Applicant:	GALDERMA LABORATORIES SOUTH AFRICA (PTY) LTD
Product proprietary name:	LOCERYL 5 %
Registration No:	27/13.9.2/0163
Dosage form and strength:	Nail lacquer, 50 mg/ml (5 %) amorolfine

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S1

LOCERYL 5 %

Nail lacquer

Amorolfine

Read all of this leaflet carefully because it contains important information for you.

LOCERYL 5 % is available without a doctor's prescription, for you to treat a mild infection. Nevertheless, you still need to use LOCERYL 5 % carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share LOCERYL 5 % with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve.

What is in this leaflet

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

1. What LOCERYL 5 % is and what it is used for

LOCERYL 5 % nail lacquer belongs to a group of medicines known as antifungals.

It kills a wide variety of fungi that can cause nail infections.

LOCERYL 5 % nail lacquer is used to treat fungal infections of the nails.

2. What you need to know before you use LOCERYL 5 %

Always tell your health care provider if you are taking any other medicine. If you are pregnant or breast feeding your baby please consult your health care provider for advice before using this medicine.

Do not use LOCERYL 5 %

- If you are hypersensitive (allergic) to amorolfine or any of the other ingredients of LOCERYL 5 % listed in section 6.

Warnings and precautions

Take special care with LOCERYL 5 %

- LOCERYL 5 % nail lacquer should not be applied on the skin around the nail.
- Avoid contact of the lacquer with eyes, ears and mucous membranes.
- Use of artificial nails should be avoided during treatment with LOCERYL 5 % nail lacquer.
- After applying LOCERYL 5 % nail lacquer, an interval of at least 10 minutes should be allowed before application of any cosmetic nail lacquer. Before repeat application of LOCERYL 5% nail lacquer, the cosmetic nail-lacquer should be removed carefully.
- The nail lacquer is not affected by soap and water, so you may wash your hands and feet in the normal way.
- However, if you need to use chemicals or solvents such as white spirit or paint thinners, you must wear rubber gloves; otherwise the nail lacquer will dissolve.
- A systemic or local allergic reaction could possibly occur after use of this product. If this happens, the product should be stopped immediately and medical advice should be sought.
- Remove the product carefully by using a nail remover solution. The product should not be reapplied.

Children

Do not use LOCERYL 5 % in children.

Other medicines or products and LOCERYL 5 %

Always tell your health care provider if you are taking or using any other medicine. (This includes all complementary or traditional medicines.)

Using other medicines

There are no known interactions with other medicines.

Using other nail products

Avoid using artificial nails.

Cosmetic nail varnish can be used, but you have to wait at least 10 minutes after applying LOCERYL 5 % before you paint your nails.

The nail varnish should be carefully removed before repeat of LOCERYL 5 % nail lacquer.

Pregnancy and Breastfeeding

You should not use LOCERYL 5 % nail lacquer if you are pregnant or breast feeding your baby.

If you are pregnant or breastfeeding, think that you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before you use this medicine.

Driving and using machines

LOCERYL 5 % has no known effects on the ability to drive and use machines.

3. How LOCERYL 5 % is used

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

Always use LOCERYL 5 % exactly as described in this leaflet or as your health care provider have told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is:

The nail lacquer must be applied to the affected finger or toe nails once or twice weekly.

1. File the nail



File the affected nails, especially the diseased parts of the nail surface, to eliminate as much as possible of the diseased nail and the fungus affecting it, as well removing any remaining cosmetic nail lacquer, using the nail file provided.

CAUTION: Use only the files in the treatment kit. Never file a healthy nail with a file used for diseased nails, otherwise you may spread the infection.

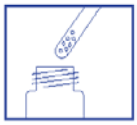
To prevent the spread of infection take care that no one else uses the files from your kit.

2. Clean the nail



Using one of the swabs provided, wipe the entire surface of the affected nail(s) and remove any previous coat of medicated nail lacquer or any remaining cosmetic nail lacquer.

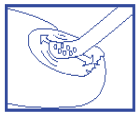
3. Take some lacquer from the bottle



Dip the applicator into the bottle of nail lacquer.

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

4. Apply the lacquer



Apply the lacquer evenly over the entire surface of the nail.

