

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 Singeldos 1% cutaneous solution

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 you doctor or pharmacist. This includes any possible side effects not listed in this leaflet.] **See section 4**

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.

<[To be completed nationally]>

What is in this leaflet

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

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

Lamisil Singeldos is a single dose treatment for tinea pedis (athlete's foot).

Lamisil Singeldos works by killing the fungus which cause 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 Singeldos.

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

Do not use Lamisil Singeldos

- **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 Singeldos**.

Warnings and precautions

Talk to your doctor or pharmacist before using Lamisil Singeldos.

- **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 Singeldos 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 (*after sun exposure or 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 your toes.
- Lamisil Singeldos contains alcohol. Keep away from naked flames.
- Should be kept out of the sight and reach of children.

Children and adolescents

Children and adolescents under 18 should not use Lamisil Singeldos.

Other medicines and Lamisil Singeldos

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 Singeldos.

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 Singeldos 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 Singeldos does not affect the ability to drive and use machines.

Lamisil Singeldos 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 SINGELDOS

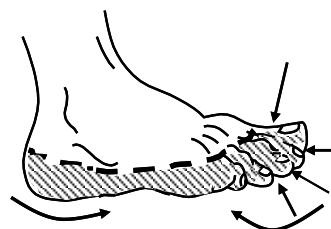
Always use this medicine exactly as described in this leaflet or as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

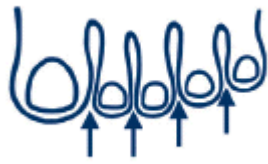
The recommended dose is to apply the gel once as indicated below.

Directions for use:

Adults aged 18 years and over

- It's best to apply Lamisil Singeldos 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 (see section 5 of the package leaflet for more information on how to throw away the 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 Singeldos. Gently pat dry your feet after gentle washing.
- Do not apply it a second time.

How often and how long should you use Lamisil Singeldos

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

Lamisil Singeldos 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 two weeks after application, contact a pharmacist to verify that 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 Singeldos 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 Singeldos 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.

[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 Singeldos, 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. They are usually mild and transient reactions.

Not known (*frequency cannot be estimated from the available data*)

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 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 SINGELDOS

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

Do not use Lamisil Singeldos 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 Singeldos 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 Singeldos looks like and contents of the pack

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

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: LAMISILONCE 1 % LÖSUNG ZUR EINMALIGEN ANWENDUNG AUF DER HAUT

Belgium: LAMISIL ONCE 1%, OPLOSSING VOOR CUTAAN GEBRUIK

Czech Republic: LAMISIL 1X KOŽNÍ ROZTOK 1%

Denmark, Germany: Lamisil Once

Estonia: Lamisil Uno, 1% nahalahus

Finland: Lamisil Solo 1 % liuos iholle

France: Lamisilate monodose 1% solution pour application cutanée

Greece: LAMISIL ONCE, Δερματικό Διάλυμα 1%

Iceland: Lamisil Once 10 mg/g húðlausn

Ireland: Lamisil Once 1% cutaneous solution

Latvia: Lamisil Uno 1% uz ādas lietojams šķīdums

Lithuania: LAMISIL UNO 1 % odos tirpalas

Luxembourg: LAMISIL Once 1%, solution pour application cutanée

Netherlands: LAMISIL Once 1%, oplossing voor cutaan gebruik

Norway: LAMISIL LINIMENT, OPPLØSNING 1%

Poland: LAMISILATT 1

Portugal: Lamisil 1, 10 mg/g, solução cutânea

Slovakia: Lamisil 1x

Spain: LAMICOSIL UNI 10 MG/G SOLUCIÓN CUTÁNEA

Sweden: Lamisil singeldos 1% kutan lösning

This leaflet was last revised in 2020-11-26

<[To be completed nationally]>

Detailed information on this medicine is available on the website of {name of MS Agency (link)}.