

This medicine is to be supplied without doctor's prescription

# Lamisil DermGel



## Active ingredient and its quantity in dosage unit:

Terbinafine 10 mg/g

For a list of inactive ingredients and allergens in the medicine - please see section 6.

**Read this package insert carefully in its entirety before using this medicine.** This leaflet contains concise information about this medicine. If you have any further questions, refer to the doctor or the pharmacist. This medicine is intended for patients above 12 years of age, under this age consult and contact the doctor.

The medicine should be used in a proper manner. For more information consult a pharmacist. Refer to the doctor if the signs of the illness (symptoms) get worse or do not improve after 4 weeks.

### 1. What is the medicine intended for

The medicine is intended for the treatment of fungal skin infections.

**Therapeutic group:** Antifungal for local use.

### 2. Before using this medicine

#### Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient or to any of the other ingredients that this medicine contains.

#### Special warnings regarding the use of this medicine

- This medicine is intended for external use only, avoid contact with the eyes. In case of contact with the eyes, rinse with water thoroughly.
- Use carefully on open wounds since the medicine contains alcohol, which may cause irritation.
- Do not apply the medicine on the face.

#### Before the treatment with Lamisil DermGel, tell your doctor if:

- The fungal infection is severe or if there is fungal infection of the nails.

**If you are taking or have recently taken other medicines, including nonprescription medications and nutritional supplements, inform your doctor or pharmacist.**

#### Pregnancy and breastfeeding

If you are pregnant or breastfeeding, you should consult a doctor before using Lamisil DermGel.

#### Driving and using machines

Lamisil DermGel does not affect the ability to drive or to use machines.

#### Important information about some of the medicine's ingredients

Lamisil DermGel contains alcohol, which may cause irritation on open wounds.

### 3. How should you use the medicine?

You should check with the doctor or the pharmacist if you are unsure.

The recommended dose is usually:

Tinea pedis, tinea cruris, tinea corporis - apply once a day for one week.

Pityriasis versicolor - apply once a day for one week.

The affected area should be washed and dried thoroughly before each application of the medicine. Gently massage the medicine into the affected area and the area surrounding it.

If the treatment is applied to skin folds, the area can be covered with gauze dressing, especially at night. Change the gauze at each application.

#### Do not exceed the recommended dose.

For use in adults and children over 12 years of age.

If there is no improvement in your condition within 4 weeks, refer to your doctor.

Apply the gel for the recommended period even if you see an improvement in your condition after several days. Usually an improvement is already observed after several days, however the infection may reappear if the medicine is not applied as recommended or for the recommended period of time.

Even if an improvement is observed after several days, complete cure of

the affected skin following disappearance of the fungus may take some time, up to 4 weeks.

Do not swallow! This medicine is intended for external use only.

If you have taken an overdose, or if a child has accidentally swallowed the medicine, go immediately to a hospital emergency room and bring the medicine package with you. Do not induce vomiting unless explicitly instructed by the doctor!

**If you forget to take the medicine** at the scheduled time, do not apply a double dose. Apply the next dose at the usual time and consult your doctor.

How can you contribute to the success of the treatment?

Moisture encourages the growth of fungus, therefore it is important to keep the affected area dry. The affected area should be washed and dried thoroughly before each application of the medicine. Avoid scratching the area since this may cause damage and slow the rate of healing or cause infection spreading.

When treating the feet-it is advisable to wear cotton socks, and avoid wearing socks made of wool or synthetic materials. It is advisable to change your socks a few times a day (according to the amount of sweat). During suitable seasons, it is recommended to wear sandals without socks. Since the infection may be contagious, ensure using a personal towel and wash it often to prevent re-infection

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

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

### 4. Side effects

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

**Stop treatment and refer immediately to the doctor** if you experience any of the following effects, which may indicate an allergic reaction:

- Difficulties breathing and swallowing
- Swelling of the face, lips, tongue or throat
- Severe skin itching accompanied by redness or raised blisters

Common side effects, frequency of up to 1:10: itching, skin peeling

Uncommon side effects, frequency 1:100: local irritation and stinging, redness. If these side effects persist and/or are bothersome, refer to your doctor.

If any side effect becomes worse, or if you suffer from a side effect not mentioned in the leaflet, you should consult the doctor.

Side effects can be reported to the Ministry of Health by the online form in the following link:

<http://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic%40moh.health.gov.il>

### 5. How to store the medicine?

- Avoid poisoning! This medicine and all other medicine should be kept in a safe place out of the reach of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed by the doctor.

- Do not use the medicine after the expiry date (exp. date) which appears on the package and the label. The expiry date refers to the last day of that month.

- Storage conditions: Store at a temperature not exceeding 30°C.

Use within 4 month after opening the medicine for the first time.

### 6. Additional information

In addition to the active ingredients the medicine also contains -

Purified water, ethanol 96%, isopropyl myristate, polysorbate 20, carbomer, sorbitan laurate, benzyl alcohol, sodium hydroxide, butylhydroxytoluene.

#### What does the medicine look like and what are the contents of the package

Lamisil DermGel is a white – off-white colored gel.

Registration holder name and address: NCH Ltd., 14 Hamefalsim st., Petach-Tikva. Manufacturer name and address: Novartis Pharma, Switzerland.

This leaflet was checked and approved by the Ministry of Health in: July 2015.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 132193105311