

PACKAGE LEAFLET: INFORMATION FOR THE USER



Read all of this leaflet carefully before you start using this medicine because it contains important information for you. Always use this medicine exactly as described in this leaflet or as your pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects talk to your pharmacist. This includes any possible side effects not listed in this leaflet.
- You must talk to a doctor if you do not feel better or if you feel worse within 1 week after application.

What is in this leaflet

1. What **Lamisil Once** is and what it is used for
2. What you need to know before you use **Lamisil Once**
3. How to use **Lamisil Once**
4. Possible side effects
5. How to store **Lamisil Once**
6. Contents of the pack and other information

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 do 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**.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE LAMISIL ONCE

Do not use **Lamisil Once**

- If you are allergic to terbinafine or any of the other ingredients of this medicine (listed in section 6).

Tell your doctor or pharmacist if this applies to you and do not use **Lamisil Once**.

Warnings and precautions

Talk to your doctor or pharmacist before using **Lamisil Once**.

- 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.
- **Lamisil Once** is for external use only. Do not use it in the mouth or swallow it.
- Avoid contact of the solution with your face, eyes or damaged skin where alcohol could be irritating. For example, after sun exposure or in case of severe skin scaling.
- If the solution accidentally gets into your eyes, rinse thoroughly with running water. If any discomfort persists, see your doctor.
- Only use to treat the skin of your feet and toes.
- **Lamisil Once** contains alcohol. Keep away from naked flames.
- **Lamisil Once** should be kept out of the sight and reach of children.

Children and adolescents

Children and adolescents under 18 should not use **Lamisil Once**.

Other medicines and **Lamisil Once**

Tell your doctor or pharmacist if you are using, have recently used or might use any 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**.

Pregnancy and breastfeeding

- If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. **Lamisil Once** should not be used during pregnancy unless clearly necessary.
- This medicine can pass into your breast milk. If you are breastfeeding, ask your doctor for advice before using this medicine.
- Do not allow infants to come into contact with any treated areas, including the breasts.

Driving and using machines

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

Lamisil Once contains ethanol 96%

This medicine 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

Always use this medicine exactly as described in this leaflet or as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is to apply the gel once as indicated below.

Directions for use:

Adults aged 18 years and over

- It's best to apply **Lamisil Once** after a shower or a bath.
- This is a single application treatment.
- Wash both feet and dry them carefully.
- Wash and dry your hands.
- Remove the cap from the tube.
- 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 with fingers to each foot as shown below. 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.
- 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.

How often and how long should you use **Lamisil Once**

Apply only once. 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.

If you have not noticed any signs of improvement within 2 weeks after application, ask your doctor or pharmacist to verify the product is correctly used or a doctor to verify diagnosis.

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

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

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.

If you accidentally swallow some of the product

Tell your doctor who will advise you what to do. Alcohol content has to be considered.

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, this medicine can cause side effects, although not everybody gets them.

People may be allergic to **Lamisil Once**, which could cause swelling and pain, itching, blistering of skin, skin rashes or hives. This has been very rarely reported (may affect up to 1 in 10,000 people).

If you experience an allergic reaction or any of the above symptoms when using this product, remove the film with denatured alcohol (can be obtained in pharmacies), wash your feet with warm soapy water, rinse off and dry them and consult your doctor or pharmacist.

The following side effects have also been reported:

Uncommon (may affect up to 1 in 100 people)

Application site reactions, which may include skin dryness, skin irritation or burning sensation, skin peeling, chapped skin, skin colour changes and redness. They are usually mild and transient reactions.

Not known

Skin colour changes, skin peeling, redness, application site pain. If accidentally applied to the eyes, eye irritation may occur.

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

5. HOW TO STORE LAMISIL ONCE

- Keep this medicine out of the sight and reach of children.
- Do not use **Lamisil Once** after the expiry date which is stated on the box and on the tube. The expiry date refers to the last day of that month.
- Store in the original package to protect it from light. Do not store above 30 °C.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What **Lamisil Once** contains

The active substance is terbinafine (as hydrochloride). Each gram of cutaneous solution contains 10 mg terbinafine (as hydrochloride).

The other ingredients are acrylates/octylacrylamide 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 4 g.

Marketing Authorisation Holder

GlaxoSmithKline Consumer Healthcare (Ireland) Limited, 12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland.

Manufacturer

GlaxoSmithKline Consumer Healthcare (UK) Trading Limited, Brentford, TW8 9GS, U.K.

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