

**PATIENT LEAFLET IN ACCORDANCE WITH THE
PHARMACISTS' REGULATIONS
(PREPARATIONS) – 1986**

This medicine is dispensed without a doctor's prescription

Lamisil Once Solution 10mg/g

Active ingredient: Terbinafine Hydrochloride 10 mg/g

Inactive ingredients and allergens in the preparation - see section 6 and section 2 under the title "Important information about some ingredients of the medicine".

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have any other questions, refer to the doctor or the pharmacist.

Use the preparation according to the instructions in the dosage section of this leaflet. Consult the pharmacist if you need more information. Refer to the doctor if the symptoms of the disease do not improve after 7 days.

1. What is the medicine intended for?

Treatment of athlete's foot.

Therapeutic class: Anti-fungal for external use.

The preparation kills the fungi that cause athlete's foot.

2. Before using the medicine

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient **terbinafine hydrochloride or to any one of the other components the medicine contains** (see section 6)

Special warnings regarding the use of the medicine:

- Do not use this product after the expiry date stated on the package.
- Do not use this product if the tube seal is damaged or if the packaging does not appear intact.
- Do not use this medicine in children and adolescents under the age of 15.
- Tell the doctor or pharmacist if you are pregnant or planning to become pregnant.
- This medicine is not suitable for:
 - Long term treatment of fungal infection of the soles of the feet and heels with thick edges and/or peeling skin.
 - Treatment of fungal nail infection (fungus inside or under the nail) with discoloration of the nail and change in nail texture (thickening or peeling).

Tell the doctor or pharmacist if you think you may have these conditions, because you may need another preparation.

Only use Lamisil Once to treat the skin of your feet.

Ensure that the medicine does not come in contact with your face, near your eyes or in your mouth.

In case of contact with the eyes, rinse thoroughly with running water. Contact your doctor if you still feel any discomfort after rinsing.

Use with caution if your skin is broken or inflamed.

Lamisil Once contains alcohol and may be irritating to damaged skin.

Smoking: Do not light a cigarette or expose yourself to fire before the preparation has completely dried.

Drug interactions:

If you are taking or have recently taken other medicines including non-prescription medicines and nutritional supplements, tell the doctor or the pharmacist.

Do not apply other medicines and do not perform other treatments on your feet (including those you bought without a doctor's prescription) during treatment with Lamisil Once.

Pregnancy, breastfeeding and fertility:

Pregnancy: Due to the fact that there is limited information on the use of this medicine in pregnant women, do not use Lamisil Once unless your doctor has decided that the benefit outweighs the possible risk.

Breastfeeding: Avoid using Lamisil Once while breastfeeding, as terbinafine passes into breastmilk.

Fertility: Animal studies have not shown any effect on fertility or harm to the fetus.

Driving and operating machinery: Lamisil Once has no or negligible influence on the ability to drive or operate machinery.

Important information about some ingredients of the medicine: The medicine contains 863mg/g alcohol at a concentration of 96%. May cause a burning sensation to damaged skin.

3. How should you use the medicine?

Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the preparation.

The generally accepted dosage is:

Apply the preparation Lamisil Once to both feet, even on areas where your skin looks healthy. Most people with athlete's foot have the infection on both feet, even when signs of fungal infection such as itching and cracked skin are only present on one foot. Treating both feet with Lamisil Once helps prevent re-infection.

Follow the instructions for use carefully for optimal treatment results.

Method of use:

1. Wash your feet and hands and dry them carefully.
2. Remove the lid from the tube.
3. Use about half the amount in the tube for each foot, in order to cover the skin. Finish treating one foot before treating the other.
4. Apply to each foot with your fingers as shown in Figure 1. Apply first on the skin between, under, and over the toes. Then apply over the sole and sides of the foot. It is important to treat the whole foot, even areas of skin that look healthy.



