using Lamisil 1% Cream
Infections may come back if you do not use the cream regularly, or if you stop the treatment too early.

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 1% Cream can cause side effects, although not everybody gets them.

STOP using the cream 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 a red rash or raised lumps, hives or blisters.

Lamisil 1% Cream can occasionally cause redness, stinging, peeling, itching, pain, irritation or scabbing at the application site. There may also be some change in skin colour at the application site. These effects are usually harmless and you can carry on using the cream.

Some side effects are common:
(may affect up to 1 in 10 people): skin peeling, itching.

Some side effects are uncommon: (may affect up to 1 in every 100 people): skin lesions, scab, skin colour changes, redness, burning, pain and irritation at the site of application.

Some side effects are rare: (may affect up to 1 in 1000 people): eye irritation, dry skin, contact dermatitis, eczema, worsening of symptoms.

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2;
Tel: +353 1 6764971; Fax: +353 1 6762517.
Website: www.hpra.ie; E-mail: medsafety@hpra.ie.
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Lamisil 1% Cream

Keep out of the sight and reach of children
Do not store above 30°C.
Do not use this medicine after the expiry (EXP) date shown on the box and tube. The expiry date refers to the last day of that month.
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 1% Cream contains
The **active** ingredient is terbinafine hydrochloride 1.0% w/w.

The **other** ingredients are sodium hydroxide, benzyl alcohol, sorbitan stearate, cetyl palmitate, cetyl alcohol, stearyl alcohol, polysorbate 60, isopropyl myristate and purified water.
(See also end of Section 2 for further information on some of the ingredients).

What Lamisil 1% Cream looks like and contents of the pack
The cream is a white, smooth glossy cream, available in tubes of 15g or 30g. Not all pack sizes may be marketed.

Product procured from within the EU, repackaged and distributed by the Parallel Product Authorisation holder:
PCO Manufacturing, Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath

Manufacturer:
Novartis Pharma Productions, GmbH 79664 Wehr, Germany or Novartis Consumer Health SA, Nyon, Switzerland or Novartis Farmaceutica S.A. Gran Via de les Corts Catalanes, 764 08013 Barcelona, Spain or Novartis (Hellas) AEBE, National Road No. 1, 12th km. 14451 Metamorfosi, Attica, Greece or GlaxoSmithKline Consumer Healthcare GmbH & Co. KG, Barthstrasse 4, 80339 München, Germany

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