

**Patient leaflet in accordance with the Pharmacists' Regulations  
(Preparations) 1986**

This medicine is to be dispensed without a doctor's prescription

# Mycoster® 8% nail lacquer

**Active ingredient:** ciclopirox 8% w/w

Each gram of Mycoster 8% nail lacquer contains 80 mg of ciclopirox.

Inactive ingredients and allergens: See section 6 "Additional information".

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

The medicine is not intended for children under the age of 12.

This medicine does not require a doctor's prescription. Use this medicine correctly. Consult a pharmacist if you need further information. Keep this leaflet in case you need to read it again. Consult a doctor if signs of your illness (symptoms) get worse or do not improve after 6 months.

## **1. What is this medicine used for?**

Mycoster 8% nail lacquer is intended for the treatment of fungal infections of the nails.

**Therapeutic group:**

Antimycotic (antifungal) agent from the Hydroxypiridone group.

## **2. Before using this medicine**

### **☒ Do not use this medicine:**

- If you are sensitive (allergic) to the active ingredient ciclopirox or to any of the other ingredients that this medicine contains. See section 6 "Additional information".
- In children under the age of 12.

### **⚠ Special warnings regarding use of this medicine**

#### **● Before treatment with Mycoster 8% nail lacquer, tell the doctor if:**

- You are sensitive to any food or medicine.
  - You have diabetes and are being treated with insulin.
  - You have a diabetic neuropathy or you have problems with prickling (paresthesia) in your fingers or toes.
  - You have or have had in the past a suppressed immune system (for instance, if you have had a transplant).
  - You are taking epilepsy medicines.
  - You regularly use topical corticosteroids (on a monthly basis).
  - You regularly use inhalers that contain steroids.
- This medicine is for applying to nails and the surrounding skin only. Do not use this medicine on eyes, mouth, or inside your vagina, and do not apply to skin (except for the skin surrounding the infected nail).
  - Do not light a cigarette or expose yourself to flames until the product has dried completely.
  - Avoid contact with eyes and mucous membranes. In case of contact with eyes, rinse thoroughly with water for a long while. Do not apply nail polish or other cosmetic products to the infected nail during the course of this treatment.
  - Avoid contact with skin, except for the skin near the nail.
  - If you are diabetic or have a diabetic neuropathy, inform your healthcare provider so they can decide how to remove and/or cut the infected nail.

**If you are taking or have recently taken other medicines, including nonprescription medications and nutritional supplements, tell your doctor or pharmacist.**

To date, there have been no known interactions with other medicines.

### **Pregnancy and breastfeeding**

Ciclopirox may be used in pregnant or breast-feeding women.

Ask your doctor or pharmacist for advice before taking any medicine.

### **Driving and using machines**

Mycoster 8% nail lacquer has no effect on the ability to drive and use machines.

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

Method of administration:

Do not swallow, for external use only.

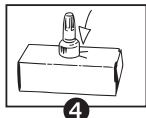
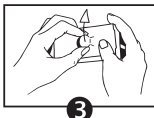
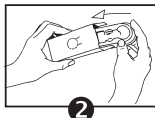
Always use exactly as described in this leaflet or according to the doctor's or pharmacist's instructions. Check with your doctor or pharmacist if you are not sure.

The recommended dose is usually:

One application daily, preferably in the evening.

**Do not exceed the recommended dose.**

### **Instructions for use:**



1. Remove the bottle from its tray.
2. Replace the tray in the box.
3. Remove the cover of the indentation that is used to hold the bottle.
4. Stand the bottle in the indentation.

After each use, follow the storage instructions (see section 5).

### **Before starting treatment with Mycoster 8% nail lacquer:**

- remove the unhealthy nail parts using nail clippers, a disposable nail file, or scissors.

### **Throughout the duration of treatment:**

- apply a thin layer of Mycoster 8% nail lacquer all over the affected nail, once daily, preferably in the evening.

