

Loceryl[®]

AMOROLFINE 5 % AS THE HYDROCHLORIDE
NAIL LACQUER

CONSUMER MEDICINE INFORMATION

Pronounced LOS-IR-RIL.

Contains the active ingredient amorolfine 50mg/mL as the hydrochloride.

What is in this leaflet

This leaflet answers some common questions about LOCERYL nail lacquer.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

What LOCERYL is used for

LOCERYL contains the active ingredient amorolfine. It is used to treat fungal infections of the nails.

LOCERYL belongs to a family of medicines called anti-fungal drugs. These medicines work by killing a wide variety of fungi that can cause nail infections.

This medicine is available from a pharmacy. A doctor's prescription is not required.

LOCERYL treatment alone is not suitable for use in severe infections where the lunula is affected. In this case, you should talk to your healthcare practitioner. The lunula is the crescent-shaped area at the base of the nail – see the illustration on the LOCERYL carton.

Because fungal nail infections are hard to treat, treatment may be required for 6-12 months or longer and a full cure cannot be expected in all cases. After 6 months of treatment, improvement can be expected in 70% to 80% of people, with full cure expected in approximately one in three people.

Before you use LOCERYL

When you must not use it

Do not use LOCERYL if:

1. you have had an allergic reaction to LOCERYL or any ingredients listed at the end of this leaflet.
2. the package shows signs of tampering.
3. the expiry date (EXP) printed on the pack has passed.
4. you are pregnant or breast-feeding or intend to become pregnant or breast-feed.

The safety of LOCERYL in pregnancy and breast-feeding has not been established. If you are not sure whether you should start using LOCERYL, talk to your doctor or pharmacist.

Use in children.

Do not use in children under 12 years. The safety and effectiveness of LOCERYL in children have not been established.

The product should be kept out of sight and reach of children.

Before you start to use LOCERYL

Check with your doctor or pharmacist if:

1. you are allergic to any other medicines, foods, dyes or preservatives.
2. you have any other health problems.
3. you are taking any other medicines.

LOCERYL treatment alone is not suitable for use in severe infections where the lunula is affected. In this case, you should talk to your healthcare practitioner. The lunula is the crescent-shaped area at the base of the nail - see the illustration on the LOCERYL carton.

How to use LOCERYL

LOCERYL is for external use only, do not swallow LOCERYL. Apply only to finger nails and toe nails, avoid the surrounding skin.

How to apply the nail lacquer:

Follow these instructions each time the lacquer is used

1. Place everything you need for the LOCERYL treatment within easy reach:

- LOCERYL nail lacquer.
- nail file (supplied).
- cleaning pad (supplied).
- reusable spatula attached to the bottle cap (supplied).

First application of LOCERYL:

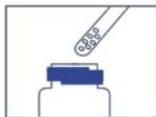


2. Before painting with LOCERYL nail lacquer, file down the infected areas of the nail (particularly the nail surfaces) as thoroughly as possible using the nail file.

CAUTION: Nail files used on an infected nail must **not** be used on healthy nails.



3. Clean the surface of the infected nail with a cleaning pad. Put the cleaning pad aside, do not discard.



4. Dip the reusable spatula into the lacquer. Do not wipe it on the neck of the bottle.



5. Using the spatula, paint LOCERYL nail lacquer over the entire surface of the infected nail.



6. When you have finished treating all of your infected nails, clean the spatula and the neck of the bottle with the same cleaning pad that was used during the treatment.



7. To avoid evaporation, **close the bottle tightly.**



8. Allow time for the nails to dry (3 to 5 minutes).

9. Discard used cleaning pad and nail file. Stow spatula and nail lacquer for next treatment.

Subsequent applications of LOCERYL:

File the infected areas of the nail using the nail file as required to remove any remaining lacquer, ensure that you do not over-file to avoid damage to the nail and surrounding area. Repeat steps 3-9.

Cosmetic lacquers artificial nails, or occlusive dressings should not be used during treatment with LOCERYL Nail Lacquer.

How often to apply LOCERYL

Paint LOCERYL once or twice weekly onto the infected fingernails or toenails or as otherwise directed by your doctor or pharmacist.

