

Package leaflet: Information for the user  
Loceryl® Nail lacquer against nail fungus  
50 mg/ml medicated nail lacquer  
Active ingredient: Amorolfine hydrochloride

Read the entire package leaflet carefully before you start using this medicine because it contains important information.

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

Keep the package leaflet. You may want to read it again later.

Ask your pharmacist if you need more information or advice.

If you notice any side effects, contact your doctor or pharmacist. This also applies to side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What is Loceryl® nail lacquer and what is it used for?
2. What should you consider before using Loceryl® nail lacquer?
3. How to use Loceryl® nail lacquer?
4. What side effects are possible?
5. How to store Loceryl® nail lacquer?
6. Contents of the package and further information

## 1. WHAT IS LOCERYL® NAIL LACQUER AND WHAT IS IT USED FOR?

Loceryl® nail lacquer is a medication (broad-spectrum antifungal) for the treatment of fungal infections (mycoses) of the nails without involvement of the nail root (nail matrix). Loceryl® nail lacquer contains the active ingredient amorolfine, a fungicide to combat a variety of different fungi that cause a can cause nail fungus infection. The active ingredient amorolfine penetrates into and under the nail plate (into the nail bed). It inhibits the growth of the fungi and kills them, thereby combating the fungal infection and improving the appearance of your nails.

Loceryl® nail lacquer is used to treat nail fungus when up to 80% of the nail is affected (especially in the front area).

## 2. WHAT SHOULD YOU CONSIDER BEFORE USING LOCERYL® NAIL LACQUER?

Loceryl® nail lacquer must not be used,

- if you are allergic to amorolfine or any of the other ingredients of this medicine listed in section 6.

Warnings and precautions:

Please talk to your doctor or pharmacist before using Loceryl® .

Nail files used for affected nails must not be used for healthy nails.

Loceryl® nail lacquer should not be applied to the skin around the affected nail.

Loceryl® Nail lacquer contains ethanol, which is a flammable substance and should not be used near an open flame, a lit cigarette, or certain devices (e.g., hairdryers).

Avoid any contact with eyes, ears, and mucous membranes.

During the use of Loceryl® nail lacquer, artificial nails should not be used. Patients working with organic solvents (thinners, test gasoline, etc.) must wear impermeable gloves to protect the layer of Loceryl® nail lacquer on the fingernails. Otherwise, the Loceryl® nail lacquer will be removed.

All medicines can cause allergic reactions and although these are mostly mild, some can be severe. If this is the case, stop using the medicine, remove Loceryl nail lacquer immediately with nail polish remover or the alcohol swabs included in the package for cleaning, and seek medical advice. Loceryl nail lacquer should not be used again.

If you develop any of the following symptoms, you need urgent medical help:

- Difficulty breathing
- Swelling of the face, lips, tongue, or throat
- Severe skin rash

In the case of severe nail fungus involving the nail growth area (nail matrix), treatment with Loceryl® nail lacquer alone is not sufficient. Please discuss with your treating physician whether a combination therapy with orally taken (systemically effective) antifungals is a suitable treatment option in your case.

#### Children and adolescents

There is no experience with the use of Loceryl® nail lacquer in infants, children, and adolescents.

#### Use of Loceryl® nail lacquer with other medicines:

Inform your doctor or pharmacist if you are taking/using, have recently taken/used, or intend to take/use other medicines. No interactions with other medicines are known for Loceryl® nail lacquer. You can use Loceryl® nail lacquer together with other medicines. For simultaneous use with cosmetic nail polish, see section 3. or intend to take/use other medicines. No interactions with other medicines are known for Loceryl® nail lacquer. You can use Loceryl® nail lacquer together with other medicines. For simultaneous use with cosmetic nail polish, see section 3.

