PROFESSIONAL INFORMATION

SCHEDULING STATUS

S1

1 NAME OF MEDICINE

LYRECOL 5 % (MEDICATED NAIL LACQUER)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

LYRECOL 5 % medicated nail lacquer contains 5 % w/v amorolfine in the form of hydrochloride. Each 1 ml of medicated nail lacquer contains 55,74 mg amorolfine hydrochloride (equivalent to 50 mg of amorolfine).

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Medicated nail lacquer.

A clear and colourless solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

LYRECOL 5 % medicated nail lacquer is indicated for the treatment of onychomycoses caused by dermatophytes, yeasts and moulds. (Limited experience is available in cases where the nail matrix was involved).

4.2 Posology and method of administration

Posology

Onychomycoses

LYRECOL 5 % medicated nail lacquer should be applied to affected finger or toenails once or twice weekly.

Special populations

Elderly

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 LYRECOL 5 % medicated nail lacquer.

Method of administration

The patient should apply LYRECOL 5 % medicated nail lacquer as follows:

Step 1:

Before the first application of LYRECOL 5 %, 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 LYRECOL 5 %, 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.

Step 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.

Step 3:

When working with organic solvents (thinners, white spirit, etc.) wear impermeable gloves in order to protect the LYRECOL 5 % 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 toenails.

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.

4.3 Contraindications

LYRECOL 5 % medicated nail lacquer is contraindicated in:

- Patients with known hypersensitivity to amorolfine or to any of the excipients (see section 6.1);

4.4 Special warnings and precautions for use

Use of cosmetic lacquers or artificial nails should be avoided during treatment with LYRECOL 5 % medicated nail lacquer.

After applying LYRECOL 5 % medicated nail lacquer, an interval of at least 10 min should be respected before application of any cosmetic nail lacquer. Before repeat application of LYRECOL 5 % medicated nail lacquer, the cosmetic nail lacquer should be removed carefully.

LYRECOL 5 % medicated 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 LYRECOL 5 % medicated nail lacquer will be removed.

A systemic or local allergic reaction could possibly occur after use of LYRECOL 5 % medicated nail lacquer. If this happens, LYRECOL 5 % medicated nail lacquer should be stopped immediately, and medical advice should be sought.

Remove LYRECOL 5 % medicated nail lacquer carefully by using a nail remover solution. LYRECOL 5 % medicated nail lacquer should not be reapplied.

<u>Paediatric population</u>

Owing to the lack of clinical experience available to date, children should not be treated with LYRECOL 5 % medicated 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 LYRECOL 5 % medicated nail lacquer .

4.6 Fertility, pregnancy and lactation

Pregnancy

No experience exists with pregnancy and the use of LYRECOL 5 % medicated nail lacquer should therefore be avoided during pregnancy.

Breastfeeding

No experience exists with nursing and the use of LYRECOL 5 % medicated nail lacquer should therefore be avoided during breastfeeding.

Fertility

No experience exists with fertility and the use of LYRECOL 5 % medicated nail lacquer should therefore be avoided during pregnancy.

4.7 Effects on ability to drive and use machines

The effect of LYRECOL 5 % medicated nail lacquer on the ability to drive and use of machines is unknown.

4.8 Undesirable effects

a. 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*.

* Post-marketing experience

b. 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. Health care 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 LYRECOL 5 % nail lacquer. In case of accidental oral ingestion, appropriate symptomatic measures should be taken if needed.

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 the following [*in onychomycosis]:

Yeasts:	**Candida*
	Malassezia or *Pityrosporum*
	Cryptococcus
Dermatophytes:	**Trichophyton*
	**Microsporum*
	**Epidermophyton*
Moulds:	**Hendersonula*
	**Alternaria*
	**Scopulariopsis*
	Scytalidium
Dematiacea:	**Cladosporium*
	Fonsecaea
	Wangiella
Dimorphic Fungi:	*Coccidioides immites*
	Histoplasma capsulatum

Sporothrix schenckil

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 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

Ethanol

6.2 Incompatibilities

None.

6.3 Shelf life

3 years.

6 months after opening bottle for use.

6.4 Special precautions for storage

Store at or below 25 ºC.

Protect from heat. Keep bottle tightly closed after use.

KEEP OUT OF REACH OF CHILDREN.

6.5 Nature and contents of container

The primary packaging material consists of a bottle made of hydrolytic class 1 or 3 (for 2,5 ml and 3,0 ml) and class 3 (for 5,0 ml) respectively. The cap is made of polyethylene (PE). Inside the cap there is a liner made of PTFE/PE/PTFE laminate.

Pack Sizes: 2,5 ml (1 x 2,5 ml)

3,0 ml (1 x 3,0 ml)

5,0 ml (1 x 5,0 ml)

7,5 ml (1 x 2,5 ml & 1 x 5,0 ml)

10,0 ml (2 x 5,0 ml)

All packs contain cleansing swabs, spatulas and nail files.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special instructions.

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

7 HOLDERS OF CERTIFICATE OF REGISTRATION

Trinity Pharma (Pty) Ltd.

3 Gwen Lane, Fourth Floor,

Sandton, Gauteng,

South Africa

1686

8 REGISTRATION NUMBER(S)

56/13.9.2/0174

9 DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

19 September 2023

10 DATE OF REVISION OF THE TEXT

19 September 2023