

Patient Leaflet According to the Pharmacists' Regulations (Preparations) – 1986

This medicine is sold without a doctor's prescription

Dermasil Cream

Active ingredient and its quantity in dosage unit:

Terbinafine Hydrochloride 1%

For the list of the additional ingredients, see section 6.

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have any further questions, please refer to your doctor or pharmacist.

The medicine is intended for adults and children over 12 years of age, under this age, refer to your doctor. Use this medicine according to the instructions in the dosage section in this leaflet. Consult the pharmacist if you require additional information. Refer to your doctor if the symptoms of the illness worsen or do not improve after a week.

1. What is the medicine intended for?

The medicine is a broad-spectrum antifungal agent 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.
- Do not use this medicine if you are breastfeeding.

Special warnings regarding the use of this medicine:

- The cream is intended for external use only.
- Do not use this cream in your mouth and do not swallow it.
- Avoid contact with the eyes, nose, mouth or other mucous membranes. If the cream comes into contact with your eyes, rinse thoroughly with water. Refer to your doctor if you feel discomfort.

Drug interactions:

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

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding, think you are pregnant or are planning a pregnancy, consult the doctor or pharmacist before using the medicine.

- Do not use the cream if you are pregnant, unless usage is necessary by doctor's instruction.
- Do not use the cream if you are breastfeeding.
- Avoid contact of infants with area treated with this 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 local irritation of the skin (such as: contact dermatitis).
- Dermasil cream contains 1% benzyl alcohol that may cause an allergic reaction and mild local irritation.

3. How to use this medicine?

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

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

The standard dosage is usually:

Foot fungal infection that appears between the toes (Tinea Pedis), Tinea Cruris (groin fungal infection), Tinea Corporis (body fungal infection) - apply once daily for one week.

Foot fungal infection that appears on the foot sole and/or the sides of the foot [Plantar - type Tinea Pedis (Moccasin Type)] - apply twice daily, for two weeks.

Pityriasis versicolor (sun fungus) - apply once to twice daily, for two weeks.

Wash and dry the affected area thoroughly before each application of the cream. Gently massage the cream on the affected area and around it.

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

Do not exceed the recommended dose.

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

Apply the cream for the recommended period even if improvement in the condition is seen after a few days. Usually an improvement is seen after a few days, yet the infection may recur if the cream is not applied as recommended or for the recommended period of time.

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

If you accidentally used a higher dosage: If you have swallowed the medicine, refer to a doctor to advise you what to do.

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

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

If you forgot to apply the cream at the required 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 enhances fungal growth, therefore the affected area should be kept dry. Wash and dry the affected area thoroughly before each application of the cream. Avoid scratching the area since that may harm and slow the rate of recovery or cause the infection to spread.

If you are treating the feet - it is recommended to use cotton socks, and to avoid wearing socks made of wool or synthetic materials. It is recommended to change them several times a day (dependent on the amount of perspiration). During the suitable seasons, it is recommended to wear sandals without socks. Since the infection might be contagious, make sure to use a personal towel and in order to prevent reinfection, launder it frequently.

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

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

Additional side effects:

Common side effects (appear in 1-10 users out of 100): itching and peeling of the skin.

Uncommon side effects (appear in 1-10 users out of 1,000): wounds, scabs and skin disorders, change in skin color, redness, burning sensation and skin pain, and also pain and irritation at the site of application.

Rare side effects (appear in 1-10 users out of 10,000): dryness of skin, eczema.

If a side effect appears, if one of the side effects worsens, or 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 on side effects following medicinal treatment" on the homepage of the Ministry of Health website (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 infants, 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: 1347431484

This leaflet was revised in October 2020.

262004-I