

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

The medicine is dispensed with a doctor's prescription only

Loceryl

Lacquer for treatment of nail fungal infections

The active ingredient:

Amorolfine (as hydrochloride) 5% w/v

Inactive ingredients and allergens in the preparation: see section 2, subsection "Important information about some of the ingredients of the medicine" and section 6 "Additional information".

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?

Loceryl is intended for topical treatment of nails infected with different kinds of fungi, yeasts and molds.

Therapeutic class: Antifungals for topical use.

2. Before Using The Medicine

Do not use this medicine if:

Do not use if you are hypersensitive (allergic) to the active ingredient or to any of the other ingredients the medicine contains (for a list of inactive ingredients – see section 6).

Special warnings regarding the use of the medicine:

- Using Loceryl may cause allergic reactions which can be serious. If an allergic reaction occurs, discontinue use, remove the lacquer immediately using a nail varnish remover or using the cleaning swabs in the package, and seek medical treatment. Do not use the lacquer again.

You should seek urgent medical assistance if you experience one or more of the following symptoms:

- Breathing difficulties.
- Swelling of the face, lips, tongue or throat.
- Severe skin rash.

Talk to the doctor or pharmacist before using Loceryl.

- Do not apply the lacquer on the skin around the nail.
- Avoid the lacquer coming into contact with the eyes, ears or mucous membranes (e.g., mouth, 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 the lacquer.
- If you need to use organic solvents (such as: paint thinners or white spirit), wear suitable impermeable gloves (to protect the lacquer on the nails and to prevent it from being removed).
- Do not light a cigarette or expose yourself to fire until the medicinal product has completely dried.

Drug interactions:

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

There are no known drug interactions with other medicines.

Using other nail products:

- Do not use artificial nails during the period of treatment with Loceryl.
- Cosmetic nail varnish can be used, but you should wait at least 10 minutes after applying Loceryl before painting your nails. Remove the cosmetic nail varnish before reapplying Loceryl.

Use in children:

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

Tests and follow-up:

- Medical follow-up is recommended to monitor the progress of the treatment, approximately every three months.
- If your condition has not improved within 6 months for fingernails and 9 to 12 months for toenails, contact your doctor.

Pregnancy and breastfeeding:

Do not use Loceryl without consulting the doctor if you are pregnant, planning a pregnancy or breastfeeding. The doctor will decide whether you should use the medicine.

Before using any medicine, talk to the doctor or pharmacist.

Driving and operating machinery:

Loceryl has no effect on the ability to drive and operate machinery.

Important information about some of the ingredients of the medicine:

Loceryl contains 552 mg alcohol (ethanol) in each gram of lacquer, which is equivalent to 55.2% w/w. There may be a burning sensation on damaged skin. Ethanol is a flammable substance and should not be used near an open fire, a lit cigarette or certain devices (e.g., hair dryer).

3. How should you use the medicine?

Always use Loceryl according to the doctor's instructions.

Check with the doctor or pharmacist if you are uncertain about the dosage and how to use Loceryl.

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

The generally accepted dosage is:

The lacquer should be applied to the infected nails once or twice a week, according to the doctor's instructions.

Do not exceed the recommended dose.

This medicine is intended for external use only.

Instructions for use:**1. Filing the nail**

Before the first treatment, clean the nails well and file down the surface of the infected nail thoroughly using the nail file provided.

Caution: do not use a nail file that was used to treat an infected nail on a healthy nail, to avoid spreading the fungal infection.

Be careful not to file down the area surrounding the nail. Make sure that no one else uses your nail files.

2. Cleaning the nail

Clean the nail surface using a cleaning swab from the package.

Repeat steps 1 and 2 for each infected nail.

3. Taking lacquer out of the bottle

Dip the applicator into the lacquer solution in the bottle. Do not remove lacquer from the applicator by wiping it off on the edge of the bottle opening.

4. Applying the lacquer

Using the applicator, apply an even layer of lacquer over the entire surface of the infected nail.

Repeat steps 3 and 4 for each infected nail.

5. Drying

Allow the treated nails to dry for about 3 to 5 minutes.

Wait at least 10 minutes before applying cosmetic nail varnish.

6. Cleaning the applicator and additional instructions

The applicator is reusable. It is important to clean it thoroughly after each treatment using a cleaning swab. Clean the applicator before treating another infected nail (using one of the cleaning swabs provided). Avoid contact of the cleaning swab with nails recently treated with the lacquer.

Close the bottle tightly.

Dispose of the cleaning swab safely, as it is flammable.

- Before using Loceryl again – first clean the remains of Loceryl lacquer and any other nail varnish off the nails, using a cleaning swab. File down the infected nail again (if necessary).
- Apply the lacquer again according to the steps described above.
- When the lacquer is dry, it is not affected by water and soap, so you may wash your hands and feet as normal. If you need to use chemical substances such as: paint thinners or white spirit, wear rubber gloves or other waterproof gloves to protect the lacquer on the nails.

Treatment period:

It is important to carry on with the treatment until the infected area has healed and the nail has regrown.

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

If Loceryl accidentally gets into the eyes or ears, wash immediately with water and immediately refer to the doctor, pharmacist or nearest hospital.

If you accidentally used a higher dosage, it is recommended to consult the doctor or pharmacist.

If you took an overdose or if a child accidentally swallowed this medicine, go to the doctor or to a hospital 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 instructions for use.

Follow the treatment as recommended by the doctor.

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

If you stop using the medicine before the end of the treatment period prescribed by the doctor, the fungal infection may return.

Do not take medicines in the dark! Check the label and the dose every time you take a 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 Loceryl may cause side effects in some users. Do not be alarmed when reading the list of side effects, you may not suffer from any of them.

Stop using the medicine and seek immediate medical assistance if an allergic reaction occurs. Symptoms of an allergic reaction may include: difficulty breathing; swelling of the face, lips, tongue or throat; severe skin rash. See also section "Special warnings regarding the use of the medicine".

Additional side effects:

Rare side effects – effects that occur in 1-10 users out of 10,000:

- Damage to the nails, nail discoloration, nail brittleness, formation of cracks.

Very rare side effects – effects that occur in less than one user out of 10,000:

- Burning sensation on the skin.

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

- Systemic allergic reaction (a serious allergic reaction accompanied by swelling of the face, lips, tongue or throat, difficulty breathing and/or severe skin rash).
- Redness, itching, blisters, hives, allergic skin reaction.

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

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 via the following link: <https://sideeffects.health.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 and sight 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 below 25°C. Keep away from heat. Keep the bottle closed tightly.
- After first opening, the product may be used for 6 months, but no later than the expiry date imprinted on the package.
- Do not discard medicines in wastewater or domestic trash. Ask the pharmacist how to dispose of medicines no longer in use. These measures will help protect the environment.

6. Additional Information

In addition to the active ingredient the medicine also contains:

Ethanol anhydrous; ethyl acetate; ammonio methacrylate copolymer, type A; butyl acetate; glycerol triacetate

What does the medicine look like and what are the contents of the package?

Medical lacquer. A clear, colorless or nearly colorless solution, in 2.5 ml or 5 ml bottles.

The package includes applicators or a cap with an applicator, single-use nail files and cleaning swabs.

Not all package sizes may be marketed.

Manufacturer: Laboratoires Galderma , Z.I. Montdesir 74540, Alby sur Cheran, France.

Marketing authorization holder: A.M.I. Medical Technologies Limited., Hanagar 22, Hod Hasharon, 4501317, Israel.

Registration number of the medicine in the national drug registry of the Ministry of Health:
133-12-30949-00

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