If you forget to paint on the LOCERYL nail lacquer, use it as soon as you remember. Then go back to using LOCERYL as you would normally.

How long LOCERYL should be used

Treatment should be continued without interruption until the infected nails are completely cured and re-grown. Usually, treatment of fungal infections of the nails takes around six months for the fingernails and nine to twelve months for the toenails.

Don't be discouraged if after several weeks of therapy no improvement is visible. A healthy nail only grows by approximately 2mm per month.

Because fungal nail infections are hard to treat, treatment may be required for 6-12 months or longer and a full cure cannot be expected in all cases. After 6 months of treatment, improvement can be expected in 70% to 80% of people, with full cure expected in approximately one in three people.

If symptoms persist or improvement is not observed, see your doctor or pharmacist.

In case of accidental swallowing

Immediately telephone your doctor or Poisons Information Centre (Australia 13 11 26, New Zealand 0800 POISON or 0800 764 766) for advice or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have swallowed LOCERYL, even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using LOCERYL

Things you must do

Tell your doctor or pharmacist that you are using Loceryl if you are about to be started on a new medicine.

Wear gloves to protect the coat of nail lacquer on your fingernails if you work with solvents (e.g. paint thinners, turpentine substitute, petrol, paraffin etc.).

Things you must not do

Do not use nail files for infected nails on healthy nails.

Do not use artificial nails during treatment with LOCERYL.

Do not apply other medication(s) on the nail(s) being treated.

Do not give LOCERYL to anyone else to use, even if they have the same condition as you.

Do not use LOCERYL to treat other complaints unless your doctor says to.

Side effects

All medicines can have side effects. LOCERYL helps most people with fungal infections of the nails but it may have unwanted side effects in a few people.

Tell your doctor, or pharmacist if you notice any of the following and they worry you:

- burning feeling in the area surrounding the treated nail(s). This is usually mild and short-lasting.
- itching or redness of the skin, contact dermatitis, **urticaria**, blister
- rare cases of nail disorder (nail discolouration, brittle or broken nails) have been reported during treatment with LOCERYL nail lacquer. However these reactions may also be linked to the nail infection itself.
- **Adverse drug reaction “Hypersensitivity (systemic allergic reaction)**
- **A systemic or local allergic reaction could possibly occur after use of this product. If this happens, the product should be stopped immediately and medical advice should be sought. Remove the product carefully in using a nail remover solution. This product should not be reapplied.**

After using LOCERYL

Storage

Screw the bottle top of the LOCERYL nail lacquer tightly immediately after use.

Keep LOCERYL in a cool dry place where the temperature stays below 30°C. Heat and dampness can destroy some medicines.

Do not store it, or any other medicine, in a bathroom or near a sink.

Do not leave it in the car or on window sills.

Keep LOCERYL where young children cannot reach it. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Product description

What it looks like

LOCERYL nail lacquer comes in one strength, 5% amorolfine (50 mg/ mL) in an amber glass bottle.

LOCERYL comes in a pack containing:

- 1 bottle of 2.5mL or 5 mL nail lacquer
- 1 reusable spatula fixed to the bottle cap
- 30 cleaning pads saturated with 70% Isopropyl alcohol in foil packets
- 30 nail files

Ingredients

Active - amorolfine

Each 2.5mL or 5 mL bottle contains 125mg or 250mg of amorolfine as the hydrochloride.

Inactives – methacrylic acid copolymer, Tricetin, butyl acetate, ethyl acetate, absolute ethanol.

If you require extra nail files or cleaning pads they will be supplied free of charge. In Australia contact Galderma toll free on 1800 800 765.
In New Zealand contact Galderma free-phone on 0800 174 104.

Auckland New Zealand
Call 0800 174 104 (New Zealand)

LOCERYL has been clinically tested.

Distributor

Galderma Australia Pty
Ltd



Healthcare Logistics'
13B Narabang
Way

58 Richard Pearce Drive
Belrose NSW
2085

Airport Oaks

Australia
Call 1800 800 765 (Australia)

Australian Registration Number: AUST R 57051

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