

PACKAGE LEAFLET: INFORMATION FOR THE USER

Loceryl 5% w/v Medicated Nail Lacquer Amorolfine (as amorolfine hydrochloride)

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.

What is 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. Contents of the pack and other information

1. WHAT LOCERYL IS AND WHAT IT IS USED FOR

- Loceryl is used to treat fungal infections of the nails.
- Loceryl contains the active ingredient amorolfine (as the hydrochloride), which belongs to a group of medicines known as antifungals. It kills a wide variety of fungi that can cause nail infections.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE LOCERYL

Do not use Loceryl if you are

- Allergic (hypersensitive) to amorolfine or any of the other ingredients of Loceryl. Please check by reading the list of ingredients in section 6. If you answer yes, you must inform your doctor before starting treatment.

Please seek immediate medical attention if you experience symptoms of an allergic reaction. Signs or symptoms of a severe allergic reaction may include a rash, with or without itching, swelling of the face, eyelids or lips and difficulty in breathing.

Warnings and precautions

Talk to your doctor or pharmacist before using Loceryl.

- Avoid the lacquer coming into contact with the eyes, ears or mucous membranes (e.g. mouth and nostrils).
- Do not inhale.
- Do not apply to the nail bed as it may cause localised effects such as contact dermatitis.
- Wear impermeable gloves when using organic solvents to stop the nail lacquer from being removed.

Using other medicines

There are no known interactions with other medicines.

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Using other nail products

Nail varnish or artificial nails should not be used while using Loceryl.

Pregnancy and breast-feeding

You should not use Loceryl and tell your doctor if you are pregnant, planning to become pregnant or are breast-feeding. Your doctor will then decide whether you should use Loceryl.

Ask your doctor or pharmacist for advice before taking any medicine.

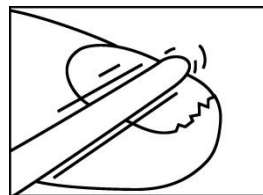
3. HOW TO USE LOCERYL

Always use Loceryl exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Due to the lack of clinical experience, there is no specific dosage recommendation for children.

Method of Administration for Adults

Loceryl should be applied to the affected finger or toe nails once weekly.

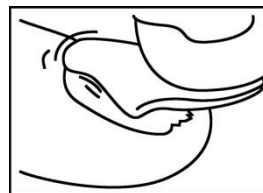


Step 1. File the nail

Before the first application, file down the infected areas of nail, including the nail surface, as much as possible using the nail file provided.

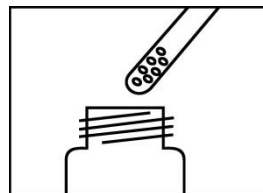
CAUTION: Do not use nail files used for infected nails on healthy nails, otherwise you may spread the infection.

To prevent the spread of infection take care that no one else uses the files from your kit.



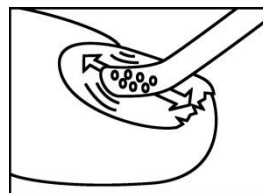
Step 2. Clean the nail

Use one of the swabs provided to clean the nail surface. Repeat steps 1 and 2 for each affected nail.



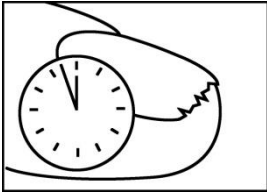
Step 3. Take some lacquer from the bottle

Dip one of the re-usable applicators into the bottle of nail lacquer. The lacquer must not be wiped off on the edge of the bottle before it is applied.



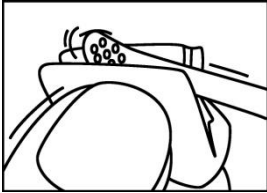
Step 4. Apply the lacquer

Apply the nail lacquer evenly over the entire surface of the nail. Repeat steps 3 and 4 for each affected nail.



Step 5. Allow to dry

Let the treated nail(s) dry for approximately 3 minutes.



Step 6. Clean the applicator

The applicators provided are re-usable. However, it is important to clean them thoroughly after completing each treatment procedure, using the same swab you used for nail cleansing. Avoid touching newly treated nails with the swab. Close the nail lacquer bottle tightly. Dispose of the swab carefully as it is inflammable.

- Before using Loceryl again, first remove the old lacquer from your nails using a swab, then file down the nails again if necessary.
- Re-apply the lacquer as described above.
- When dry the nail lacquer is unaffected by soap and water, so you may wash your hands and feet as normal. If you need to use chemicals such as paint thinners or white spirit, rubber or other impermeable (waterproof) gloves should be worn to protect the lacquer on your fingernails.
- It is important to carry on using Loceryl until the infection has cleared and healthy nails have grown back. This usually takes 6 months for finger nails and 9 to 12 months for toe nails. Your doctor will probably check how your treatment is progressing every 3 months or so.

If you get Loceryl in your eyes or ears

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

If you accidentally swallow Loceryl

If you, or anyone else, accidentally swallows the lacquer contact your doctor, pharmacist or nearest hospital straight away.

If you forget to use Loceryl

Do not worry if you forget to use the lacquer at the right time. When you remember, start using the product again, in the same way as before.

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, this medicine can cause side effects, although not everybody gets them. In addition to the beneficial effects of Loceryl, it is possible that unwanted effects will occur during treatment, even when it is used as directed.

Rare side effects (occurring in less than 1 in 1000 people)

Your nail may become discoloured, broken or brittle.

Very rare side effects (occurring in less than 1 in 10,000 people)

A burning sensation may occur in the area around the nail.

Unknown frequency of occurrence

Redness, itching, hives, blisters and allergic skin reaction (contact dermatitis).

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

IRELAND: FREEPOST, Pharmacovigilance Section, Irish Medicines Board, Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace, Dublin 2, Ireland.
Tel: +353 1 6764971, Fax: +353 1 6762517,
Website: www.imb.ie, e-mail: imbpharmacovigilance@imb.ie.

5. HOW TO STORE LOCERYL

- Keep out of the sight and reach of children.
- Do not use Loceryl after the expiry date which is stated on the carton and bottle. The expiry date refers to the last day of that month.
- Store below 30°C. Protect from heat. Keep bottle tightly closed after use.
- Bottles should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of bottles no longer required. These measures will help to protect the environment.
- If you have any left-over/unused bottles, please return these to your pharmacist for safe disposal

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Loceryl contains

The active substance is amorolfine. Loceryl contains 50mg/ml (5% w/v) of amorolfine (equivalent to 6.4% w/v amorolfine hydrochloride).

The other ingredients are:

ammonio methacrylate copolymer A, triacetin, butyl acetate, ethyl acetate and ethanol.

What Loceryl looks like and contents of the pack

1 bottle with screw cap, together with cleansing swabs, spatulas and nail files.

Each bottle contains 5ml of solution.

You can get more information on Loceryl Nail Lacquer from your doctor or pharmacist.

Manufacturer:

Loceryl is manufactured by: Laboratoires Galderma, ZI-Montdésir, 74540 Alby-sur-Chéran, France.

Procured from within the EU by the Parallel Product Authorisation holder: Imbat Ltd., Unit L2, North Ring Business Park, Santry, Dublin 9.

The product is repackaged by: Doncaster Pharmaceuticals Group Ltd., Kirk Sandall, Doncaster, South Yorkshire, DN3 1QR, UK.

Distributed by: Eurodrug Ltd, Santry, Dublin 9.

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