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

The medicine is dispensed without a doctor's prescription.

FUNGITRIM POWDER

Active ingredients and their concentration per dosage unit:

Zinc undecylenate 20%

Undecylenic acid 2%

For inactive ingredients in the preparation - see section 6 "Further Information".

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

This medicine is not usually intended for children and infants under two years of age, unless instructed otherwise by the doctor and under his supervision. Use it properly. Consult the pharmacist if you need further information. Refer to the doctor if your condition worsens or if it does not improve within 4 weeks.

1. WHAT IS THE MEDICINE INTENDED FOR?

FUNGITRIM intended as prophylaxis and treatment of mycotic skin infections particulary athlete's foot

Therapeutic group: Antimycotic

2. BEFORE USING THE MEDICINE:

Do not use the medicine if:

- you are sensitive (allergic) to the active ingredients or to any of the other ingredients which the medicine contains.
- the skin is injured.

Special warnings regarding use of the medicine

- If you are sensitive to any food or medicine, inform the doctor before taking the medicine.
- Avoid contact with the eyes and inhalation of the powder.

Before treatment with Fungitrim, tell the doctor if:

- you are suffering, or have suffered in the past, from impaired function of the blood vessels.
- you suffer from diabetes.

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. Especially, inform the doctor or pharmacist if you are taking another topical preparation applied to the same area of the skin.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, consult the doctor or pharmacist before use, since there is no safety information regarding use while breastfeeding or during pregnancy.

3. HOW SHOULD YOU USE THE MEDICINE?

Check with the doctor or pharmacist if you are uncertain about its use.

The usual dosage is: twice a day, between the toes, in socks and shoes. Before use, clean the affected area and its surrounding, and dry thoroughly. Continue applying to the feet for approximately two weeks even after healing, in order to prevent fungal infection recurrence. In addition, the powder can be used in the winter as prophylaxis.

In cases of fungal infections, the patient must adhere to appropriate hygiene measures such as showering at least once a day in addition to treatment with the preparation.

This medicine is not usually intended for children and infants under two years of age, unless instructed otherwise by the doctor and under his supervision. If there is no improvement in your condition within 4 weeks, refer to the doctor.

Do not exceed the recommended dose.

Do not swallow, for external use only. This preparation is not effective when used on the scalp or nails.

If you took an overdose, or if a child accidentally swallowed the Medicine:

- Iimmediately refer to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.
- Swallowing the preparation may result in the following symptoms: nausea, vomiting, other gastrointestinal disturbances.
- Do not induce vomiting without explicit instruction from the doctor.

How can you contribute to the success of the treatment?

Moisture enhances fungal growth. Therefore, the affected area should be kept dry.

Wash the affected area before each application of the medicine.

When treating the feet - it is important to wash and dry them thoroughly, especially between the toes. It is advisable to use cotton socks; avoid wearing wool or synthetic socks. It is advisable to change socks several times a day (depending on the amount of perspiration).

During the appropriate seasons, it is advisable to wear sandals without socks.

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

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

4. SIDE EFFECTS

As with any medicine, use of Fungitrim 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.

Refer to a doctor if the following effects develop:

Local irritation, inflammation or rash.

If a side effect occurs, if any of the side effects worsen, or if you are suffering from a side effect not mentioned in this leaflet, consult the doctor.

Reporting on side effects

Side effects can be reported to the Ministry of Health by clicking the link "Report of side effects due to medication" on the home page of the Ministry of Health website (www.health.gov.il), which will open an online form for reporting side effects.

5. HOW SHOULD THE MEDICINE BE STORED?

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

Close firmly to prevent penetration of air and humidty.

- Store in a cool and dry place, below 25°C.

6. FURTHER INFORMATION

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

Talc, Colloidal silicon Dioxide, Terpineol

What does the medicine look like and what are the contentsof the package?

A plastic container that contains 80 grams of white, Terpineol -scented powder.

Registration holder and manufacturer: Rekah Pharmaceutical Industry Ltd., 30 HaMelacha Street, Holon, Israel

FOR: Trima,Trading (1961) Ltd., Maabarot 4023000 Israel.

This leaflet was checked and approved by the Ministry of Health in June 2017.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 158-59-35250-00