Figure 1

5. Treat the other foot in the same way.
6. Spread the preparation on your whole foot quickly and evenly. Do not rub or massage into the skin.
7. Leave to dry for 1-2 minutes. A transparent film will form on the foot.
8. Close the tube with the lid and discard any remaining product. Do not keep or give the remaining product to another person.
9. Wash your hands with soap and warm water at the end of the treatment.
10. You may wear socks and shoes once the transparent film formed following the application of the product has dried.
11. Do not wash or wet your feet for 24 hours after applying Lamisil Once. Then rinse gently and dry your feet with gentle pats.
12. Do not apply the preparation a second time.

Do not exceed the recommended dose.

When to use the preparation?

Use Lamisil Once after a shower or bath, and wait 24 hours before washing your feet again.

To get better results, do not wet your feet for 24 hours after applying the preparation.

Duration of treatment:

Apply the preparation Lamisil Once only once. Do not use on the skin twice even if the fungal infection has not passed.

Even if the film left on the skin is almost invisible, it continues to deliver the active substance into the skin. The substance continues to kill the fungus for several days after the single use of the preparation.

You should feel a relief after a few days. Although Lamisil Once will start killing the fungus as soon as it is applied, it will take the skin about 4 weeks to heal completely. If you do not feel an improvement a week after treatment, consult your doctor or pharmacist.

Things that may help your condition while using Lamisil Once:

- Keep your feet clean by washing them frequently after the first 24 hours following application. After washing, dry your feet well without rubbing.
- Do not scratch the area despite the itching sensation you may feel, as scratching the area may cause further damage, slow down the healing process or spread the infection.
- Use your own towel and clothes and do not share them with other people, as the fungal infection may be passed on to them. Wash your towel and clothes frequently to prevent re-infection.

For external use only.

If you took an overdose or a child accidentally swallowed this medicine, go to the doctor or the emergency room of the hospital immediately and take the package of the medicine with you.

Do not take medicines in the dark! Check the label and the dose every time you take the medicine. Wear glasses if you need them.

If you have any other questions regarding the use of the medicine, consult the doctor or the pharmacist.

4. Side effects

As with any medicine, using Lamisil Once may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

Stop using Lamisil Once and refer to a doctor immediately, if one of the following effects occur:

- Difficulty breathing or swallowing.
- Swelling of the face, lips, tongue or throat.
- Severe itching of the skin, with a red rash or blisters.

All of the above effects may indicate an allergic reaction.

Uncommon side effects - side effects that occur in 1-10 out of 1,000 users: dry skin; skin irritation; burning sensation in the treated areas.

These are mild side effects that subside quickly.

If you experience a rash, itching, blistering of the skin, hives or any of the above side effects, remove the product with denatured alcohol, and wash your feet with warm soapy water.

If a side effect occurs, or if one of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

Side effects may be reported to the Ministry of Health by clicking on the link "Report side effects due to medicinal treatment" found on the Ministry of Health website homepage (www.health.gov.il), which will direct you to the online form for reporting side effects, or by clicking on the following link: <https://sideeffects.health.gov.il>

5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.
- Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.

Storage conditions: Store at a temperature below 30°C.
Do not light a cigarette or expose yourself to fire before the preparation has completely dried.

6. Additional information

• **In addition to the active ingredient, the medicine also contains:**

Ethyl Alcohol 96%(v/v); Acrylates/octylacrylamide copolymer; medium chain triglycerides;
Hydroxypropylcellulose

• **What does the medicine look like and what are the contents of the package:**

A clear to slightly opaque viscous solution, packed in an aluminum tube containing 4 grams with a screw-on polyethylene lid.

• **Marketing authorization holder and address:** Chemipal LTD, 44 Giborei Israel st., Netanya 4250432.

• **Name and address of the manufacturer:**

Karo Healthcare AB, Box 16184, 103 24 Stockholm, Sweden

• Registration number of the medicine in the national drug registry of the Ministry of Health: 137 26 31486

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