PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986
The medicine is dispensed without a doctor's prescription

Name of the preparation and its form:

Batrafen Nail Lacquer

Active ingredient and its concentration:
Each 1 gram contains:
Ciclopirox 80 mg
Inactive ingredients - see section 6 - Further information.

Read the 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 intended for use in children under the age of 12; under this age, refer to a doctor.

This medicine does not require a doctor's prescription. You must always use it as described in this leaflet or in accordance with the instructions you received from the doctor or pharmacist. Consult the pharmacist if you need further information. Refer to the doctor if the symptoms of the illness worsen or are not improving after 6 months of treatment.
Keep this leaflet, you may need to read it again.

1. WHAT IS THE MEDICINE INTENDED FOR?

The medicine is intended for the treatment of fungal infections of the fingernails and toenails.

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

2. BEFORE USING THE MEDICINE

Do not use the medicine:
- If you are sensitive (allergic) to the active ingredient, ciclopirox, or to any of the additional ingredients contained in the medicine (see Section 6).
- If you are pregnant or breastfeeding.
- In children under the age of 12.

Special warnings regarding use of the medicine:
- In the following cases, do not use the preparation without consulting a doctor before starting treatment:
  If you are a diabetic patient being treated with insulin or if you have diabetic neuropathy, if you suffer or have suffered in the past from immune system suppression, for example: if you have undergone a transplant, if you are taking medicines for epilepsy, if you are using topical corticosteroids regularly (on a monthly basis), if you are regularly using inhalers containing steroids.
- The medicine is intended to be applied to the nails only. Do not apply to the skin.
- Do not light a cigarette or be exposed to fire until the preparation has completely dried.

Children and adolescents
This medicine is not intended for use in children under the age of 12.

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 nail polish or other cosmetic products on the affected nail while using the medicine.

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

3. HOW SHOULD YOU USE THE MEDICINE?

Always use as described in this leaflet or in accordance with the instructions you received from the doctor or pharmacist. Check with the doctor or pharmacist if you are uncertain about the preparation dosage and treatment regimen.
The usual treatment regimen is generally:
For use on nails.
Before beginning treatment with the preparation, remove, as much as possible, the affected part of the nail with scissors or a disposable nail file. If there are no other instructions, during the first month apply a thin layer of Batrafen Lacquer on the affected part of the nail, on alternating days. This way, the nail will be saturated with the active ingredient. During the second month of treatment, the medicine can be applied at least twice a week and from the third month, use can be reduced to once a week. Throughout the treatment period, remove the entire coat of Batrafen Lacquer once a week with alcohol swabs. Then, the affected part of the nail should be removed again,as much as possible, with a disposable nail file.
If during treatment, the coat of lacquer cracks, reapply Batrafen Lacquer to the cracked areas only.
Do not apply nail polish or other cosmetic products on the affected nail while using the medicine.
Duration of use:
The duration of use of the preparation depends on the severity of the infection but should not exceed a period of 6 months. The need for further treatment beyond 6 months will be determined by a doctor. During this time, the microorganisms that caused the fungal infection in the nail are usually eliminated.
Talk to your doctor or pharmacist if you are unsure whether to continue treatment.
Keep the treated area dry. For toenails: It is advisable to wear cotton socks.
Avoid contact with the eyes and mucous membranes. In case of contact with the eyes – rinse with tap water for a long time.
Do not exceed the recommended dosage.
Do not swallow. For external use only.
If you accidentally used a higher dosage or if a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room, and bring the package of the medicine with you.
If you stop using Batrafen Nail Lacquer
Fungal infection of the nails is usually very persistent. Interruption or premature termination of treatment may cause your fungal nail infection to worsen. Ask your doctor or pharmacist if you are unsure whether your nail condition is improving.
Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.
If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Batrafen Lacquer may cause side effects in some users. Do not be alarmed by reading the list of side effects. You may not suffer from any of them.
Stop use and refer to a doctor immediately if you suffer from the following side effects:
Acute skin reaction in area of use, such as redness, burning sensation, stinging, blistering, swelling, rash or peeling: rare (occur in more than 1 in 10,000 patients and in less than 1 in 1,000 patients).
An additional rare side effect: an allergic reaction manifested by dermatitis in the area of contact.
Very rare side effects (occur in less than 1 in 10,000 patients): redness and peeling of the skin around the nails, if the preparation comes into contact with the skin around the nail.
If a side effect occurs, if any of the side effects worsen or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.
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

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 reach and sight of children and/or infants in order 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) that appears on the package. The expiry date refers to the last day of that month.

Storage conditions:
Store below 25°C. Store in the original packaging in order to protect from light. Close the bottle tightly after each use in order to prevent drying up of the lacquer.
Avoid contact of the lacquer with the threaded part of the bottle to prevent the cap from sticking to the bottle.
After first opening, can be used for 6 months.
Do not mix different medicines in the same container.

6. FURTHER INFORMATION

- **In addition to the active ingredient, the medicine also contains:**
  Isopropyl alcohol, Ethylacetate, Poly (Buthylhydrogenmaleate, Methoxyethylene) (1:1)
- **What the medicine looks like and the contents of the package:** A clear, colorless to pale yellowish solution in a glass bottle with a screw-on cap and brush. The bottle contains 3 grams of Batrafen Lacquer.
- **License holder and address:** sanofi-aventis Israel ltd., P.O.B. 8090, Netanya 4250499.
- **Manufacturer's name and address:** Sanofi-Aventis Germany, Frankfurt, Germany.
- This leaflet was checked and approved by the Ministry of Health in June 2019.
- **This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, please ask your doctor.**
- Registration number in the National Drug Registry of the Ministry of Health: 1212927875