

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

In this leaflet:

1. What Loceryl® is and what it is used for
2. What you need to know before you use Loceryl®
3. How to use Loceryl®
4. Possible side effects
5. How to store Loceryl®
6. Further information

1. What is Loceryl® and what it is used for?

This product is a topical antifungal which is used for treatment of nail mycoses (fungal disorders).

2. What you need to know before you use Loceryl®?

a. Do not use Loceryl® if you are

- If you are allergic to amorolfine or one of the other ingredients contained in this medicine, as listed in section 6.
- If in doubt, ask your doctor or pharmacist for advice.

b. Take special care with Loceryl®

- By avoiding contact with the eyes, ears and mucous membranes.
- If you are diabetic,
- If you are being treated for an immune system disease (a disease that reduces your body's natural defenses),
- If you have poor circulation in your hands or feet.
- If your nail is severely damaged (more than two thirds of your nail is affected) or infected. In these cases, your doctor may prescribe you an oral treatment in addition to the medicinal lacquer.
- Do not use cosmetic nail varnish or false nails whilst using LOCERYL. If organic solvents are to be handled, waterproof gloves must be worn or the lacquer will be dissolved.

c. Taking other medicines with Loceryl®

Tell your doctor or pharmacist if you are currently taking, have recently taken, or might take any other medicinal product.

d. Pregnancy and Breastfeeding

There is limited data available on the use of amorolfine in pregnant and breastfeeding women. LOCERYL must not be used during pregnancy and breastfeeding, unless it is really necessary.

If you are pregnant or breastfeeding, if you think you may be pregnant or you plan to become pregnant, talk to your doctor or pharmacist prior to using any medication.

e. Important information about some of the ingredients of Loceryl®

Loceryl contains ethanol (alcohol). Prolonged or improper use may result in irritation or dryness of the skin surrounding the nail.

3. How to use Loceryl®

Apply LOCERYL on affected nails once or twice per week, with normal usage; this bottle contains enough for approximately 134 applications.

Follow the direction of your doctor or pharmacist.

Method and route of administration

To apply the lacquer, carefully follow the Instructions of use.

Instructions for proper use

For packages without accessories:

1. Before applying LOCERYL for the first time, clean the nails well and file the infected area of the nail (especially the surface of the nail), as thoroughly as possible. Take care not to file the periungual skin.
2. Clean the surface of the nail and remove oil using a compress or tissue dampened with nail polish remover.
3. Paint the lacquer over the entire surface of the affected nail using one of the reusable spatulas provided. Always clean the reusable spatula before moving on to the next nail, in order to avoid contaminating the lacquer. Do not wipe the spatula on the edge of the bottle.
4. Clean the spatula with a pad or tissue soaked with nail polish remover.
5. Close the vial tightly.

Repeat all the above steps for each infected nail.

Special instructions:

- Do not reuse the files on healthy nails
- Before each new application, file with nail varnish remover to remove any residual lacquer.
- Waterproof gloves should be worn when handling organic solvents (white spirit, thinners...) to protect the coat of LOCERYL lacquer on the nails.
- Cosmetic nail lacquers may be applied at least 10 min after LOCERYL nail lacquer application.

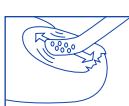
For packages with accessories:



a) Before first use of LOCERYL, carefully clean and prepare the nails, filing down the affected areas (especially the surface of the nail) as thoroughly as possible. Take care not to file the periungual skin.



b) Clean the surface of the nail and remove oil using one of the cleansing wipes provided, in order to remove any residual lacquer.



c) Paint the lacquer over the entire surface of the infected nail using one of the reusable spatulas provided. Always clean the reusable spatula before moving on to the next nail, in order to avoid contaminating the lacquer. Do not wipe the spatula on the edge of the bottle.



d) Clean the spatula with one of the cleansing wipes provided. Tightly close the bottle.

Repeat all the above steps for each infected nail.

Special instructions:

- Do not reuse the files on healthy nails
- Before each new application, file the infected nails if necessary, and in all cases, clean them with the cleansing wipes to remove any residual lacquer.
- Waterproof gloves should be worn when handling organic solvents (white spirit, thinners...) to protect the coat of LOCERYL lacquer on the nails.
- Cosmetic nail lacquers may be applied at least 10 min after LOCERYL nail lacquer application.

Frequency of administration

Treatment should be continued without interruption until the nail has fully regrown and recovered.

Duration of treatment

Treatment generally lasts for 6 months for fingernails and 9 months for toenails.

a. If you use more Loceryl® than you should

Immediately contact your doctor or pharmacist.

b. If you forget to use Loceryl®

Don't worry if you forget to use Loceryl at the right time. When you remember, start using the product again, in the same way as before.

c. If you stop using Loceryl®

Do not stop using Loceryl before your doctor tells you to or your infection could come back.