#### Pregnancy and lactation

There is only limited experience with the use of Loceryl

There is only limited experience with the use of Loceryl<sup>®</sup> nail lacquer during pregnancy and breastfeeding. Loceryl

<sup>®</sup>nail lacquer should not be used during pregnancy and breastfeeding unless it is clearly necessary. Driving and using machines

#### Loceryl

<sup>®</sup>nail lacquer Nail polish has no or a negligible influence on the ability to drive and use machines. This medicine contains 0.552 g of alcohol (ethanol) per g, equivalent to 55.2% w/w.

### 3. HOW TO USE LOCERYL® NAIL POLISH?

Always use Loceryl® nail polish exactly as described in this leaflet or as agreed with your doctor or pharmacist. Ask your doctor or pharmacist if you are not sure.

Unless otherwise prescribed by the doctor, Loceryl® nail polish is used as follows:

Apply Loceryl® nail polish once a week to the affected fingernails or toenails. Continue the treatment until the diseased nails have grown out healthy (normal appearance of the nail).

Please be sure to observe the following instructions when using:

Before the 1st application:

Be sure to file down the diseased parts of the nail surfaces as much as possible. For all further applications, file as needed (e.g., in case of thickening of the nails).

Before each further application:

1. In any case, use an alcohol swab to clean the nail surface (already included in the 3 ml or 5 ml package). Users of the 1.25 ml or 2.5 ml nail polish packages can use commercially available alcohol swabs. or use a cotton ball soaked with nail polish remover. Any remaining polish will also be removed.
2. Please remove the nail polish with one of the supplied reusable spatulas or the spatula integrated into the cap. Dip the spatula anew for each nail to be treated and do not wipe it off on the neck of the bottle (risk of drying out).
3. Apply Loceryl® nail polish evenly over the entire surface of the affected nail using the spatula.
4. Close the bottle tightly immediately after each use to prevent the solution from drying out.
5. Allow the treated nails to dry for 10 minutes.
6. For reuse, clean the spatula after use with an alcohol swab or a cotton ball soaked with nail polish remover. After applying Loceryl® nail polish, cosmetic nail polish can be applied once Loceryl® nail polish has dried (after 10 minutes). Before reapplying Loceryl® nail polish, the cosmetic nail polish should be carefully removed. However, the use of a nail polish remover should be avoided in between. What else should be considered in the treatment of nail fungus?

What else should be considered in the treatment of nail fungus?

A nail file used for treatment must no longer be used for the care of healthy nails, as otherwise healthy nails can become infected with nail fungus. Use separate disposable files for the treatment of diseased nails (already included in the 3 ml or 5 ml package). Users of the 1.25 ml or 2.5 ml nail polish packages can use commercially available disposable files.

The lacquer layer from Loceryl® nail polish on the fingernails can be dissolved or removed when handling organic solvents (nitro thinner, turpentine substitute, etc.). Therefore, when working with such substances, you must wear impermeable gloves to protect the layer of polish. Nail polish on fingernails can be dissolved or removed when handling organic solvents (nitro thinner,

turpentine substitute, etc.). Therefore, when working with such agents, you must wear impermeable gloves to protect the layer of polish.

Duration of use:

Fungal infections are often very persistent. Therefore, you must carry out the treatment continuously once a week (as described above) until the nail has completely grown back healthy. The time required for this is generally 6 months (fingernails) or 9 to 12 months (toenails), with the degree of infestation playing a significant role. The nail growth rate is approximately 1 to 2 mm per month.

Important: If you or someone else has accidentally swallowed the nail polish, seek your doctor, pharmacist, or the nearest hospital immediately.

Please talk to your doctor or pharmacist if you have the impression that the effect of Loceryl® nail polish is too strong or too weak.

If you have further questions on the use of the medication, ask your doctor or pharmacist.

#### 4. WHAT SIDE EFFECTS ARE POSSIBLE?

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following frequency categories are used to evaluate side effects:

Very common:	may affect more than 1 in 10 treated
Common:	may affect up to 1 in 10 treated
Occasionally:	may affect up to 1 in 100 treated
Rare:	may affect up to 1 in 1000 treated
Very rare:	may affect up to 1 in 10000 treated
Not known:	Frequency not assessable based on available data

Possible side effects:

Loceryl® Nail lacquer is generally well tolerated, side effects are rare.

