

PACKAGE LEAFLET: INFORMATION FOR THE USER

LAMISIL® 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 if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Lamisil Cream is and what it is used for
2. Before you use Lamisil Cream
3. How to use Lamisil Cream
4. Possible side effects
5. How to store Lamisil Cream
6. Further information.

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

Lamisil Cream is used to treat patients with fungal and certain yeast infections of the skin. It attacks and kills the fungus or yeast which is causing your infection.

2. Before you use Lamisil Cream

Do NOT use Lamisil 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 Cream

The cream is for external use only. Do not use on the face. Avoid contact with eyes. 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.

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 Cream is not expected to affect your ability to drive or operate machinery.

Important information about some of the ingredients of Lamisil Cream

- This medicine contains 36 mg benzyl alcohol in each daily dosage which is equivalent to 10 mg/g. Benzyl alcohol may cause allergic reactions.
- 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 cream

Adults

Your doctor will decide the right amount of Lamisil 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. Infections usually appear to improve within a few days of starting to use Lamisil 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, 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 Cream during the second week for athlete's foot, 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

Use in children is NOT recommended, since there are no data to support use in this population.

If you accidentally swallow Lamisil Cream

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

If you forget to use Lamisil 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 risk the infection returning.

If you stop using Lamisil 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 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.

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 cream.

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 effect 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 on this leaflet. You can also report side effects directly via the Yellow Card Scheme at: 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 Cream

- **KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.**
- Do not store above 30°C.
- Store in the original package.
- Replace the cap on the tube after use. Keep the tube closed and in the carton.
- Do not use Lamisil Cream after the expiry date printed on the carton or tube label.
- If the medicine becomes discoloured or shows any other signs of deterioration, you should seek the advice of your pharmacist who will tell you what to do.
- 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 protect the environment.

6. Further Information

What Lamisil Cream contains

- Lamisil Cream contains 1% w/w of active ingredient, terbinafine hydrochloride.
- Lamisil Cream also contains the following inactive ingredients: sodium hydroxide, benzyl alcohol, sorbitan monostearate, cetyl palmitate, cetyl alcohol, stearyl alcohol, polysorbate 60, isopropyl myristate and purified water.

What Lamisil Cream looks like and contents of the pack

Lamisil Cream is a white, smooth, homogenous glossy cream.

Lamisil Cream is available in tubes of 15g or 30g (2 x 15g).

Product Licence holder

Procured within the EU and repackaged by the Product Licence holder: S&M Medical Ltd., Chemilines House, Alpertons Lane, Wembley, HA0 1DX.

Manufacturer

This product is manufactured by:

- Novartis (Hellas) AEBE, 12th Km. National Road No 1, 14451 Metamorphosis, Athens, Greece.
- GlaxoSmithKline Consumer, Healthcare GmbH & Co. KG, Barthstrasse 4, 80339 Munchen, Germany.

POM PL: 19488/0181

Leaflet revision date: 27 October 2022

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PACKAGE LEAFLET: INFORMATION FOR THE USER
TERBINAFINE HYDROCHLORIDE 1% w/w CREAM

The name of your medicine is Terbinafine Hydrochloride 1% w/w Cream and will be referred to as Terbinafine Cream throughout the following leaflet.

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- 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 if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Terbinafine Cream is and what it is used for
2. Before you use Terbinafine Cream
3. How to use Terbinafine Cream
4. Possible side effects
5. How to store Terbinafine Cream
6. Further information.

1. What Terbinafine Cream is and what it is used for

Terbinafine Cream is used to treat patients with fungal and certain yeast infections of the skin. It attacks and kills the fungus or yeast which is causing your infection.

2. Before you use Terbinafine Cream

Do NOT use Terbinafine 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 Terbinafine Cream

The cream is for external use only. Do not use on the face. Avoid contact with eyes. 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.

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

Terbinafine Cream is not expected to affect your ability to drive or operate machinery.

Important information about some of the ingredients of Terbinafine Cream

- This medicine contains 36 mg benzyl alcohol in each daily dosage which is equivalent to 10 mg/g. Benzyl alcohol may cause allergic reactions.
- cetyl alcohol and stearyl alcohol: May cause local skin reactions (e.g. contact dermatitis).

For other ingredients see Section 6.

3. How to use Terbinafine cream

Adults

Your doctor will decide the right amount of Terbinafine 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. Infections usually appear to improve within a few days of starting to use Terbinafine 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.
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