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 DermGel 1 % gel
Terbinafine

[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 your 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 DERMGEL IS AND WHAT IT IS USED FOR

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

Lamisil DermGel 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 pytiriasis versicolor.

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

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

Do not use Lamisil DermGel

- **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 DermGel**.

Warnings and precautions:
Talk to your doctor or pharmacist before using Lamisil DermGel.

- Lamisil DermGel is for external use only. Do not use it in the mouth or swallow it.
- Avoid contact of the gel with your face, eyes or damaged skin where alcohol could be irritating. If the gel accidentally gets into your eyes, rinse thoroughly with running water. If any discomfort persists, see your doctor.

Children and adolescents

Children and adolescents under 18 should not use Lamisil Dermgel.

Other medicines and Lamisil DermGel
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 DermGel.

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 DermGel 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 DermGel does not affect your ability to drive and use machines.

Lamisil Dermgel contains butylhydroxytoluene (E321).
Lamisil Dermgel contains butylhydroxytoluene (E321) which can cause skin reactions such as contact dermatitis. It can also irritate the eyes and mucous membranes.

Lamisil Dermgel contains ethanol 96%
This medicine contains 100 mg/g of 96% ethanol (alcohol).
It may cause burning sensation on damaged skin.

Lamisil Dermgel contains benzyl alcohol

This medicine contains 5 mg/g Benzyl alcohol.
Benzyl alcohol may cause allergic reactions.

3. HOW TO USE LAMISIL DERMGEL

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 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, if you are using the gel for the first time, use the point in the cap to pierce the top of the tube.
- Gently squeeze the tube to apply a thin layer of the gel to the affected skin and the surrounding area.
- Gently rub the gel into the skin.
- Replace the cap on the tube.
- Wash your hands after applying the gel, otherwise you may spread the infection to other parts of your own skin or to other people.

If you are treating an infection within the folds of your skin 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 gel.

How often and how long should you use Lamisil DermGel

Apply Lamisil DermGel to the infected areas as follows:

- **Athlete's foot**: apply once a day for one week.
- **Dhobie (jock) itch and ringworm:** apply once a day for one week.
- **Pityriasis versicolor**: apply once a day for one week.

Use the gel 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 gel 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 gel 16 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 DermGel

If you forget an application of the gel, 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 gel 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 DermGel, 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, 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 DermGel 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 possible 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 DERMGEL

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 on the tube after EXP. The expiry date refers to the last date of that month.
Do not store above 30^{o}C.
Replace the cap on the tube after use. Discard any remaining gel 16 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 DermGel contains
- The active substance is terbinafine. One gram of Lamisil DermGel contains 10 mg of terbinafine (1% w/w).

- The other ingredients are purified water, ethanol 96%, isopropyl myristate, polysorbate 20, carbomer, sorbitan laurate, benzyl alcohol, sodium hydroxide, butylhydroxytoluene (E321).

What Lamisil DermGel looks like and contents of the pack
Lamisil DermGel is a white to off-white glossy gel.
Lamisil DermGel 1% gel is available as a 5g, 15g or 30g aluminum tube or laminated tube with a screw cap
Not all pack sizes may be marketed.

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:

Austria: LAMISIL 1 % DERMGEL, GEL
Denmark: Lamisil 1% Gel
Finland: Lamisil DermGel 1 % geeli
France, Luxembourg, Netherlands, Sweden: Lamisil DermGel 1%
Greece: Lamisil DermGel 1% Γέλη
Italy: LAMISIL DermGEL 1%, GEL
Portugal: Lamisil DermGel, 10 mg/g, gel

This leaflet was last revised in 11 February 2021