Applicant: GALDERMA LABORATORIES SOUTH AFRICA (PTY) LTD
Product proprietary name: LOCERYL 5 %
Dosage Form and Strength Nail lacquer / 50 mg/ml (5 %) amorolfine

PROFESSIONAL INFORMATION

SCHEDULING STATUS: **S1**

1. NAME OF THE MEDICINE

LOCERYL® 5 % Nail Lacquer

Lacquer

2. QUALITATIVE AND QUANTITATIVE COMPOSITION:

LOCERYL® 5 % Nail Lacquer contains 5 % w/v (50 mg/1 ml) amorolfine

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

LOCERYL 5 % Nail Lacquer: Colourless to almost colourless clear liquid.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Onychomycoses caused by dermatophytes, yeasts and moulds.

Only little experience is available in cases where the nail matrix was involved.

4.2 Posology and method of administration

Nail Lacquer: To be applied to affected finger or toe nails once or twice weekly.

The patient should apply the nail lacquer as follows:

1. Before the first application of LOCERYL 5 % Nail Lacquer, it is essential that the affected areas of nail (particularly the nail surfaces) should be filed down as thoroughly as possible using a disposable nail file supplied. The surface of the nail should then be cleansed and degreased using an alcohol-soaked swab (as supplied).

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

application.

Before repeating application of LOCERYL 5 % Nail Lacquer, any remaining nail lacquer, and cosmetic nail lacquer if any, should be removed carefully, then the affected nails should be filed down again as required, and must at all times first be cleansed with an alcohol soaked swab to remove any remaining lacquer.

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

2. With the applicator supplied, apply the nail lacquer to the entire surface of the affected nails and allow it to dry for approximately 3 - 5 minutes.

   For each nail to be treated, dip the applicator into the nail lacquer without wiping off any of the lacquer on the bottle neck.

   After use, clean the applicator with the same pre-soaked swab used before for nail cleansing.

   Keep the bottle tightly closed.

   Caution: When working with organic solvents (thinners, white spirit, etc.) wear impermeable gloves in order to protect the LOCERYL 5 % Nail Lacquer on the nails.

   Treatment should be continued without interruption until the nail is regenerated and the affected areas are finally cured. The required duration of treatment depends essentially on intensity and localisation of the infection and on growth rate of the nails, but in general, it is six months for fingernails and nine to twelve months for toe nails.

A review of the treatment is recommended at intervals of approximately 3 months.

Co-existent tinea pedis should be treated with an appropriate antimycotic cream.

Special populations

Older people

There are no specific dosage recommendations for use in elderly patients.

Paediatric population

Owing to a lack of clinical experience to date, children should not be treated with LOCERYL 5 % Nail Lacquer.

4.3 Contra-indications:

Hypersensitivity to amorolfine or to any of the excipients listed in section 6.1

4.4 Special warnings and precautions for use

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.

When organic solvents are used impermeable gloves shall be used otherwise LOCERYL 5 % nail lacquer will be removed.

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.

Paediatric population

Owing to the lack of clinical experience available to date, children - particularly young children and infants - should not be treated with LOCERYL 5 % Nail Lacquer.

4.5 Interactions with other medicines and other forms of interaction

No interaction studies have been performed.

Use of artificial nails should be avoided during treatment.

4.6 Fertility, pregnancy and lactation:

Pregnancy

No experience exists with pregnancy and the use of LOCERYL 5 % Nail Lacquer should therefore be avoided during pregnancy.

Breastfeeding

No experience exists with nursing and the use of LOCERYL 5 % Nail Lacquer should therefore be avoided during breastfeeding.

Fertility

No experience exists with fertility and the use of LOCERYL 5 % Nail Lacquer should therefore be avoided during pregnancy.

4.7 Effects on ability to drive and use machines

The effect of LOCERYL 5% Nail Lacquer on the ability to drive and use of machines is unknown

4.8 Undesirable effects

Hypersensitivity, nail disorders (e.g. nail discolouration, broken nails, brittle nails) skin burning sensation, contact dermatitis, erythema, pruritus, urticaria and blister, may occur.