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

4. Possible Side Effects

Like all medicines, LOCERYL 5% medicinal nail lacquer can cause adverse effects, although not everybody gets them.

- Rare adverse effects (affect less than 1 in 1,000 people):

- Nail damage, discolouration of the nails, brittle or weak nails

- Very rare adverse effects (affect less than 1 in 10,000 people):

- Skin burning sensation

- Adverse effects of unknown frequency (cannot be determined based on the available data):

- Redness, itching, urticaria (hives), skin vesicles, contact allergies
- Systemic allergic reaction (a serious allergic reaction that can be associated with swelling of the face, lips, tongue or throat, difficulty breathing and/or a severe skin rash)
- All medicines can cause allergic reactions; although most are mild, some can be serious. If this happens, stop applying LOCERYL, immediately remove LOCERYL with a nail varnish remover or the cleaning swabs provided with the package and seek medical advice. LOCERYL must not be reapplied.
- You must get immediate medical help if you have any of the following symptoms:
 - You have difficulty breathing
 - Your face, lips, tongue or throat swell
 - Your skin develops a severe rash.

Reporting of side effects:

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

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

You can report thru the Middle East Pharmacovigilance:

ME.Pharmacovigilance.AEDXB@galderma.com

To report any side effect(s) in the Kingdom of Saudi Arabia:

- National Pharmacovigilance centre (NPC)
- * Fax: +966-11-205-7662
- * Call NPC at +966-11-2038222, Ext: 2353-2356-2317-2354-2334-2340
- * Toll-free: 8002490000
- * E-mail: npc.drug@sdfa.gov.sa
- * Website: www.sdfa.gov.sa/npc

5. How to store Loceryl®

- Keep out of the reach and sight of children.
- Store below 30°C
- Protect from heat
- Do not use after the expiry date which is stated in the pack. The expiry date refers to the last day of the month.
- Medicines should not be disposed via wastewater or household waste. Ask your physician or pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

6. Further Information

a. What Loceryl® Contains

- The active substance is:

Amorolfine hydrochloride..... 5.574 g

Quantity equivalent to amorolfine..... 5.000 g

For 100 ml.

- Other ingredients:

Methacrylic acid copolymer (EUDRAGIT RL100), triacetin, butyl acetate, ethyl acetate, absolute ethanol.

b. What Loceryl® looks like and contents of the pack

- This medication is in the form of a medicinal nail lacquer.

- **Packaging:** 5ml glass amber bottle with attached reusable spatula, 30 cleansing wipes, 30 nail files; and 2.5ml glass amber bottle with attached reusable spatula

- **Pack Sizes:** 2.5 mL and 5 mL (not all packaging may be marketed).

c. Marketing Authorization Holder and Manufacturer

Galderma International

Tour Europlaza

20, avenue André Prothion

92927 La Defense Cedex- France

Manufacturer

Laboratoires Galderma

ZI – Montdésir

74 540 Alby sur Chéran

France

For any information about Loceryl®, please write to us on ME.Regulatory.AEDXB@galderma.com

d. This leaflet was last revised on 05/2018.

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THIS IS A MEDICAMENT

- A Medicament is a product, which affects your health, and its consumption, contrary to instruction, is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not, by yourself, interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

Keep medicaments out of the reach of children

Council of Arab Health Ministers

Union of Arab Pharmacists

ADVICE AND RECOMMENDATIONS TO SUPPORT YOUR TREATMENT

Nail mycosis (onychomycosis): what are the risk factors?

For toenails:

- repeated microtrauma to the toenails, poor positioning of the toes,
- wearing closed-cap shoes and/or plastic shoes or socks made from synthetic materials, which encourage maceration,
- exposed professions that require boots/protective shoes be worn, as these increase sweating,
- high-impact sports, especially those practising barefoot: swimming, judo, marathon running.

For fingernails:

- Look for signs of foot mycosis (known as dermatophytosis).
- Repeated contact with water (which may cause a type of mycosis called candidiasis),
- Trauma or irritation to the nail by:
 - repeated microtrauma (e.g. caused by gardening),
 - contact with detergent (washing-up liquid and other corrosive substances),
 - exposed professions (hairdresser, manicurist, podiatrist).

Nail mycosis (onychomycosis): how can I prevent and avoid contamination?

- Disinfect your shoes and socks. Ask your pharmacist for advice if necessary.
- Treat any skin damage between your toes and on the soles of your feet as quickly as possible.
- Use your own towels to avoid contamination from other people.
- Dry your feet and the skin in between your toes thoroughly after showering or bathing to prevent contaminating other nails and areas of skin.

Nail mycosis (onychomycosis): why is it important to follow the treatment properly?

In order to be effective, the treatment must be continued for the entire duration prescribed until the nail has completely grown out, without interruption.

DO NOT GIVE UP!

- It can take 6 months for fingernails and 9-12 months for toenails.
- All of the treatments take a long time, because that is what is needed for the healthy nail to grow out.