

Approved Patient Information Leaflet

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S1

LOVACIL 5 % w/v Medicated Nail Lacquer¹

Amorolfine hydrochloride

Read all of this leaflet carefully before you start using this medicine

because it contains important information for you.

LOVACIL is available without a doctor's prescription, for you to treat

a mild infection. Nevertheless, you still need to use LOVACIL

carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share LOVACIL with any other persons.
- If you have any further questions, ask your Healthcare provider or pharmacist.
- You must see a doctor if your symptoms worsen or do not improve.

What is in this leaflet

1 What LOVACIL is and what it is used for

2 What you need to know before you use LOVACIL

3 How to use LOVACIL

¹ Naming and Scheduling approved name, LOVACIL, will be used in this PIL

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4 Possible side effects

5 How to store LOVACIL

6 Contents of the pack and other information

1. What LOVACIL is and what it is used for

LOVACIL contains the active substance amorolfine (as amorolfine hydrochloride), which belongs to a group of medicines known as antifungals. It kills a wide variety of fungi that can cause nail infections.

LOVACIL is used to treat fungal infections of the nails.

2. What you need to know before you use LOVACIL

Do not use LOVACIL:

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

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 varnish remover or the cleansing swabs provided with the package and seek medical advice. The product must not be reapplied.

Talk to your doctor or pharmacist before using LOVACIL

- The lacquer should not be applied on the skin around the nail.
- Avoid the lacquer coming into contact with the eyes, ears or mucous membranes (e.g. mouth and nostrils).
- Do not inhale.

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- Wear impermeable gloves when using organic solvents to stop the nail lacquer from being removed.

Children and adolescents

Children should not be treated with LOVACIL owing to the lack of clinical experience available to date.

Other medicines and LOVACIL

Tell your healthcare provider or pharmacist if you are taking, have recently taken or might take any other medicines.

(This includes all complementary or traditional medicines).

Using other nail products.

Artificial nails should not be used while using LOVACIL.

Cosmetic nail varnish can be used, but you should wait at least 10 minutes after applying LOVACIL before painting your nails.

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

Pregnancy and breast-feeding

You should not use LOVACIL if you are pregnant or breastfeeding your baby.

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

Driving and using machines

If LOVACIL nail lacquer affect you in any way, do not drive, operate machinery or do anything that requires you to be alert.

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It is not always possible to predict to what extent LOVACIL nail lacquer may interfere with your daily activities.

You should ensure that you do not engage in the above activities until you are aware of the measure to which LOVACIL nail lacquer affects you.

3. How to use LOVACIL

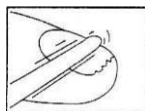
Do not share medicines prescribed for you with any other person.

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

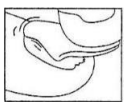
Check with your doctor, pharmacist or nurse if you are not sure.

LOVACIL should be applied to the affected finger or toe nails once or twice a week exactly as directed by your doctor.

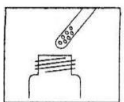
Instructions for use



1. Before the first application of LOVACIL, carefully clean your nails: file down the affected area of the nail (particularly its surface) as completely as possible using the nail file provided. Take care not to file the skin around the nail.

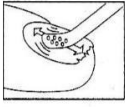


2. Clean the surface of the nail and remove any grease using the swabs provided.

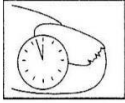


3. Apply the varnish using one of the reusable spatulas (provided in the carton) to the entire affected nail. Clean the reusable spatula between use on different nails, to avoid contaminating the varnish. Do not wipe the spatula on the edge of the bottle.

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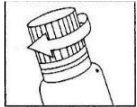
4. Repeat the operations 1 to 3 for each affected nail.



5. Let the treated nail(s) dry for approximately three to five minutes.



6. Clean the spatula using the swabs provided.



7. Seal the bottle completely. Let the treated nail(s) dry for approximately 3 minutes.

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.

The spatulas 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 LOVACIL 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.

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- It is important to carry on using LOVACIL until the infection has cleared and healthy nails have grown back. This usually takes 6 months for fingernails and 9 to 12 months for toe nails.

Your doctor or healthcare provider will probably check how your treatment is progressing every 3 months or so.

If you use more LOVACIL than you should

If you follow the instructions for, use it should not be possible to use too much or overdose.

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

If you accidentally swallow LOVACIL

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

If you forget to use LOVACIL

Don't worry if you forget to use LOVACIL at the right time.

When you remember, start using the product again, in the same way as before.

If you stop using LOVACIL

Do not stop using LOVACIL until the infection has cleared and healthy nails have grown 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, LOVACIL can cause side effects, although not everybody gets them.

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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

Not all side effects for LOVACIL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using LOVACIL please consult your healthcare provider for advice.

Tell your doctor if you notice any of the following:

Less Frequent:

- Nail damages, nail discoloration, fragile or brittle nails.
- A burning sensation may occur in the area around the nail.

Frequency unknown:

- 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, blisters, allergic skin reaction.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via Med Safety APP (Medsafety X SAHPRA) and 158 eReporting platform (who-umc.org)

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found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of LOVACIL.

5. How to store LOVACIL

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

Protect from heat. Keep bottle tightly closed after use.

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

What LOVACIL contains

- The active substance is amorolfine hydrochloride. 1 ml of Amorolfine

Nail Lacquer contains amorolfine hydrochloride corresponding to 50 mg amorolfine.

What LOVACIL looks like and contents of the pack

Colourless to almost colourless clear liquid

Pack sizes: 2.5ml, 3 ml, 5 ml

Type i or type iii amber glass bottle, spatula.

All packs contain 30 Disposable nail files, 30 cleansing swabs,

impregnated with 70 % isopropyl alcohol in foil packs}

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Not all pack sizes may be marketed.

HOLDER OF CERTIFICATE OF REGISTRATION

Astral Pharma (Pty) Ltd

125 Meade Street

Beacon Place

George, 6529

REGISTRATION NUMBER(S)

56/13.9.2/1212

This leaflet was last revised

18 March 2025