System Organ Class	**Frequency**	**Adverse Drug Reaction**
Immune system disorders	Unknown frequency*	Hypersensitivity (systemic allergic reaction)*
Skin and subcutaneous tissue disorders	Rare (≥ 1/10,000 and < 1/1,000)	Nail disorder, nail discolouration, broken nails, brittle nails.
	Very Rare (< 1/10,000)	Skin burning sensation
	Unknown frequency*	Contact dermatitis*, erythema*, pruritus*, urticaria*, blister*

*post marketing experience

Reporting of suspected adverse reactions:

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are asked to report any suspected adverse reactions 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

4.9 Overdose

No systemic signs of overdose are expected following topical application of LOCERYL 5 % nail lacquer.

In case of accidental oral ingestion, appropriate symptomatic and supportive measures should be taken if needed.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and Class: A: 13.9.2 - Fungicides

Amorolfine has both *in vitro* fungicidal and fungistatic properties based on an alteration of the fungal cell membrane targeted primarily on sterol biosynthesis. The ergosterol content is reduced, and at the same time unusual sterically nonplanar sterols accumulate.

Amorolfine has a broad spectrum of action *in vitro* against:

Yeasts: **Candida, Malassezia or Pityrosporum, Cryptococcus*

Dermatophytes: **Trichophyton, *Microsporum, *Epidermophyton*

Moulds: **Hendersonula, *Alternaria, *Scopulariopsis, Scytalidium*

Dematiacea: **Cladosporium, Fonsecaea, Wangiella*

[* in onychomycosis]

Dimorphic fungi: *Coccidioides, Histoplasma, Sporothrix*

With the exception of *Actinomyces*, bacteria are not sensitive to amorolfine.

Propionibacterium acnes is only slightly sensitive

Clinical experience indicates that cure is achieved after six months in approximately 50 % of distal onychomycosis cases in which less than 80 % of the nail surface was affected. Mycological cure was achieved in 60 - 80 % of cases.

5.2 Pharmacokinetic properties

Absorption

Amorolfine from nail lacquer penetrates into and diffuses through the nail plate and is thus able to eradicate poorly accessible fungi in the nail bed.

Systemic absorption of the active ingredient is very low with this type of application.

Following prolonged use of Loceryl Nail Lacquer, there is no indication of drug accumulation in the body.

5.3 Preclinical safety data

Studies in animals have shown reproductive toxicity at high oral doses.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients:

Ammonio methacrylate copolymer A

butyl acetate

ethanol absolute

ethyl acetate

triacetin

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Protect from heat. Store at or below 30 ºC.

Keep bottle tightly closed after use.

6.5 Nature and contents of container

LOCERYL 5 % Nail Lacquer 5 ml and 2,5 ml

Not all pack sizes may be marketed.

Supplied with:

1 Applicator attached to the cap

30 Disposable nail files

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

6.6 Special precautions for disposal

No special requirements

7. HOLDER OF CERTIFICATE OF REGISTRATION

Galderma Laboratories South Africa (Pty) Ltd

17 Muswell Road South

Bryanston

2021

8. REGISTRATION NUMBERS

LOCERYL 5 % Nail Lacquer: 27/13.9.2/0163

9. DATE OF FIRST AUTHORISATION

01 September 1993

10. DATE OF REVISION OF THE TEXT

08 November 2021

Directions for use

1. File the nail



1.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. Fungal infections are contagious; to prevent the spread of infection, take care that no other person uses the files from your kit.

2. Clean the nail



2.Using one of the pre-soaked pads provided, wipe the entire surface of the affected nail(s). Take care to remove any previous coat of medicated nail lacquer or any remaining cosmetic nail lacquer.

3. Take some lacquer from the bottle



3.Dip the applicator into the bottle of medicated 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



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

5. Allow to dry



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

6. Clean the applicator



6.The applicator provided is re-usable. However, it is important to clean it thoroughly after completing each treatment procedure, using the same pad 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.



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