

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

This medicine is dispensed without a doctor's prescription

## **Lamisil Spray**

Active ingredient and its quantity in a dosage unit:

Terbinafine Hydrochloride 10 mg/g

Inactive ingredients and allergens in the preparation - please see section 6 and section 2 under the title "Important information about some of the 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 this 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 signs of the ailment (symptoms) worsen or do not improve after one month.

### **1. What is the medicine intended for?**

The medicine has a broad-spectrum antifungal activity, intended for the treatment of fungal infection of the skin.

**Therapeutic class:** antifungal for topical use.

### **2. Before using the medicine**

#### **X Do not use this medicine if:**

You are sensitive (allergic) to the active ingredient or any of the additional components the medicine contains.

### **! Special warnings regarding the use of the medicine**

#### **Before treatment with Lamisil Spray tell the doctor if:**

- You suffer from another disease.
- You are allergic.
- You are using other medicines, including non-prescription medicines.

### **! Additional warnings**

- Lamisil Spray is intended for external use only.
- Avoid contact with the eyes. In case of accidental contact with the eyes, eye irritation may occur. If the preparation comes in contact with the eyes, immediately rinse the eyes thoroughly with running water. Refer to a doctor if the eye irritation persists.
- Infants and young children should not come into contact with the treated skin areas.
- Do not inhale the preparation.
- Do not spray the preparation on the face or on damaged skin, as the preparation contains alcohol which may cause irritation.
- In the event of severe athlete's foot or if the fungus has spread to the nails, please consult a doctor.

### **! Smoking**

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

### **! Children and adolescents**

No studies have been conducted on the use of Lamisil Spray in children under 12 years of age. Due to limited clinical data, it is not recommended to use Lamisil Spray in children under 12 years of age.

### **! Drug interactions**

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

Do not use other medicines on skin areas treated with Lamisil Spray.

### **! Pregnancy, breastfeeding and fertility**

**Pregnancy**

Do not use Lamisil Spray during pregnancy, unless the doctor has decided that it is absolutely necessary.

**Breastfeeding**

Terbinafine is excreted in small quantities into breast milk. Do not use Lamisil Spray if you are breastfeeding.

Infants and young children should not come into contact with the treated skin areas.

### **! Driving and operating machinery**

Lamisil Spray has no effect on the ability to drive and operate machinery.

### **! Important information about some of the ingredients of the medicine**

- Lamisil Spray contains 3.4165 grams of alcohol in the 15 ml package and 6.834 grams in the 30 ml package, a concentration equivalent to 25 mg/gram. Alcohol may cause irritation on damaged skin.
- Lamisil Spray contains 0.707 gram of propylene glycol in the 15 ml package and 1.414 grams of propylene glycol in the 30 ml package, a concentration equivalent to 50 mg/gram.

### **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.

Clean the treated area with cotton wool and warm water and dry the area well before treatment with the preparation.

The generally accepted dosage for adults and children above 12 years of age is:

Athlete's foot, fungal infection of the groin, fungal infection of the body – spray once a day, for one week.

Pityriasis versicolor (sun fungus) – spray twice a day, for one week.

Spray enough substance to ensure that the treated area and the area around it will be wet.

If the treatment is within the folds of the skin, the area can be covered with a gauze dressing. Covering the area is especially recommended at night. Change the gauze at each spray.

**Do not exceed the recommended dose.**

### **Duration of treatment**

If your condition does not improve within 4 weeks, refer to a doctor.

The preparation should be used for the recommended period (one week) even if your condition seems to improve after a few days. Relief is usually seen after a few days, but the infection may return if the preparation is not used as recommended or for the recommended period of time.

Even when relief is seen after a few days, complete healing of the damaged skin after the fungus disappears can take some time, up to 4 weeks.

Do not swallow, this medicine is intended for external use only.

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

If you have forgotten to use this medicine at the required time, do not use a double dose. Take the next dose at the scheduled time and consult a doctor.

### **How can you contribute to the success of the treatment?**

If the treatment is on your feet:

- Change your socks once a day.
- Avoid wearing tight shoes.
- Dry your skin well after washing.
- Change your towel every day.
- Avoid walking barefoot. In addition, spray or pad the inside of your socks and shoes with special products for the prevention of athlete's foot.
- Wash your hands thoroughly after using the preparation and after contact with the affected skin areas, to avoid spreading the fungal infection.

**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 Spray 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.

**Discontinue use and refer to a doctor immediately** if you experience one of the following effects, which may indicate an allergic reaction:

- Difficulty breathing or swallowing.
- Swelling of the face, lips, tongue or throat.
- Severe itching of the skin accompanied by redness or raised blisters (even beyond the area that came in contact with the medicine).

Common side effects – side effects that occur in 1-10 out of 100 users: itching, peeling of the skin.

Uncommon side effects – side effects that occur in 1-10 out of 1,000 users: skin sores, scabs, skin discoloration, redness, burning sensation, pain and irritation at the site of application.

Rare side effects – side effects that occur in 1-10 out of 10,000 users: dry skin, contact dermatitis or eczema. A fungal infection that can worsen. In case of contact with the eyes, eye irritation may be caused (see warnings section).

Very rare side effects – side effects that occur in less than one out of 10,000 users: rash or blisters.

**If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult your 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](http://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 store in the refrigerator.
- Once opened for the first time, use within 3 months.

#### **6. Additional information**

- **In addition to the active ingredient, the medicine also contains:**  
Purified water, Ethanol (96%), Propylene glycol, Macrogol cetostearyl ether.
- **What does the medicine look like and what are the contents of the package:**  
Lamisil Spray is a clear to clear light-yellow liquid.  
The preparation is available in packages of 15 ml and 30 ml. Not all package sizes may be marketed.
- **Marketing authorization holder:** GSK Consumer Healthcare Israel Ltd.,  
P.O.box 3256, Petach Tikva.
- **Name and address of the manufacturer:** GSK Consumer Healthcare S.A.,  
Nyon, Switzerland.
- Revised in May 2021 in accordance with the Ministry of Health guidelines.
- Registration number of the medicine in the national drug registry of the Ministry of Health: 117-13-29732.

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