PROFESSIONAL INFORMATION

SCHEDULING STATUS: **S1**

NAME OF THE MEDICINE:

LOVACIL 5 % Nail Lacquer

2. QUALITATIVE AND QUANTITATIVE COMPOSITION:

LOVACIL nail lacquer contains amorolfine hydrochloride equivalent to 5 % w/v (50 mg/l ml) amorolfine base.

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM:

LOVACIL 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 LOVACIL 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).

Before repeating application of LOVACIL Nail Lacquer, 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.

3. When working with organic solvents (thinners, white spirit, etc.) wear impermeable gloves in order to protect the LOVACIL 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 43 appropriate antimycotic cream.

Special populations

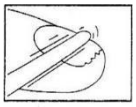
Elderly population

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

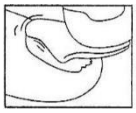
Paediatric population

Owing to a lack of clinical experience to date, children should not be treated with LOVACIL 5 % nail lacquer.

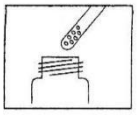
Directions for use



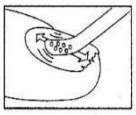
1.File the affected nails, especially the diseased parts of the nail surface, to eliminate as much as possible of the diseased nail and the fungus affecting it. Caution: Use only the files in the treatment kit. Never file a healthy nail with a file used for diseased nails, otherwise you may spread the infection. Fungal infections are contagious; to prevent the spread of infection, take care that no other person uses the files from your kit.



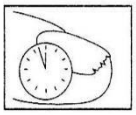
2. Using one of the pre-soaked pads provided, wipe the entire surface of the affected nail(s). Take care to remove any previous coat of medicated nail lacquer.



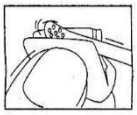
3.Dip the applicator into the bottle of medicated nail lacquer. The lacquer must not be wiped off the applicator on the edge of the bottle before it is applied.



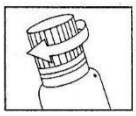
4. Apply the nail lacquer evenly over the entire surface of the nail. Repeat steps 3 and 4 for each affected nail.



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



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 pad.



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.

Remember: Successful treatment depends on your patience and perseverance.

4.3 Contraindications:

LOVACIL 5% nail lacquer is contraindicated in patients who have shown hypersensitivity to amorolfine or to any of the excipients

listed in section 6.1.

4.4 Special warnings and precautions for use:

Use of cosmetic lacquers or artificial nails should be avoided during treatment with LOVACIL Nail Lacquer**.**

After applying LOVACIL nail lacquer, an interval of at least 10 min should be respected before application of any cosmetic nail lacquer. Before repeat application of LOVACIL nail lacquer, the cosmetic nail lacquer should be removed carefully.

LOVACIL nail lacquer should not be applied on the skin around the nail.

Avoid contact of the lacquer with eyes, ears and mucous membranes.

When organic solvents are used impermeable gloves shall be used otherwise LOVACIL nail lacquer will be removed.

A systemic or local allergic reaction could possibly occur after use of LOVACIL nail lacquer.

If this happens, LOVACIL nail lacquer should be stopped immediately, and medical advice should be sought.

Remove LOVACIL nail lacquer carefully by using a nail remover solution.

LOVACIL nail lacquer should not be reapplied.

Paediatric population

Owing to the lack of clinical experience available to date, children should not be treated with LOVACIL Nail Lacquer.

4.5 Interaction with other medicines and other forms of Interaction:

No interaction studies have been performed.

Use of artificial nails should be avoided during treatment with LOVACIL nail lacquer.

4.6 Fertility, pregnancy and lactation:

Pregnancy
No experience exists with pregnancy and the use of LOVACIL nail lacquer should therefore be avoided during pregnancy.

Breastfeeding
No experience exists with nursing and the use of LOVACIL nail lacquer should therefore be avoided during breastfeeding.

Fertility

No experience exists with fertility and the use of LOVACIL nail lacquer should therefore be avoided during pregnancy.

4.7 Effects on ability to drive or use machines

The effect of LOVACIL nail lacquer on the ability to drive and use of machines is unknown.

4.8 Undesirable effects:

Tabulated summary of adverse reactions

System Organ Class	Frequency	Undesirable effect
Immune system disorders	*Frequency unknown*	Hypersensitivity* (systemic allergic reaction)
Skin and subcutaneous tissue disorders	*Less frequent*	Skin burning sensation. Nail disorder, nail discolouration, broken nails, brittle nails. However, these reactions can also be linked to the onychomycosis itself.
	Frequency unknown	Erythema*, pruritus*, urticaria*, blister*, contact dermatitis*.

Reporting of suspected adverse reactions

Reporting adverse reactions after authorisation of the medicine is important.

It allows continued monitoring of the benefit/risk balance of the medicine.
Healthcare professionals are asked to report any suspected adverse reactions to SAHPRA via the "the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA 126 website

4.9 Overdose:

No systemic signs of overdose are expected following the topical application of LOVACIL Nail Lacquer.

Should LOVACIL Nail Lacquer be ingested, treatment should be symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES:

5.1 Pharmacodynamic properties

Category and class A: 13.9.2 – Fungicides
Pharmacotherapeutic group: Other antifungals for topical use.
ATC code: D01AE16

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 immites, Histoplasma capsulatum, Sporothrix schenckil*

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

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 Pharmacokinetics:

Amorolfine from the nail lacquer penetrates and diffuses through the nail plate and effective concentrations accumulate in the nail bed where access to fungi is critical.

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

Following prolonged topical use of amorolfine nail lacquer there is no indication of drug accumulation in the body.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ammonio methacrylate copolymer A,

triacetin,

butyl acetate,

ethyl acetate,

absolute ethanol

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years

6.4 Special precautions for storage

Protect from heat Store below 30 °C

Keep the container tightly dosed.

6.5 Nature of contents of container:

LOVACIL Nail Lacquer 2,5 ml, 3 ml, 5 ml with applicator cap Supplied with:

Type i or type iii amber glass bottle, spatula.

30 Disposable nail files

30 leansing swabs, impregnated with 70 % isopropyl alcohol in foil packs}

6.6 Special precautions for disposal:

No special instructions.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements

7. THE HOLDER OF THE CERTIFICATE OF REGISTRATION

Astral Pharma (Pty) Ltd

125 Meade Street

Beacon Place

George

6529

8. **REGISTRATION NUMBER**:
56/13.9.2/1212

9. DATE OF FIRST AUTHORIZATION/RENEWAL OF THE AUTHORIZASTION
18 March 2025

10. DATE OF REVISION OF TEXT
18 March 2025