

Package leaflet: Information for the user

Loceryl, 50 mg/ml, medicated nail lacquer

Amorolfinum

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

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

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- 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.
- You must talk to a doctor if you do not feel better or if you feel worse.

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

Contents

1. What Loceryl is and what it is used for	1
2. What you need to know before you use Loceryl	1
3. How to use Loceryl	2
4. Possible side effects	4
5. How to store Loceryl	4
6. Contents of the pack and other information	4

1. What Loceryl is and what it is used for

Loceryl is an antifungal medicine in the form of nail lacquer, for topical use. The active substance of the medicine – amorolfine – is active against various fungi causing nail infections (onychomycoses).

The indications for using Loceryl are onychomycoses caused by dermatophytes, yeasts and moulds. Loceryl is indicated for use in the treatment of onychomycosis without involvement of the nail bed (the place where the nail plate is formed) and limited to 2 nail plates.

The medicine can be used when as a result of fungal nail infection, the colour of the nail plate has changed (white, yellow or brown discolourations) or the nail plate is thickened.

Loceryl is indicated for use in the case of fungal infections affecting only the upper part of the nail plate – **as for example in Photo No. 1.**

If the fungal lesion affects a larger part of the nail plate (e.g. as presented in Photo No. 1 or 3), you should consult a doctor.



2. What you need to know before you use Loceryl

Do not use Loceryl:

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

Warnings and precautions

The medicine is intended only for application to the nail plate.

Loceryl should not be applied on the skin around nails.

Artificial nails should not be used while using the medicine.

You should wait at least 10 minutes after applying Loceryl before painting your nails with any cosmetic nail varnish.

The cosmetic nail varnish should be carefully removed before repeat application of Loceryl.

If you use organic solvents impermeable gloves must be used, otherwise amorolfine nail lacquer will be removed.

If Loceryl gets into your eye or ear, flush this place with a large amount of water and contact a doctor or the nearest hospital. Avoid contact of the lacquer with mucous membranes (of the mouth or nose). Do not smell (inhale) the lacquer.

Children and adolescents

Do not use Loceryl because there are no adequate studies on its use in children.

Other medicines and Loceryl

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

No data available. No studies on interactions between Loceryl and other medicines have been performed.

Pregnancy, breast-feeding and fertility

If you are either pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Loceryl should not be used by pregnant or breast-feeding women, unless the doctor considers it necessary.

Driving and using machines

No effects of Loceryl on ability to drive and use machines have been evidenced.

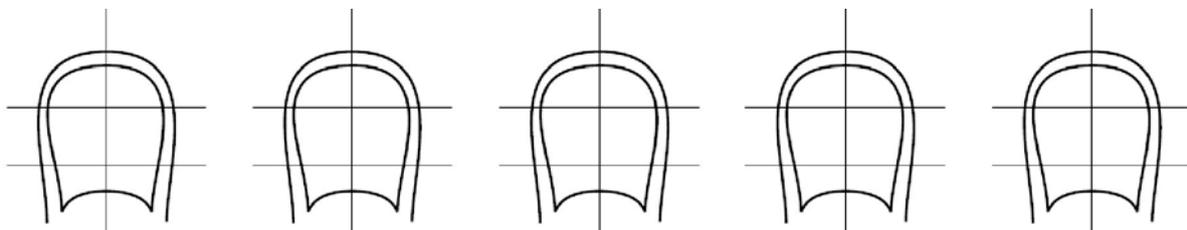
3. How to use Loceryl

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Before starting the treatment

In the diagram below, shade the area affected by the fungal nail infection. This will help assess the treatment results.

Every month, shade the area now affected until the infected nail has completely grown out. If 2 nail plates are affected, select the more seriously affected plate for the assessment of treatment results.



Before treatment

month 1

month 2

month 3

month 6

Dosage

Loceryl should be applied to the infected nail once a week.

Treatment should be continued until a completely healthy nail plate appears, which occurs after about 6 months in the case of finger nails and after 9 to 12 months in the case of toe nails. Nail growth is a

slow process, which is why the first sign of improvement of the nail plate condition are usually visible after 2 to 3 months of treatment.

If the appearance of the nail plate does not improve, check with your doctor.

Apply Loceryl to the nail as described below.

1. Before the first application of Loceryl, remove the previously applied lacquer layers (e.g. cosmetic lacquers). The affected nail (particularly its surface) should be filed down as thoroughly as possible using the nail file supplied.

Caution: Do not use the same nail file for infected nails and healthy nails, to prevent the infection from spreading to healthy nails.



2. The surface of the nail should then be cleansed and degreased using the enclosed cleansing swab moistened with isopropyl alcohol. The moistened swab may later be used to remove the lacquer from the spatula. Before repeat application of Loceryl, the affected nail should be prepared as presented above and in each case it should be first cleansed from any remaining lacquer with the enclosed nail files and cleansing swabs.



