

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

The medicine is dispensed without a doctor's prescription

## Dermasil

### Cream

**The active ingredient and its concentration in a dosage unit:**

Terbinafine Hydrochloride 1%

For the list of the additional inactive ingredients and allergens, see section 6 and section 2 entitled 'Important information about some of the medicine's ingredients'.

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

Use the medicine according to the instructions in the dosage section in this leaflet. Consult the pharmacist if you require additional information. Refer to the doctor if the symptoms of the illness worsen or do not improve after a week (7 days).

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

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

**Therapeutic group:** Antifungal.

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

**Do not use the medicine if:**

- You are sensitive (allergic) to the active ingredient or to any of the additional ingredients the medicine contains (listed in section 6).
- Do not use the medicine if you are breastfeeding.

#### **Special warnings concerning use of the medicine**

- Before starting the treatment with Dermasil cream, tell the doctor if you are suffering from another illness or from allergies.
- Dermasil cream is not recommended for use in children under the age of 12 .
- Dermasil cream is intended for external use only.
- Do not use the cream in the mouth and do not swallow it.
- Avoid contact with the eyes, nose, mouth or other mucous membranes. If the cream comes in contact with the eyes, rinse immediately and thoroughly under running water. Refer to a doctor if you feel discomfort in the eyes.
- In the case of extensive fungal infection on the sole of the foot or if the fungal infection also involves the nails, refer to a doctor.

#### **Drug interactions:**

**If you are taking, or have recently taken any other medicines, including non-prescription medicines and nutritional supplements, please tell the doctor or pharmacist.** Do not apply additional medicines on the treated area.

#### **Children and adolescents:**

There is no information regarding the safety and efficacy of using this medicine in children under the age of 12.

## **Pregnancy and breastfeeding:**

### **Pregnancy**

- Do not use the cream if you are pregnant, unless the doctor instructed that its use is necessary.
- If you are planning to become pregnant, consult the doctor before using Dermasil cream.

### **Breastfeeding**

- Do not use the cream if you are breastfeeding.
- Avoid contact of babies with the area treated with the medicine.

## **Driving and use of machinery:**

Dermasil cream has no effect on the ability to drive and operate machinery.

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

- Dermasil cream contains cetyl alcohol and stearyl alcohol that may cause skin reactions, e.g. eczema (such as contact dermatitis).
- Dermasil cream contains 1% benzyl alcohol that may cause an allergic reaction and local skin irritation.

## **3. How to use the medicine?**

Check with the doctor or pharmacist if you are not sure about the dosage and the manner of treatment with the medicine.

Before using Dermasil cream, wash the affected area and dry it thoroughly.

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

Dermasil cream can be applied once or twice a day (morning and/or evening). Gently apply a thin layer of Dermasil cream on and around the affected area.

### **The standard dosage is usually:**

- For a foot fungal infection that appears between the toes (Tinea Pedis), groin fungal infection, body fungal infection - apply once daily for one week.
- For a foot fungal infection that appears on the sole of the foot and/or the sides of the foot [Plantar - type Tinea Pedis (Moccasin Type)] - apply twice daily, for two weeks.
- For a fungal skin infection (skin candidiasis) - apply once to twice daily, for a week.
- For pityriasis versicolor (sun fungus) - apply once to twice daily, for two weeks.

If the treatment is between skinfolds, you can cover the area with gauze bandaging; covering the area is recommended, especially at night. Change the gauze with every application. Wash your hands after every application to the affected area.

### **Do not exceed the recommended dose.**

To prevent reinfection, treat the fungal infection according to the instructions in this leaflet.

If there is no improvement in your condition within a week, refer to a doctor.

Treat the fungal infection with the dosages indicated in the leaflet. If you feel that the effect of the medicine is too strong or too weak, refer to a doctor or pharmacist.

### **Do not swallow, the medicine is intended for external use only.**

### **If you accidentally used a higher dosage:**

If you have used an overdose or if a child has accidentally swallowed the medicine, refer immediately to a hospital emergency room, and bring the medicine package with you.

**If you forgot to apply the cream** at the set time, do not apply a double dose. Apply the next

dose at the usual time and consult the doctor.

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

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

To prevent foot fungal infection, perform the following actions:

- Change clothes that were in contact with the affected area every day.
- Avoid wearing tight clothes or clothes that do not allow airing of the skin.
- Gently dry the affected area after washing it.
- Change towels every day.
- If you suffer from foot fungal infection, do not walk barefoot. In addition, powder or spray your shoes with products intended for an anti-foot fungal infection. Wash your hands thoroughly after use of the medicine and contact with the affected skin area, in order to prevent spreading of the infection.

**If you have further questions concerning the use of the medicine, consult a doctor or pharmacist.**

#### **4. Side effects**

As with any medicine, the use of Dermasil cream may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

**Stop using the cream and refer to the doctor immediately** if you experience one or more of the following side effects, which may indicate an allergic reaction:

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

Side effects of the immune system:

Very rare (side effects that appear in less than one user out of 10,000): hives

Side effects of the eyes:

Rare (side effects that appear in 1-10 users out of 10,000): irritation

Skin side effects:

Common (side effects that appear in 1-10 users out of 100): peeling, itching

Uncommon (side effects that appear in 1-10 users out of 1000): sores, scabs, skin disorders, change in skin color, redness, burning sensation

Rare (side effects that appear in 1-10 users out of 10,000): dry skin, eczema, contact dermatitis

Very rare (side effects that appear in less than one user out of 10,000): skin rash or pimples

General side effects and side effects at the treated area:

Uncommon (side effects that appear in 1-10 users out of 1000): pain, pain or irritation at the treated area

Rare (side effects that appear in 1-10 users out of 10,000): worsening of the fungal infection

**If a side effect appears, if one of the side effects worsens, or when 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 on side effects following medicinal treatment" on the homepage of the Ministry of Health website ([www.health.gov.il](http://www.health.gov.il)) which leads to an online form for reporting side effects, or by entering the link: <https://sideeffects.health.gov.il/>

## **5. How to store the medicine?**

- Avoid poisoning! This medicine, and any other medicine, must be stored in a closed place out of the reach and sight of children and/or babies, to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) stated on the package. The expiry date refers to the last day of that month.
- Storage conditions: Store below 25°C. The cream may be used for up to 6 months from the day the tube is first opened, but not later than the expiry date imprinted on the package.

## **6. Additional information**

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

Isopropyl myristate, cetyl alcohol, sorbitan monostearate, cetyl ester wax, stearyl alcohol, polysorbate 60, benzyl alcohol, sodium hydroxide, HCl, purified water.

**What does the medicine look like and what does the package contain:** white cream in an aluminum tube containing 15 grams or 30 grams. Not all package sizes may be marketed.

**Manufacturer and registration holder:** Rafa Laboratories Ltd., P.O. Box 405, Jerusalem 9100301.

Marketed exclusively by: Super-Pharm (Israel) Ltd, P.O. Box 2171, Herzliya 4672516.

**Medicine registration number in the National Medicines Registry of the Ministry of Health:** 134-74-31484

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