Repeat steps 3 and 4 for each affected nail.

5. Allow to dry



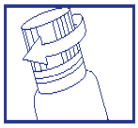
Let the treated nail(s) dry for approximately three to five minutes.

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.

7. Close the nail lacquer bottle tightly and throw away the used swab.



Close the nail lacquer bottle tightly and throw away the used swab. The medicated nail lacquer provided is not affected by soap and water, so you may wash your hands and feet in the normal way. However, if you handle solvents such as white spirit and paint thinner, you must wear rubber gloves, otherwise the nail lacquer will dissolve.

Every step of the treatment procedure is important. For a successful cure you must repeat each of the steps every time you treat your nails.

These measures and precautions may appear fussy; however, they are indispensable because they speed up healing and prevent healthy nail from becoming infected.

Cosmetic nail lacquer may be applied at least 10 minutes after LOCERYL 5 % nail lacquer application.

Avoid the eyes, lips, ears and mucous membranes to come in contact with LOCERYL 5 % nail lacquer.

Remember: Successful treatment depends on your patience and perseverance.

It is important to carry on using LOCERYL 5 % nail lacquer until the infection has cleared and healthy nails have grown back. This usually takes 6 months for fingernails and 9 to 12 months for toenails.

If you use more LOCERYL 5 % than you should

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

If you get LOCERYL 5 % in your eyes or ears, wash out with water immediately and contact your doctor, pharmacist or go to your nearest hospital

If you accidentally swallow the lacquer, contact your doctor or pharmacist straight away. If neither is available, seek help at the nearest hospital or poison-center.

If you forgot to use LOCERYL 5 %

Don't worry if you forget to apply your LOCERYL 5 % nail lacquer.

When you remember, start using LOCERYL 5 % again, in the same way as before.

If you stop using LOCERYL 5 %

It is important to carry on using LOCERYL 5 % nail lacquer until the infection has cleared and healthy nails have grown back. This usually takes 6 months for fingernails and 9 to 12 months for toenails.

4. Possible side effects

LOCERYL 5 % nail lacquer can have side-effects.

Not all side-effects reported for LOCERYL 5 % are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using, LOCERYL 5 %, please consult your health care provider for advice.

If any of the following happens, stop using LOCERYL 5 % nail lacquer and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing
- Fainting

- Rash or itching

These are all very serious side effects.

If you have them, you may have had a serious allergic reaction to LOCERYL 5 % nail lacquer. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Rare side-effects:

- Nail disorder, nail discolouration, broken nails, brittle nails

Very rare side-effects

- Skin burning sensation

Frequency unknown side-effects:

- Hypersensitivity (systemic allergic reaction) , with symptoms such as swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing).
- contact dermatitis (an allergic skin reaction)
- redness of the skin or mucous membranes (erythema)
- itchy skin (pruritis)
- hives, an outbreak of swollen, pale red bumps or plaques (wheals) on the skin (urticaria)
- blister

If you have any of these or any other unusual effects, and they are bad enough to trouble you, consult your doctor.

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 the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

By reporting side effects, you can help provide more information on the safety of LOCERYL 5 % nail lacquer.

5. How to store LOCERYL 5 %

Keep all medicines out of the reach of children.

Protect from heat.

Store at or below 30 °C.

Keep the bottle tightly closed.

Do not use after the expiry date stated on the carton and bottle label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What LOCERYL 5 % contains

The active substance is: amorolfine 50 mg/ml

The other ingredients are: butyl acetate, ethanol absolute, ethyl acetate, methracrylic acid copolymer and triacetin

What LOCERYL 5 % looks like and contents of the pack

LOCERYL 5 % Nail Lacquer is a colourless to almost colourless clear liquid.

LOCERYL 5 % Nail Lacquer is available in a 2,5 ml and 5 ml bottle

Not all pack sizes may be marketed.

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Supplied with:

1 Applicator attached to the cap

30 Disposable nail files

30 cleansing swabs, impregnated with 70 % isopropyl alcohol in foil packs.

Holder of Certificate of registration

Galderma Laboratories South Africa (Pty) Ltd

17 Muswell Road South

Bryanston

2021

This leaflet was last revised in

08 November 2021

Registration number

27/13.9.2/0163