Rare cases of nail changes (e.g., discoloration, brittle or broken nails) have been reported with the use of Loceryl® nail lacquer. This reaction may also be attributed to the nail fungal infection itself.

Very rarely, a slight, transient burning sensation around the treated nail (periungual burning) has been observed after the application of Loceryl® nail lacquer.

With unknown frequency, severe allergic reactions, which may be accompanied by swelling of the face, lips, tongue, or throat, breathing problems and/or a severe skin rash, allergic skin reactions (contact dermatitis\*, at the application site or extensively beyond the application site), itching\*, skin redness\*, hives\* and blistering\* have been reported.

\*Experiences from the post-marketing period

## Reporting of side effects

If you notice any side effects, contact your doctor or pharmacist. This also applies to side effects not listed in this leaflet.

You can also report side effects directly to the

Federal Institute for Drugs and Medical Devices  
Dept. Pharmacovigilance  
Kurt-Georg-Kiesinger Allee 3  
D-53175 Bonn  
Website: <http://www.bfarm.de>

By reporting side effects, you can help provide more information on the safety of this medicine.

## 5. HOW TO STORE LOCERYL® NAIL LACQUER?

Keep this medicine out of the reach of children.

Do not use the medicine after the expiry date stated on the bottle and the outer carton after 'Use by'. The expiry date refers to the last day of that month.

Never dispose of medicines via wastewater (e.g., do not dispose of via the toilet or sink). Ask your pharmacist how to dispose of medicines you no longer use. You will help protect the environment. For more information, see [www.bfarm.de/arzneimittelentsorgung](http://www.bfarm.de/arzneimittelentsorgung).

### Storage conditions:

There are no special storage conditions for this medicine.

## 6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Loceryl® Nail polish contains:

The active ingredient is amorolfine. 1 ml of medicated nail polish contains: 55.74 mg amorolfine hydrochloride (equivalent to 50 mg amorolfine).

The other ingredients are: ethanol; ethyl acetate; poly(ethyl acrylate, methyl methacrylate, trimethylammonioethyl methacrylate chloride) 1 : 2 : 0.2; butyl acetate; triacetin.

What Loceryl® nail polish looks like and contents of the pack:

Loceryl® nail polish is an almost colorless clear solution with a characteristic odor, filled in brown glass bottles with a white screw cap. Loceryl® nail polish is available in packs with 1.25 ml and 2.5 ml of medicated nail polish (including a spatula integrated into the cap for application), 3 ml of medicated nail polish (including 30 swabs for cleaning, a spatula integrated into the cap for application, and 30 nail files for the affected nails), as well as in packs with 5 ml of medicated nail polish (including 30 swabs for cleaning, a spatula integrated into the cap for application, and 30 nail files for the affected nails).

Not all pack sizes may be marketed.

Pharmaceutical company  
Galderma Laboratorium GmbH  
Toulouser Allee 23a  
40211 Düsseldorf  
Phone: +49 (0) 800 – 58 88 850  
Fax: +49 (0) 211 – 6355 - 8270  
Email: patientenservice@galderma.com

Manufacturer  
Laboratoires Galderma  
ZI - Montdésir  
F-74540 Alby-sur-Chéran

or

Galderma Laboratorium GmbH  
Toulouser Allee 23a  
40211 Düsseldorf

If you require further information about the medicinal product, please contact the local representative of the pharmaceutical company (see above under "Pharmaceutical Company").

This package leaflet was last revised in July 2022.

#### Properties

A nail fungal infection usually appears as a light to yellowish discoloration and thickening of the free edge of the nail and/or a thickening of the horny layer under the nail. The fungi usually spread from front to back—opposite to the growth direction of the nail—and lead to the changes described above. The active ingredient amorolfine inhibits the growth of the fungi and kills them.

#### Further tips for treatment support:

- Do not use nail files used for treating infected nails on healthy nails
- Wash towels as frequently as possible at at least 60 °C
- Allow shoes to air and dry well