- at least once a week, before applying Mycooster 8% nail lacquer, remove the layers of lacquer with a commercially available nail polish remover such as acetone. Then buff the nail with a disposable nail file. This will allow the active ingredient to penetrate the nail.
- at every application, remove as much of the unhealthy nail as possible.
- avoid using a cosmetic nail polish.
- keep the infected area dry. If treating toenails, cotton socks are recommended.

#### **Duration of treatment**

Treatment duration will be determined according to severity of the infection, and the affected area.

The minimum duration of treatment is 3 months (fingernail mycosis) and should not exceed 6 months (toenail mycosis). You must contact a doctor if your symptoms worsen or do not improve after 6 months. Do not continue this treatment for longer than 6 months.

If you have any doubts about continuing your treatment, ask your doctor or pharmacist for advice.

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

**If you forget to take the medicine** at the scheduled time, do not use a double dose to make up for a missed application. Carry on with your treatment as instructed in section 3 of this leaflet.

#### **If you stop taking the medicine**

**If you suspend or stop the treatment too soon**, mycosis may recur. If you are not sure whether the condition of your nail has improved, please ask your doctor or pharmacist for advice.

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

Moisture promotes fungal growth, so keep the affected area dry.

Wash the affected area before each application. Between applications, you may use an antifungal powder to dry the area.

When treating toenails, wash thoroughly and dry carefully, especially between your toes. Cotton socks are preferable; avoid socks made of wool or synthetic fibers. It is advisable to change your socks several times a day (depending on how much you sweat).

When the weather allows it, sandals without socks are advisable.

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

If you have any other questions about using this medicine, consult your doctor or the pharmacist.

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

Like all medicines, Mycooster 8% nail lacquer may cause side effects in some people. Do not be alarmed by this list of side effects. You may not experience any of them.

**Stop treatment and consult your doctor** as soon as possible if you develop a sensitivity to this medicine or it causes chemical irritation or if you experience a severe skin reaction in the treated area, such as: redness, stinging sensation, tingling, blistering, swelling, rash, or flaking (rare) (occur in more than 1 in 10000 patients and fewer than 1 in 1000 patients).

Contact your doctor in cases of itch or discharge.

Allergic contact dermatitis (a rash such as eczema) may occur; it appears as skin inflammation at the site of contact with the medicine. However, the frequency of this side effect is unknown.

Additional side effects: a rash that appears as mild and transient redness around the nail, or redness of the cuticle. Other nail disorders may occur, including change in nail color and shape, and ingrown nails.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in the leaflet, consult your doctor.

#### **Reporting side effects**

You can report side effects to the Ministry of Health (MoH) by following the link 'Reporting Side Effects of Medication' on the MoH home page ([www.health.gov.il](http://www.health.gov.il)) which links to an online form for reporting side effects. You can also use this link:

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

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

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place out of reach of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) appearing on the carton and bottle. The expiry date refers to the last day of that month.
- Even if stored as recommended, medicines only keep for a limited period. Please note the expiry date of this medicine! If you are not sure, consult the pharmacist who dispensed the medicine to you.
- Store at a temperature below 25°C.
- Store in the original package, in a dark place.
- After opening, keep the bottle tightly closed.
- Use within 90 days of first opening the bottle.
- Do not discard the medicine via wastewater or household waste. Ask the pharmacist how to dispose of the medicine. These measures will help protect the environment.

#### **6. Additional information**

- In addition to the active ingredient the medicine also contains: Ethyl acetate, isopropanol, copolymer of methylvinyl ether and maleic acid monobutylester.
- **What the medicine looks like and what are the contents of the package:** Colourless glass bottle with a white screw cap fitted with a brush (LDPE). Pack size: One 3 ml bottle.
- License holder name and address: Perrigo Israel Agencies Ltd., 29 Lehi St., Bnei-Brak
- Manufacturer name and address: Pierre Fabre Medicaments, Boulogne Cedex, France
- This leaflet was reviewed and approved by the Ministry of Health in: 31.07.2016
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 139-30-31564