

Patient Leaflet According to the Pharmacists' Regulations (Preparations) – 1986

This medicine is sold with a doctor's prescription only

Loceryl Lacquer to treat fungal nail infections

Active ingredient:

Amorolfine hydrochloride 6.4% w/w, equivalent to Amorolfine 5% w/v.

For the list of the additional ingredients, see section 6.

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have any further questions, please refer to your doctor or pharmacist.

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

1. What is the medicine intended for?

Loceryl is intended for topical treatment of fungal infections of different types, yeasts and molds.

Therapeutic Group

Antifungal for topical use.

2. Before using the medicine

Do not use the medicine if:

Do not use if you are sensitive (allergic) to the active ingredient or to any of the additional ingredients the medicine contains (for a list of the additional ingredients, see section 6).

Special warnings regarding the use of this medicine:

- The use of Loceryl may cause allergic reactions which may be serious. If an allergic reaction appears, discontinue the use, remove the lacquer immediately with a nail varnish remover, or with the cleaning swabs in the package. Seek medical advice. Do not use the lacquer again. See also the 'Side Effects' section for details of possible symptoms of an allergic reaction.
- Do not apply the lacquer on the skin around the nail.
- Avoid contact with the eyes, ears and/or mucous membranes (such as the mouth, inside the nose). If the lacquer came into contact with these areas, rinse immediately with water and proceed to a doctor or an emergency room as quickly as possible.
- Do not inhale the lacquer.
- If you need to use organic solvents (e.g. paint thinners or white spirit) - wear suitable impermeable gloves (in order to protect the lacquer on the nails and prevent its removal).
- Do not light a cigarette or expose to fire until the preparation has dried completely.
- If you are taking, or have recently taken any other medicines, including non-prescription medicines and nutritional supplements, please tell your doctor or pharmacist.

Using other nail products:

- Do not use artificial nails during the 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 nail varnish before reapplying Loceryl.

Pregnancy and breastfeeding: do not use the medicine without consulting a doctor if you are pregnant, planning to become pregnant or you are breastfeeding.

Use in Children:

This medicine is not intended for use in children and adolescents under 18 years of age since there is no data on this age group.

Tests and follow-up:

- You should see your doctor every three months for follow-up of the progress of the treatment.
- If there is no improvement in your condition within 6 months for fingernails and 9-12 months for toenails, refer to the doctor.

3. How to use this medicine?

Always use according to the doctor's instructions.

Check with your doctor or pharmacist if you are not sure regarding the dosage and the treatment regimen with Loceryl.

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

The standard dosage is usually:

Apply the lacquer 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 application, clean the nails well, and file the surface of the infected nail thoroughly using the nail file provided.

Caution: Do not use nail files used for infected nails on healthy nails, otherwise you may spread the fungal infection.

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

2. Cleaning the nail

Clean the nail surface with one of the cleaning swabs from the package.

Repeat Steps 1 and 2 on every infected nail.

3. Taking lacquer from the bottle

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

4. Applying the lacquer

With the applicator, apply the lacquer evenly over the entire surface of the infected nail.

Repeat Steps 3 and 4 on every infected nail.

5. Drying

Let the treated nails dry for approximately 3-5 minutes.

Wait at least 10 minutes before applying cosmetic nail varnish.

6. Cleaning the applicator and additional instructions

The applicator is reusable. It must be cleaned thoroughly after each treatment, using a cleaning swab. Clean the applicator before treatment of an additional infected nail (using one of the swabs provided).

Avoid contact of the cleaning swab with nails recently treated with lacquer.

Close the bottle tightly.

Dispose of the cleaning swab safely because it is flammable.

- Before using Loceryl again, first use a cleaning swab to remove the old Loceryl lacquer and any nail varnish from your nails. File the affected nail again (if necessary).
- Reapply the lacquer according to the stages described above.
- When dry, the nail lacquer is unaffected by soap and water, so you may wash your hands and feet as normal.
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The treatment period:

It is important to continue treatment until the infected area has healed and the nail has grown back.

The treatment period depends on the severity of the infection and its location, and the rate of growth of the nail: usually 6 months for fingernails and 9-12 month for toenails.

If you accidentally get Loceryl in your eyes or ears wash out with water and contact your doctor, pharmacist or the nearest hospital straight away.

If you accidentally used a higher dosage than recommended, consult your doctor or pharmacist.

If a child has accidentally swallowed the lacquer, refer immediately to a doctor or hospital emergency room and bring the package of the medicine with you.

If you forgot to use this medicine on time, use the medicine normally as soon as you remember, according to the instructions for use.

Adhere to the treatment as recommended by your doctor.

Even if there is an improvement in your health condition, do not stop the 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 come back.

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

If you have further questions concerning the use of the medicine, consult your doctor or pharmacist.

4. Side effects

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

Discontinue the use and seek medical assistance immediately if an allergic reaction occurs.

The symptoms of an allergic reaction may include: difficulty breathing, swollen face, lips, tongue or throat; severe skin rash. See also the 'Special warnings regarding the use of the medicine' section.

Additional side effects:

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

- Damage to the nails, nail discoloration, fragile nails, forming of cracks.

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

Skin burning sensation.

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

- Severe allergic reaction together with swelling of the face, lips, tongue or throat, difficulty breathing and severe skin rash.
- Redness, itchiness, blisters, hives, allergic skin reaction.

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

Side effects may be reported to the Ministry of Health by clicking on the link "Report on side effects following medicinal treatment" on the homepage of the Ministry of Health website (www.health.gov.it) which leads to an online form for reporting side effects, or by entering the link:

<https://sideeffects.health.gov.it/>

5. How to store the medicine?

- Avoid poisoning! This medicine, and any other medicine, must be stored in a closed place out of the reach and sight of children and/or infants, 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) stated 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 tightly closed.
- After the first opening, Loceryl may be used within 6 months, but no later than the expiry date marked on the package.
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6. Additional information

In addition to the active ingredient, the medicine also contains:

Ethanol anhydrous, ethyl acetate, ammonio methacrylate copolymer, butyl acetate, glycerol triacetate.

What does the medicine look like and what does the package contain?

Medicinal lacquer, in 2.5 mL or 5 mL bottles. The pack includes applicators or a cap integrated with an applicator, disposable nail files and cleaning swabs. Not all packs may be marketed.

Manufacturer: Laboratories Galderma, France.

Registration holder: Rafa Laboratories Ltd., PO Box 405, Jerusalem 9100301.

Medicine registration number in the National Medicines Registry of the Ministry of Health: 133 12 30949

This leaflet was checked and approved by the Ministry of Health in May 2014 and updated in September 2020.