3. Multiple-use spatulas should be used. Dip the spatula in the lacquer (without wiping off the lacquer on the edge of the bottle). Apply the lacquer to the entire surface of the nail and allow the lacquer to dry for 3 to 5 minutes.



If 2 nail plates are treated, repeat the procedure with the second infected nail.

Before applying the nail lacquer again, first remove the old layer of Loceryl and then apply the new one. Clean the nail, using the moistened swab, and apply the lacquer as described above.

Cosmetic nail varnish can be used, but you should wait at least 10 minutes after applying Loceryl before painting your nails. The cosmetic nail varnish should be carefully removed before repeat application of Loceryl.

After each application of Loceryl:

- Carefully clean the spatula with the moistened swab. The spatula can be used multiple times if it was cleaned after each procedure. For cleaning the spatula you can use the same swab you used for cleaning your nail.
- Remove all traces of lacquer from the screw cap, using the swab.
- After lacquer application, the bottle should be tightly closed as soon as possible.
- **Dispose of the swab carefully as it is inflammable.**

- After application of the lacquer, wash your hands after the lacquer dries completely.

When working with organic solvents, wear impermeable gloves in order to protect the Loceryl lacquer layer on the nails.

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

If you use more Loceryl than you should

The medicine is intended for application to only the nail plate. In the event of oral ingestion of Loceryl contact your doctor, pharmacist or the nearest hospital.

If you forget to use Loceryl

Do not take a double dose to make up for a forgotten dose.

If you have any further questions related to medicine use, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Loceryl can cause side effects, although not everybody gets them.

The side effects ordered by frequency are presented below.

Very common (occurring in more than 1 in 10 people)

Common (occurring in less than 1 in 10 people)

Uncommon (occurring in less than 1 in 100 people)

Rare (occurring in less than 1 in 1000 people)

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

Frequency not known (cannot be estimated from the available data).

Rare:

nail disorders, breaking nails, nail discolouration, brittle and layering nails

Very rare: redness of the skin.

Frequency unknown:

erythema (intense redness of the skin), itching, contact dermatitis, urticaria, blister on the skin, systemic allergic reaction (a serious allergic reaction that can be manifested by swelling of the face, tongue or throat, difficulty breathing and a severe skin rash).

If a serious allergic reaction develops, contact your doctor or the nearest hospital at once.

The adverse symptoms can also be caused by the development of onychomycosis itself.

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 to the Pharmacovigilance Department of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products

Al. Jerozolimskie 181C,

02-222 Warszawa

Tel.: +48 22 49 21 301

Fax: +48 22 49 21 309

e-mail: ndl@urpl.gov.pl

Side effects can also be reported to the Marketing Authorisation Holder.

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

5. How to store Loceryl

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the box.

The expiry date refers to the last day of that month.

Do not store above 30°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

It is not recommended to use cosmetic nail varnishes and false nails in the course of treatment with Loceryl.

What Loceryl contains

- The active substance of the medicine is amorolfine. One millilitre of the lacquer contains 50 mg of amorolfine.
- The other medicine ingredients are: methacrylic acid copolymer (type A), triacetin, butyl acetate, ethyl acetate, ethanol absolute.

What Loceryl looks like and contents of the pack

Loceryl is a medicated nail lacquer.

Packaging:

Orange glass bottle closed with a HDPE screw cap and with an enclosed LDPE spatula, containing 2.5 ml of nail lacquer, 30 cleansing swabs moistened with 70% isopropanol, 30 nail files, placed in a cardboard box.

Marketing Authorisation Holder and Manufacturer**Marketing Authorisation Holder**

Galderma Polska Sp. z o.o.
ul. Łączyńny 4
02-820 Warszawa, Poland
tel.: 22 331 21 80

Manufacturer:

Laboratoires Galderma
Z.I. Montdésir
74540 Alby-sur-Chéran,
France

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ADVICE AND RECOMMENDATIONS FOR TREATMENT

Fungal nail infections (onychomycosis): what are the risk factors?

Toe nails:

- Repetitive minor nail trauma, the toes being wrongly positioned.
- Wearing closed shoes or plastic shoes or synthetic fibre socks, all of which accumulate dampness.
- Professions where boots or safety shoes are necessary as this can encourage perspiration.
- Sports activity increasing the risk of infection (marathon), and in particular barefoot sports such as swimming or judo.

Finger nails:

- Fungal foot infection (dermatophytosis).
- Too frequent contact with water (may cause candidiasis).
- Nail plate traumas caused by:
 - repetitive minor traumas (gardening);
 - manual work with the use of detergents (washing powders and liquids or other harsh products).
- Certain high-risk professions (hairdresser, manicurist, podiatrist).

Fungal infections: how to prevent and avoid infections?

- Disinfect shoes and socks. Ask your pharmacist for advice if necessary.
- Treat all skin infections involving spaces between your toes and of the feet skin as soon as possible.
- Use only your own towel to avoid contaminating other people.
- Dry the spaces between your toes and the whole surface of your feet carefully, after shower or bath, to avoid contaminating the other nails or the skin.