

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

This medicine can cause allergic reactions, some can be serious. If this happens, stop applying the product, immediately remove the product with a nail varnish remover or the cleaning swabs provided with the package and seek medical advice. The product must not be reapplied. You must get urgent 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
- 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.

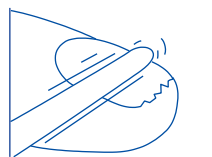
3. How to use Loceryl

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.

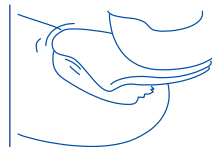


Step 1. File the nail

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.

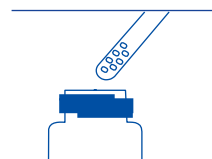
To prevent the spread of infection take care that no one else uses the files from your kit.



Step 2. Clean the nail

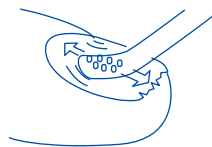
Use one of the swabs provided to clean the nail surface.

Repeat steps 1 and 2 for each affected nail.



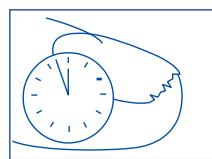
Step 3. Take some lacquer from the bottle

Dip the applicator into the bottle of nail lacquer. The lacquer must not be wiped off on the edge of the bottle before it is applied.



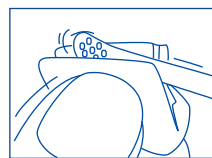
Step 4. Apply the lacquer

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 applicator provided is re-usable. However, it is important to clean it 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: may affect up to 1 in 1,000 people

- Nail damages, nail discoloration, fragile or brittle nails.

Very rare: may affect up to 1 in 10,000 people

- Skin burning sensation.

Not known: frequency cannot be estimated from the available data

- 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)
- Redness, itching, hives, blister, allergic skin reaction

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 via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. 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 carton and bottle. The expiry date refers to the last day of that month.
- Keep the pack away from heat (store below 30°C) and keep the bottle tightly closed after use.

Do not throw away any medicines via wastewater or household waste.

Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

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

This pack is 5ml size.

Each 5ml pack consists of 1 bottle filled with Loceryl medicated nail lacquer together with cleansing swabs, spatulas and nail files.

Parallel Product Authorisation Holder and Manufacturer

Parallel Product Authorisation Holder: IMED Healthcare Ltd, Unit 625 Kilshane Avenue, Northwest Business Park, Ballycoolin, Dublin 15, Ireland

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

Repackaged by: Cast Healthcare Ltd, Unit B6 The Business Centre, 5-7 Tobermore Road, Draperstown, Northern Ireland, BT45 7AG

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

This leaflet was last approved in July 2017

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

This medicine can cause allergic reactions, some can be serious. If this happens, stop applying the product, immediately remove the product with a nail varnish remover or the cleaning swabs provided with the package and seek medical advice. The product must not be reapplied. You must get urgent 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
- 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.

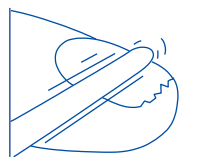
3. How to use Loceryl

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.

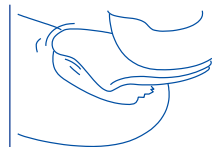


Step 1. File the nail

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.

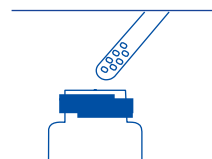
To prevent the spread of infection take care that no one else uses the files from your kit.



Step 2. Clean the nail

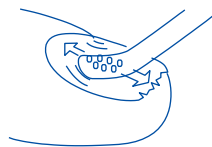
Use one of the swabs provided to clean the nail surface.

Repeat steps 1 and 2 for each affected nail.



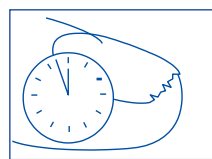
Step 3. Take some lacquer from the bottle

Dip the applicator into the bottle of nail lacquer. The lacquer must not be wiped off on the edge of the bottle before it is applied.



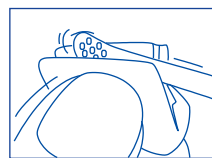
Step 4. Apply the lacquer

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 applicator provided is re-usable. However, it is important to clean it 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: may affect up to 1 in 1,000 people

- Nail damages, nail discoloration, fragile or brittle nails.

Very rare: may affect up to 1 in 10,000 people

- Skin burning sensation.

Not known: frequency cannot be estimated from the available data

- 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)
- Redness, itching, hives, blister, allergic skin reaction

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 via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. 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 carton and bottle. The expiry date refers to the last day of that month.
- Keep the pack away from heat (store below 30°C) and keep the bottle tightly closed after use.

Do not throw away any medicines via wastewater or household waste.

Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

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

This pack is 5ml size.

Each 5ml pack consists of 1 bottle filled with Loceryl medicated nail lacquer together with cleansing swabs, spatulas and nail files.

Parallel Product Authorisation Holder and Manufacturer

Parallel Product Authorisation Holder: IMED Healthcare Ltd, Unit 625 Kilshane Avenue, Northwest Business Park, Ballycoolin, Dublin 15, Ireland

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

Repackaged by: Imed Pharma Ltd, Unit 625 Kilshane Avenue, Northwest Business Park, Ballycoolin, Dublin 15, Ireland.

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

This leaflet was last approved in July 2017