

The PL includes alternative texts for different legal status in different countries as follows:

- **Boxed texts** are only applicable for OTC versions.
- **Grey-shaded texts in brackets** are only applicable for prescription versions.

For OTC use in Sweden, please refer to the approved Swedish package leaflet published on our Webb site.

PACKAGE LEAFLET: INFORMATION FOR THE USER

Lamisil 1 % cutaneous solution

Terbinafine hydrochloride

[Read all of this leaflet carefully before you start using this medicine because it contains important information for you.]

- 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to you doctor or pharmacist. This includes any possible side effects not listed in this leaflet.]

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 one week after completed treatment.

<[To be completed nationally]>

What is in this leaflet:

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

1. WHAT LAMISIL SOLUTION IS AND WHAT IT IS USED FOR

Lamisil Solution is an antifungal agent for use on the skin. It works by killing the fungi causing skin problems.

Lamisil Solution is used to treat:

- Athlete's foot (tinea pedis)
- Dhobie or jock itch (tinea cruris)
- Ringworm (tinea corporis)
- A yeast infection of the skin called pityriasis versicolor.

If you are not sure about the cause of your infection, please talk to your doctor or pharmacist before using Lamisil Solution and they will advise you.

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

Do not use Lamisil Solution

- **If you are allergic** to terbinafine or **any of the other ingredients** of this medicine (listed in section 6 and at the end of Section 2).

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

Warnings and precautions

Talk to your doctor or pharmacist before using Lamisil solution.

- *Lamisil Solution* 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. If the solution accidentally gets into your eyes, rinse thoroughly with running water. If any discomfort persists, see your doctor.
- Lamisil Solution contains alcohol. Keep it away from naked flames.

Children and adolescents

Children and adolescents under 18 should not use Lamisil Solution.

Other medicines and Lamisil Solution

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 the affected area (including any you have bought without a prescription) at the same time as Lamisil Solution.

Pregnancy and breast-feeding

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 Solution should not be used during pregnancy unless clearly necessary.

This medicine can pass into your breastmilk. 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 Solution does not affect your ability to drive and use machines.

Lamisil Solution contains ethanol 96%

This medicine contains 250 mg/g of 96% ethanol.
It may cause burning sensation on damaged skin.

Lamisil Solution contains propylene glycol

This medicine contains 50mg/g of propylene glycol

3. HOW TO USE LAMISIL SOLUTION

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 solution once or twice a day for one week as indicated below.

Directions for use:

Adults Only

- Clean and dry the affected skin and surrounding area and wash your hands.
- Unscrew the cap and gently squeeze the bottle.
- Apply enough of the solution to thoroughly wet the affected skin and surrounding area.
- Replace the cap on the bottle.

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- Wash your hands after touching the infected skin so that you do not spread the infection on to yourself or on to others.

If you are treating an infection in skin folds you can cover the treated area with a gauze strip, especially at night. If you do, use a fresh, clean gauze strip each time you apply the product.

How often and how long should you use Lamisil Solution

Apply the solution once or twice a day to the affected area as shown below unless your doctor tells you otherwise:

- **Athlete's foot:** apply once a day for one week
- **Dhobie or jock itch and ringworm:** apply once a day for one week
- **Yeast infection** (pityriasis versicolor): apply twice a day for one week.

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Use the product for the recommended treatment period even if the infection seems to be better after a few days. Infections usually appear to improve within a few days but may reappear if the product is not applied regularly or is stopped too early.

The product should start to improve your skin condition in a few days.

If you have not noticed any signs of improvement within one week after completing treatment contact a pharmacist to verify that the product is correctly used or a doctor to verify diagnosis.

Discard any remaining solution 12 weeks after first opening.

To help with treatment

Keep the affected area clean by washing it regularly. Dry it carefully without rubbing but dabbing it gently. Although the area 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 do not share them with other people because these infections can be passed on easily. Wash your clothes and towels frequently to protect yourself from re-infection.

If you forget to use Lamisil Solution

If you forget an application of the solution, apply it as soon as possible and then carry on as normal. If you only remember at the time of the next application, just apply the usual amount and carry on as normal. Do not use a double dose to make up for a forgotten dose.

Use the solution as indicated. This is important as by missing applications the infection risks returning.

If you accidentally swallow some of the product

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

If you accidentally get the product in your eyes

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

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

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

People may be allergic to Lamisil Solution, which could cause **swelling and pain, skin rashes or hives**. This has been reported with unknown *frequency (cannot be estimated from the available data)*.

If you experience these particular symptoms, stop using the solution and tell your doctor or pharmacist immediately.

The following side effects have also been reported:

Common (*may affect up to 1 in 10 people*)

Skin peeling and itching at the application site.

Uncommon (*may affect up to 1 in 100 people*)

Skin lesion, scab, skin disorder, pigmentation changes, redness, burning, pain and irritation at the site of application.

Rare (*may affect up to 1 in 1,000 people*)

Dry skin, eczema, condition aggravated, contact eczema (type of skin inflammation).

If Lamisil Solution is accidentally applied to the eyes, eye irritation may occur.

Unknown (*frequency cannot be estimated from the available data*)

Rash.

Reporting of side effects

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

By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE LAMISIL SOLUTION

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and the bottle after EXP. The expiry date refers to the last day of that month.

Do not store above 30°C. Do not refrigerate or freeze.

Replace the cap on the bottle after use. Discard any remaining solution 12 weeks after first opening.

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 Solution contains

- The active substance is terbinafine hydrochloride. One gram of Lamisil Solution contains 10 mg of terbinafine hydrochloride (1% w/w).
- The other ingredients are purified water, ethanol 96%, propylene glycol (E1520), macrogol cetostearyl ether.

What Lamisil Solution looks like and contents of the pack

Lamisil cutaneous solution is a clear, colourless to faintly yellow liquid.

Lamisil 1% cutaneous solution is available as a 30 ml squeeze bottle with a dropper insert.

Marketing Authorisation Holder

<[To be completed nationally]>

{Name and address}

<{tel}>

<{fax}>

<{e-mail}>

Manufacturer

<[To be completed nationally]>

{Name and address}

<{tel}>

<{fax}>

<{e-mail}>

This medicinal product is authorised in the Member States of the EEA under the following names:

Finland: Lamisil 1 % liuos iholle

Greece: LAMISIL 1% Δερματικό Διάλυμα

Italy: Lamisil 1% soluzione cutanea

Luxembourg: Lamisil 1% solution pour application cutanée

Portugal: Lamisil, 10 mg/g, solução cutânea

Sweden: Lamisil 1% kutan lösning

This leaflet was last revised in 8 February 2021