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

The medicine is dispensed without a doctor's prescription.

FUNGINAIL

Lacquer for treatment of nails

Each 1 gram contains: 80 mg ciclopirox

Inactive and allergenic ingredients in the medicine - see section 6 in the leaflet.

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.

The medicine is not intended for children below the age of 12. Use the medicine in the correct manner.

Consult a pharmacist if you need further information.

Keep this leaflet; you may need to read it again.

1. WHAT IS THE MEDICINE INTENDED FOR?

The medicine is intended to treat fungal infections of the nails.

Therapeutic group: Antimycotic (antifungal) medicine from the hydroxypyridone group.

2. BEFORE USING THE MEDICINE

☒ Do not use this medicine:

- if you are sensitive (allergic) to the active ingredient ciclopirox or to any of the other ingredients contained in the medicine (see section 6 in the leaflet).
- if you are pregnant or breastfeeding.
- in children below the age of 12.

Special warnings regarding use of the medicine

- **Before treatment with Funginail, tell the doctor if:**
  - you are sensitive to any food or medicine.
  - you have diabetes and you are being treated with insulin.
  - you have diabetic neuropathy or you have numbness problems in the fingers or toes.
  - you are suffering, or have suffered in the past, from immune system suppression (e.g., if you underwent a transplantation).
  - you are taking medicines for epilepsy.
  - you are using topical corticosteroids regularly (on a monthly basis).
  - you are using inhalers containing steroids on a regular basis.

This medicine is intended for application on the nails and the surrounding skin only. The medicine is not intended for use in the eyes or mouth, for intravaginal use or for application on the skin (aside from the skin around the affected nail).

- **Caution! Inflammable substance; keep away from fire. Do not light a cigarette or be exposed to an open flame until the medicine has completely dried.**

Avoid contact between the medicine and the eyes and mucous membranes. In case of contact with the eyes, wash thoroughly with water for a long time. Do not apply lacquer or other cosmetic products on the affected nail while using this medicine.

Avoid contact between the medicine and the skin, aside from the skin close to the nail.

If you have diabetes or are suffering from diabetic neuropathy, inform the medical staff to decide how to remove and/or cut the affected nail.

❗ Drug interactions

If you are taking, or have recently taken other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. Do not apply lacquer or other cosmetic products on the affected nail during the course of treatment with the medicine.

- Concomitant use of Funginail and systemic antifungal medicines is not recommended.

❗ Pregnancy and breastfeeding

Do not use this medicine if you are pregnant or breastfeeding.

3. HOW SHOULD YOU USE THE MEDICINE?

Check with the doctor or pharmacist if you are uncertain.

The usual dosage is:

Apply an even coat with the applicator brush once a day, preferably in the evening.

Do not exceed the recommended dose.

Do not swallow; for external use only.

Avoid contact with the eyes and mucous membranes. In case of contact with the eyes, wash thoroughly with water for a long time. Do not apply lacquer or other cosmetic products on the affected nail during the course of treatment with the medicine.

Avoid contact between the medicine and the skin, aside from the skin close to the nail.

Instructions for use:

Before commencing treatment with the medicine, cut the affected nail with scissors as much as possible, and file with a disposable nail file.

Apply an even coat on the surface of the nail and on the skin close to the nail (5 mm).

If possible, apply on the skin under the nail and under the surface of the nail. Contact with the surrounding skin may cause mild irritation and/or redness.

To achieve maximal benefit from the treatment, the affected parts of the nail must be removed once a month by a healthcare professional.

Throughout the treatment period, apply on the previous coat, and remove the coats of lacquer once a week, with a cosmetic nail polish remover, such as acetone, to allow the active ingredient to penetrate, and file the nail with a disposable nail file. Do not remove the lacquer on a daily basis. Do not use cosmetic lacquer.

- The duration of treatment with the medicine depends on the severity of the infection and on the affected area.
- For fingernails, it is preferable to use for 3 months. For toenails, it is preferable to use for 6 months. Do not continue treatment beyond 6 months.

If you accidentally used a higher dosage or if a child or anyone else has accidentally swallowed the medicine, immediately refer to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.

How can you contribute to the success of the treatment?

Moisture enhances fungal growth; therefore, keep the affected area dry.

Wash the affected area before each application of the medicine. An antifungal powder can be used to dry the area between treatments with the lacquer.

If the treatment is for the toenails – be sure to thoroughly wash and dry, especially between the toes. It is preferable to wear cotton socks; avoid wearing socks made of wool or synthetic materials. It is preferable to change them a few times a day (depending on the amount of sweat).

It is recommended to wear sandals without socks in the appropriate seasons.

- 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.

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

4. SIDE EFFECTS

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

Discontinue use and refer to a doctor as soon as possible if sensitivity or a chemical irritation to the medicine develops or if you are suffering from a severe reaction of the skin in the treated area, such as: redness, burning sensation, tingling, blistering, swelling, rash or peeling (rare) (effects that occur in more than 1 in 10,000 patients and in less than 1 in 1,000 patients).

Refer to a doctor in cases of: itching or discharge in the treated area.

An additional rare side effect: allergic reaction manifested by skin inflammation in the treated area.

Very rare side effects (occur in less than 1 in 10,000 patients): redness and peeling of the skin around the nails, if the medicine comes into contact with the skin around the nail.

Additional side effects: rash, manifested by moderate, temporary redness around the nail or redness in the skin fold around the nail. In addition, nail disorders including: change in the color and shape of the nail and ingrown nail may occur.

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult with the doctor.

Reporting side effects:

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:

https://sideeffects.health.gov.il

In addition, you can report to Perrigo via the following address: www.perrigo-pharma.co.il

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the sight and reach of children and/or infants in order 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 and bottle label. The expiry date refers to the last day of that month.
- Store in the original package, in a cool and dark place, below 25°C.
- Can be used for 6 months after first opening, but not later than the expiry date.
- Close tightly to avoid penetration of air and moisture.

6. FURTHER INFORMATION

- In addition to the active ingredient, the medicine also contains:
  Isopropyl alcohol, Ethylacetate, Gantrez ES-435
- What the medicine looks like and the contents of the package: a bottle with 6.6 mL fluid and an applicator brush.
- Registration holder and address: Perrigo Israel Agencies Ltd., 1 Rakefet St., Shoham.
- Manufacturer: Perrigo Company, Allegan, Michigan, USA.
- Manufactured for: Super-Pharm (Israel) Ltd., P.O.B. 2171, Herzliya 4672516.
- This leaflet was checked and approved by the Ministry of Health in: February 2016.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 14690.33500