PROFESSIONAL INFORMATION

NACLER NAIL LACQUER

SCHEDULING STATUS

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1. NAME OF THE MEDICINE

NACLER 5 % Nail Lacquer

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml of nail lacquer contains amorolfine hydrochloride equivalent to 50 mg/mL amorolfine base.

For the full list of excipients, see section 6.1.

Amorolfine hydrochloride 6,40 w/w (55,74 mg/mL equivalent to amorolfine 5 % w/v (50 mg/ml amorolfine base).

3. PHARMACEUTICAL FORM

Medicated nail lacquer.

A clear, colourless to pale yellow solution.

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

Posology

Onychomycoses

NACLER is to be applied to the affected fingernails or toenails once or twice weekly.

Special populations

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

Paediatric population

Owing to the lack of clinical experience available to date, children - particularly young children and infants – should not be treated with NACLER (see section 4.4).

Method of administration

The patient should apply NACLER as follows:

1. Before the first application of NACLER, it is essential that the affected areas of nail (particularly the nail surfaces) should be filed down as thoroughly as possible using the 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 NACLER, 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 NACLER 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. *Caution:* When working with organic solvents (thinners, white spirit, etc.) wear impermeable gloves in order to protect NACLER 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

- Hypersensitivity to amorolfine or to any of the excipients of NACLER. (see section 6.1).

4.4 Special warnings and precautions for use

Avoid contact of NACLER with eyes, ears and mucous membranes.

NACLER should not be applied on the skin around the nail.

Use of artificial nails should be avoided during treatment with NACLER. When organic solvents are used with NACLER, impermeable gloves should be used otherwise NACLER 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.

Paediatric population

Owing to the lack of clinical experience available to date, children – particularly young children and infants should not be treated with NACLER (see section 4.2).

4.5 Interaction with other medicines and other forms of interaction

There are no known interactions between other medicinal products and NACLER.

Use of nail varnish or artificial nails should be avoided during treatment with NACLER.

4.6 Fertility, pregnancy and lactation

In view of the extremely low systemic exposure to amorolfine after use of the nail lacquer a foetal risk in humans appears to be negligible.

Experience with NACLER use during pregnancy and/or lactation is limited.

NACLER should not be used during pregnancy and/or lactation.

Pregnancy

Experience with NACLER use during pregnancy is limited. Studies in animals have shown reproductive toxicity at high oral doses. NACLER should not be used during pregnancy.

Breastfeeding

It is unknown whether amorolfine, as in NACLER, is excreted in human milk. NACLER should not be used during lactation.

4.7 Effects on ability to drive and use machines

NACLER is not expected to have any influence on these abilities.

4.8 Undesirable effects

Summary of the safety profile

Adverse reactions are rare. Nail disorders (e.g. nail discoloration, broken nails, brittle nails) may occur. These reactions can also be linked to the onychomycosis itself.

Tabulated list of adverse effects

System Organ Class	**Frequency**	**Side effects**
Skin and subcutaneous tissue disorders	Frequent	Nail disorder, nail discolouration, onychoclasis (broken nails), onychorrhexis (brittle nails)
		Contact dermatitis, skin burning sensation
	Less frequent	Blister, erythema, pruritus, urticaria
	Frequency unknown	

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 professionals are asked to report any suspected adverse reactions to SAHPRA via the online service for adverse drug reaction reporting by following the link: https://www.sahpra.org.za/Publications/Index/8.

An email can be sent directly to the company, pharmacovigilance@pharmadynamics.co.za to ensure safety of the product.

4.9 Overdose

Signs and symptoms:

No systemic signs of overdose are expected following topical application of NACLER.

Management of overdose:

In case of accidental oral ingestion of NACLER, treatment should be symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other antifungals for topical use

ATC code: D01AE16

Pharmacological classification: A. 13.8.2 - 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 is a broad spectrum antimycotic. It is highly active (MIC < 2 mcg/mL) *in vitro* against

yeasts:	*Candida, Cryptococcus, Malassezia*
dermatophytes:	*Trichophyton, Microsporum, Epidermophyton*
moulds:	*Hendersonula, Alternaria, Scopulariopsis*
dematiaceae:	*Cladosporium, Fonsecaea, Wangiella*
dimorphic fungi:	*Coccidioides, Histoplasma, Sporothrix*

With the exception of *Actinomyces*, bacteria are not sensitive to amorolfine. *Propionibacterium acnes* is only slightly sensitive.

5.2 Pharmacokinetic properties

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 amorolfine is very low with this type of application. Following prolonged topical use of amorolfine nail lacquer, there is no indication of amorolfine accumulation in the body.

5.3 Preclinical safety data

None stated.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ammonio methacrylate copolymer Type A

Ethanol anhydrous

Ethyl acetate

n-Butyl acetate

Triacetin

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store at or below 25 °C.

Keep bottle tightly closed and upright, and in the carton until required for use.

Protect from heat.

6.5 Nature and contents of container

NACLER is supplied in a 2,5 ml amber glass bottle with white HDPE cap and PTFE liner with tamper evident ring, packed in an outer carton which also contains the following:

10 spatulas, 30 disposable nail files and 30 swabs.

Each bottle contains 2,5 ml.

6.6 Special precautions for disposal

No special requirements.

7. HOLDER OF THE CERTIFICATE OF REGISTRATION:

Pharma Dynamics (Pty) Ltd

1st Floor Grapevine House, Steenberg Office Park

Silverwood Close

Westlake, Cape Town

7945, South Africa

8. REGISTRATION NUMBER

51/13.8.2/0101

9. DATE OF FIRST AUTHORISATION

June 2022

10. DATE OF REVISION OF THE TEXT

October 2022