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

This medicine is sold without a doctor's prescription

Fungiderm

Cream

Active ingredient: miconazole nitrate 2%.
For a list of inactive ingredients, please see section 6. See also 'Important information about some of the medicine's ingredients' in section 2.
Read this entire leaflet carefully before using this 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 not intended for children under two years of age, unless instructed by your doctor.
Use this medicine in the correct manner. Consult your pharmacist if you need additional information.
Refer to your doctor if the symptoms get worse, or do not improve after 4 weeks.

1. What is the medicine intended for?

The cream is intended for treatment of skin and nail fungal infections.
Therapeutic Group: antifungal.

2. Before using the medicine

Do not use the medicine if:

Do not use if you are sensitive (allergic) to the active ingredient (miconazole), to any other ingredients from the imidazole group and their derivatives, or to any of the other ingredients the cream contains (for a list of inactive ingredients, please see section 6).

Special warnings regarding the use of this medicine:

- Before using for the first time, it is advisable to consult your doctor to avoid unnecessary use.
- Do not use frequently, or for a long period, without consulting your doctor.
- If you are sensitive to any type of food or medicine, inform your doctor before using the cream.
- In the event of irritation, itching or any sensitivity (including hypersensitivity) to the cream, stop using it immediately.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including non-prescription medicines and nutrition supplements. In particular inform your doctor or pharmacist if you are taking oral anticoagulants, such as warfarin. If you are unsure whether you are using these medicines, please consult with your doctor or pharmacist.

Pregnancy and breastfeeding:
Do not use the medicine without consulting a doctor before starting the treatment if you are pregnant, think you may be pregnant, are planning to become pregnant or are breastfeeding. The doctor will decide if you can use the medicine during pregnancy or breastfeeding.

Use in children: this medicine is not intended for children under two years of age, unless instructed by your doctor.

Important information about some of the medicine's ingredients:
Some of the medicine's ingredients may cause skin reactions and allergy in certain people (for a list of inactive ingredients, please see section 6).

3. How to use this medicine?

- **Attention!** Not to be swallowed! This medicine is intended for external use only.
- Avoid contact with the eyes.

The standard dosage is usually:

- Apply to the infected area twice daily. Continue the treatment for seven days after all the symptoms have disappeared, in order to prevent their recurrence.
- The duration of treatment may vary from 2 to 6 weeks, according to the location and severity of the infection.

Do not exceed the recommended dose.
You should check with your doctor or pharmacist if you are not sure.
Refer to your doctor if there is no improvement in your condition within 4 weeks or if there is a deterioration.

How to apply the cream?

- Wash the infected area and dry it well.
- Apply the cream to the infected area and to the surrounding skin.
- Wash your hands thoroughly after applying the cream (unless the fungal infection is on the hands), in order to prevent spreading of the fungal infection to other areas of the body or to other people.
- Since many skin infections are contagious, make sure that you have a towel and washcloth for your exclusive use.
- Likewise, frequently change and wash clothes that were in contact with the infected areas, such as socks.

If you have accidentally used a higher dosage: excessive use is liable to lead to skin irritation, which usually disappears after discontinuing of the treatment. If somebody has accidentally swallowed the cream, proceed immediately to a doctor or a hospital emergency room and bring the package of the medicine along.

How can you contribute to the success of the treatment?
Moisture enhances fungal growth, therefore you should keep the infected area dry.
Wash the infected area before every application of the cream and dry it well with a personal towel.
If you are treating your feet - make sure you wash and dry them thoroughly, especially between the toes. Preferably you should wear cotton socks. Avoid wearing socks made of wool or synthetic materials. In the appropriate seasons it is recommended to wear sandals without socks.
Do not bandage the treated area, without your doctor's instructions.
Do not use or take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.
If you have any further questions regarding the use of the medicine, consult the doctor or pharmacist.

4. Side Effects

Like any medicine, the use of Fungiderm may cause side effects in some users. If these side effects persist or are bothersome or get worse, please consult your doctor. Do not be alarmed while reading the list of side effects, you may not suffer from any of them.

Stop the treatment and refer to the doctor immediately if any of the following side effects appear (see also special warnings in section 2):
Uncommon side effects (appear in 1-10 users out of 1,000):
Skin burning sensation, skin inflammation, local reactions in the area of application (e.g. irritation, burning, heat, itching), change in skin color (including hypopigmentation).

Side effects of unknown frequency (side effects whose frequency has not yet been determined):

- Severe allergic reaction, anaphylactic reaction or angioedema. The symptoms may include, inter alia, swelling of the face, lips, tongue or throat.
- Other allergic reactions, such as nettle rash (urticaria), skin inflammation from contact (contact dermatitis), irritated skin, rash, redness, itching.

Side effects and drug interaction in children:
Parents must inform the attending doctor of any side effect as well as any additional medicine given to the child. See above for detailed side effects and drug interactions.

If a side effect appears, if one of the side effects worsens, or if you suffer from a side effect not mentioned in the 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 you to the online form for reporting side effects, or by entering the link:

https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il

5. How to store the medicine?

- Avoid poisoning! This medicine, and any other medicine, must be stored in a safe place out of the reach 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 25^0C.

After the first opening of the tube, the cream may be used within 3 months, but no later than the expiry date marked on the package.

6. Additional information

In addition to the active ingredient, the cream also contains the following inactive ingredients:
Stearoyl macrogolglycerides, propylene glycol, isopropyl myristate, cetyl alcohol, polysorbate 80, mixture of parabens (methyl, ethyl, butyl, isobutyl and propyl paraben in 2-phenoxyethanol), sorbitan sesquioleate, carbomer, monoethanolamine, disodium edetate, water.

What does the medicine look like and what does the package contain?
White cream in aluminum tube.

Manufacturer: Rafa Laboratories Ltd., PO Box 405, Jerusalem 9100301.
Distributed solely by Super-Pharm (ISRAEL) Ltd. PO Box 2171, Herzliya 4672516

Medicine registration number in the National Medicines Registry of the Ministry of Health: 1313631024

This leaflet was checked and approved by the Ministry of Health in March 2016.
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