

PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

**Fungocin
Lacquer for treatment of fingernail fungal infections**

Active ingredient:

Amorolfine (as hydrochloride) 5% W/W

Detailed information regarding administration, see section 3.

Inactive ingredients and allergens in the preparation see section 6.

Read the entire leaflet carefully before using the medicine.

This leaflet contains concise information about the medicine. If you have any other questions, refer to the doctor or the pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

1. What is the medicine intended for?

The medicine is intended for local treatment of nails infected with different kinds of fungi, yeasts and moulds.

Therapeutic class: Local antifungals.

2. Before using the medicine:

✗ Do not use this medicine if:

You are sensitive (allergic) to the active ingredient or any of the additional components the medicine contains (for a list of inactive ingredients see section 6).

Special warnings regarding the use of the medicine:

- Avoid the lacquer coming into contact with the eyes, ears or mucous membranes (e.g. mouth and nostrils). In case of contact of the lacquer with these areas, wash immediately with water and go to the doctor or an emergency room as soon as possible.
- Do not inhale.
- Do not use nail files used for infected nails on healthy nails.
- Do not use regular nail lacquer or other cosmetics (such as artificial nails) on the treated nails.
- When fingernails are treated - wear impermeable gloves when using organic solvents to stop the nail lacquer from being removed.
- The lacquer contains ethanol (alcohol). Improper or too frequent use may cause irritation or dryness of the skin around the nail.
- Do not light a cigarette or expose yourself to fire before the preparation has completely dried.

✗ Before starting to use the medicine, tell the doctor:

- If you are suffering from diabetes or weakened immune system.
- If you have a problem with blood flow in your hands and/or legs.

✗ If you are taking or have recently taken other medicines, including non-prescription medicines and food supplements, tell the doctor or the pharmacist.

✗ Pregnancy and breastfeeding: Do not use this medicine without consulting a doctor before starting the treatment if you are pregnant, planning to become pregnant, or breastfeeding.

✗ Use in children:

The medicine is not intended to be used in children and adolescents under 18 since there are no data for this age group.

3. How should you use the medicine?

You should always use the medicine according to the doctor's orders.

Check with the doctor or pharmacist if you are uncertain.

The dosage and treatment regimen will be determined by the doctor only.

The generally accepted dosage is:

The lacquer should be applied to the affected nail once to twice a week.

Do not exceed the recommended dose!

Instructions for use:

- 1. File the nail:** Before the first application, clean the nails well and file down the surface of the infected nail thoroughly using the nail file provided. Be careful not to file down the area surrounding the nail.
- Warning: Do not use nail files used for infected nails on healthy nails, otherwise you may spread the infection. Make sure no one can use the used nail files.**

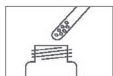


- 2. Cleaning the nail:** Use the swab that came with the package to clean the nail surface. Do not discard the swab, as you will need it later.



Repeat steps 1 and 2 for each affected nail.

- 3. Take some lacquer from the bottle:** Dip the reusable applicator in the lacquer solution. The lacquer must not be wiped off on the edge of the bottle.



- 4. Apply the lacquer:** Apply the lacquer evenly over the entire surface of the nail. Repeat this step for each affected nail.



- 5. Drying the lacquer:** Let the nails dry (3 to 5 minutes).

6. Cleaning the applicator:

The applicator provided is re-usable. However, it is important to clean it thoroughly after completing each treatment procedure, using the same swab you used for nail cleansing. Avoid touching newly treated nails with the swab.



- Close the nail lacquer bottle tightly immediately after applying the lacquer, in order to prevent evaporation of the liquid. Take precaution concerning how to discard the swab, since it contains flammable substances.
- Before using Fungocin again, first remove the lacquer remains from your nails using a swab, then file down the infected nails again if necessary.
- Re-apply the lacquer as described above.
- When the lacquer is dry, you may wash your hands and feet as normal (with soap and water).
- If you need to use chemicals such as paint thinners or white spirit, appropriate gloves (rubber or other impermeable and waterproof material) should be worn to protect the lacquer on your fingernails.

Attention!

- Do not swallow! This medicine is intended for external use only.

Treatment period:

Fingernails grow slowly, so it may take 2-3 months before you will witness an improvement in the nail's appearance. Carry on with the treatment until the infection has cleared and healthy nails have grown back.

The duration of treatment depends on the severity and location of the infection, and on the nail's growth rate: usually, the duration of treatment for fingernails is 6 months and for toenails it takes 9-12 months of treatment.

Tests and follow-up: If your condition has not improved in 6 months for fingernails and 9-12 months for toenails, contact your doctor.

If you accidentally used a higher dosage than recommended, consult the doctor or pharmacist. If someone accidentally swallowed the lacquer, go to the doctor or the emergency room immediately and take the package of the medicine with you.

If you forgot to use this medicine on time, continue using the medicine as usual as soon as you remember, according to the directions of use.

Follow the treatment as recommended by the doctor.

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor.

If you stop using the medicine the infection could come back.

Do not use or take medicines in the dark! Check the label and the dose every time you take the medicine. Wear glasses if you need them. If you have any other questions regarding the use of the medicine, consult the doctor or the pharmacist.

4. Side effects

As with any medicine, using Fungocin may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

Rare side effects (occurring in 1-10 out of 10,000 users):

- Nail discoloration and/or changes in nail texture (such as nail brittleness and cracking).

Very rare side effects (occurring in less than 1 out of 10,000 users):

- A burning sensation in the skin around the infected nail.

Side effects with unknown frequency:

Redness, itching, hives, blisters and allergic skin reaction (contact dermatitis).

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

Side effects may be reported to the Ministry of Health by clicking on the link "report side effects due to medicinal treatment" found on the Ministry of Health website homepage (www.health.gov.il), which will direct you to the online form for reporting side effects, or by clicking on the following 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 kept in a closed place out of the reach of children and/or infants to avoid poisoning.
- Do not induce vomiting without an explicit instruction from the doctor.
- Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.
- Storage conditions:
Store at a temperature lower than 25°C. Make sure the bottle is tightly closed and placed upright and vertically. Keep the bottle in its original external package.
- After opening for the first time, the medicine can be used for 6 months, but no later than the expiry date stated on the package.

6. Additional information:

- **In addition to the active ingredient the medicine also contains:**

Ethanol anhydrous, Ethyl acetate, Eudragit RL 100, n-Butyl acetate, Triacetin

- **What does the medicine look like and what are the contents of the package:**

The lacquer itself is a clear and colorless or light yellow solution.

The medicinal lacquer is found in carton packages that contain a 2.5 or 3 or 5 ml bottle, or in a package of 7.5 ml (a 2.5 ml bottle and a 5 ml bottle), or in a package of 10 ml (two 5 ml bottles).

The package includes applicators, single-use nail files and cleansing swabs.

Not all package sizes may be marketed.

- **License holder and importer:**

CTS Ltd., 4 Haharash St., Hod Hasharon 45240.

- **Manufacturer:** Chanelle Medical, Loughrea, Co. Galway, Ireland.

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

Registration number of the medicine:

158-02-34380