

LAMISIL ONCE

1% Cutaneous Solution
Terbinafine Hydrochloride

Read all of this leaflet carefully before you start using Lamisil ONCE. This medicine is available without prescription. However, you still need to use Lamisil ONCE carefully to get the best results from it.

- Keep this leaflet, you may need to read it again.
- Ask a doctor or a pharmacist if you need more information or advice.
- Contact a doctor or pharmacist if your symptoms worsen or do not improve within 1 week.
- 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 ONCE is and what it is used for
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1. WHAT LAMISIL ONCE IS AND WHAT IT IS USED FOR

Lamisil ONCE is a single dose treatment for tinea pedis (athlete's foot). Lamisil ONCE works by killing the fungus which causes tinea pedis (athlete's foot). When it's applied to the feet, it leaves a colourless film that stays on the skin delivering the active substance into the skin.

How you know that you have tinea pedis (athlete's foot)

Tinea pedis (athlete's foot) appears only on the feet. It often starts between the toes, but it can also spread to the soles and sides of the feet. The most common type of tinea pedis (athlete's foot) causes cracking or scaling of the skin. You may also have mild swelling, blisters, or weeping sores. This may often be associated with an itching or burning feeling.

If you are not sure whether your symptoms are really due to tinea pedis (athlete's foot), talk to your doctor or pharmacist, before using Lamisil ONCE.

If you are diabetic you should visit your healthcare professional for regular check ups as diabetes can increase the risk of foot problems.

2. BEFORE YOU USE LAMISIL ONCE

Do not use Lamisil ONCE:

- If you are allergic (hypersensitive) to terbinafine or any of the other ingredients of this medicine (listed over the page at the end of Section 6).
- Take special care with Lamisil ONCE:
 - Children and adolescents under 18 are not to use this medicine, since there is not enough experience.
 - If you suffer from long-term fungal infection of the soles and heels of the feet with thickened and/or obviously flaky skin, do not use this medicine. Tell your doctor if you think you may have this condition, because you may need another medicine.
 - Only use this medicine to treat the skin of your feet. Be careful not to get it on your face, in your eyes, or on damaged skin (other than at the treatment site) where it could be irritating. If it accidentally gets into your eyes, rinse thoroughly with running water. See your doctor if you are still in any discomfort.

- This medicine should be used with caution in patients with lesions where alcohol could be irritating. For example, after sun exposure or in case of severe skin scaling.
- For external use only. Do not swallow.
- Keep away from naked flames (contains alcohol).

Using other medicines

- Do not apply other medicines or treatments to your feet (including any you have bought without a prescription) at the same time as Lamisil ONCE.
- Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including any you have bought without a prescription.

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 taking this medicine.
- Do not use Lamisil ONCE while breast-feeding, as terbinafine is excreted in breast milk.

Driving and using machines

- The use of Lamisil ONCE does not affect the ability to drive and use machines.

Important information about some of the ingredients of Lamisil ONCE

- Lamisil ONCE contains 3316.8 mg alcohol (ethanol) in each daily dose which is equivalent to 863.75 mg/g of 96% ethanol. It may cause burning sensation on damaged skin.

3. HOW TO USE LAMISIL ONCE

For adults only. Do not use on patients under 18.

Apply only once. Do not apply it a second time.

You must apply Lamisil ONCE to both feet, even if signs are visible only on one foot. This is to make sure you get rid of the fungus completely: it could be present in other parts of the feet even if there are no visible signs of it. When applied to the feet, the medication dries quickly to a colourless film. The tube has enough medication to treat both feet. Lamisil ONCE delivers the active ingredient into the skin where it lasts for a number of days to kill the fungus that causes athlete's foot.

24 HRS ➤

To get the best results, do not wash or splash your feet for 24 hours after applying it.

When to use

This is a single application treatment.

- Wash both feet and dry them carefully.
- Wash and dry your hands.
- Remove the cap from the tube.

1 TIME USE ➤

Apply to both feet – use about half the tube for each foot, as needed to cover skin.

Finish one foot before treating the other.

Apply to BOTH FEET ➤

Apply with fingers to each foot as shown above.

➤ Spread evenly onto the skin between, under, and over all toes. Then apply over the sole and sides of your foot.

Do not rub or massage it in.

➤ Treat the other foot in the same way, even if the skin looks healthy. This is to make sure you get rid of the fungus completely – it could be on the other foot even if there are no signs of it.

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- Leave it to dry to a film for 1 to 2 minutes, before wearing your normal footwear.
- Replace the cap on the tube and throw away any remaining product.
- Do not keep or give any remaining product to other people.
- Wash your hands with warm soapy water after the application.
- **Do not wash or splash your feet for 24 hours after applying Lamisil ONCE.**
- Gently pat dry your feet after gentle washing.
- **Do not apply it a second time.**

Lamisil ONCE will start to kill the fungus immediately. The film that is formed means the active ingredient penetrates your skin where it continues to work for several days. Your skin should start to improve within a few days, but it may take up to 4 weeks for your skin to heal completely.

If you have not noticed any signs of improvement within 1 week after applying Lamisil ONCE, ask your doctor or pharmacist for advice.

Do not use the product a second time for a particular athlete's foot episode if it did not work after the first application.

To help with treatment

Keep the affected area clean by washing it regularly after the first 24 hours. Dry it carefully without rubbing. Although the skin may be itchy, try not to scratch it because this could cause more damage and slow the healing process or spread the infection. Use your own towel and clothes and don't share them with other people because athlete's foot can be passed on easily. Wash your clothes and towels frequently to protect yourself from re-infection.

What if you accidentally swallow some of the product.

Tell your doctor who will advise you what to do.

What if you accidentally get the product on your face or in your eyes

Rinse your face or eyes thoroughly with running water. See your doctor if you are still in any discomfort.

4. POSSIBLE SIDE EFFECTS

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

STOP using Lamisil ONCE 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.

Uncommon (may affect up to 1 in 100 people): application site reactions, which may include skin dryness, skin irritation or burning sensation, after application. They are usually mild, temporary and harmless.

Very rare (may affect up to 1 in 10,000 people): allergic reactions with rash, itching, blistering of the skin and hives.

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 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 ONCE

- Keep out of the sight and reach of children.
- Do not use Lamisil ONCE after the expiry date stated on the box and on the tube. The expiry date refers to the last day of that month.
- Store in the original package.
- 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 ONCE contains

Do not use Lamisil ONCE if you are allergic to any of these ingredients.

The active substance is terbinafine (as hydrochloride). Each gram of cutaneous solution contains 10 mg of terbinafine (as hydrochloride). The other ingredients are acrylates/octyl-acrylamide copolymer, hydroxypropylcellulose, medium chain triglycerides and ethanol.

What Lamisil ONCE looks like and contents of the pack

Lamisil ONCE is a clear to slightly cloudy gel-like solution. It is available in tubes of 4g.

Marketing Authorisation Holder:

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Box 16184
103 24 Stockholm
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Manufacturers:

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