SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Curanail 5% w/v Medicated Nail Lacquer

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Curanail 5% nail lacquer contains 5% w/v amorolfine in the form of hydrochloride. Amorolfine is chemically described as cis-4-[(RS)-3[4-(1,1-Dimethylpropyl)phenyl]-2-methylpropyl]-2,6-dimethylmorpholine.

Amorolfine hydrochloride HSE 6.40 %w/w

This medicine contains 552 mg of alcohol (ethanol) per 1 g, which is equivalent to 55.2 % w/w.

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Medicated Nail Lacquer.

4. Clinical Particulars

4.1. Therapeutic Indications

Treatment of mild cases of distal and lateral subungual onychomycoses caused by dermatophytes, yeasts and moulds limited up to 2 nails.

4.2 Posology and method of administration

Adults and Elderly

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

The patient should apply the nail lacquer as follows:

1. Before the first application of Curanail 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 nail file, as supplied. The surface of the nail should then be cleansed and degreased using an alcohol cleaning pad, as supplied. Cosmetic nail lacquer may be applied at least 10 min after amorolfine 5% nail lacquer application. Before repeat application of Curanail 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 at any rate 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. Apply the nail lacquer to the entire surface of the affected nails and allow it to dry. After use, clean the applicator with the same cleaning pad used before for nail cleaning. Keep the bottle tightly closed.

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

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

Treatment should be continued without interruption until the nail is regenerated and the affected areas are finally cured. Non-compliance with frequency of administration and recommended treatment duration might result in treatment failure, and development of resistance. The required frequency and duration of treatment depends essentially on intensity and localisation of the infection. In general, it is six months (finger nails) and nine to twelve months (toe nails). A review of the treatment is recommended at intervals of approximately three months. If the infection has not cleared after six months (finger nails) and twelve months (toe nails) medical advice should be sought.

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

Paediatric population

Due to the lack of clinical experience available, Curanail 5% nail lacquer is not recommended for patients below the age of 18 years.

4.3 Contra-indications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Amorolfine 5% Nail Lacquer should not be applied on the skin around the nail.

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

Patients with underlying conditions predisposing to fungal nail infections should be referred to a doctor. Such conditions include peripheral circulatory disorders, diabetes mellitus, and immunosuppression.

Patients with nail dystrophy, destroyed nail plate, nail pain or inflammation should be referred to their doctor.

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

During the application of amorolfine no artificial nails shall be used. After applying amorolfine 5% nail lacquer, an interval of at least 10 min should be respected before application of any cosmetic nail lacquer. Before repeat application of amorolfine 5% nail lacquer, the cosmetic nail lacquer should be removed carefully.

When organic solvents are used impermeable gloves shall be used otherwise amorolfine 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.

This medicine contains 552 mg of alcohol (ethanol) per 1 g, which is equivalent to 55.2 % w/w. It may cause a burning sensation on damaged skin. Ethanol is a flammable substance and should not be used near an open flame, a lit cigarette or some devices (e.g. hair dryers).

4.5 Interaction with other medicinal products 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

Experience with amorolfine use during pregnancy and/or lactation is limited. Only a few cases of exposure to topical amorolfine use in pregnant women have been reported in the post-authorisation setting, therefore the potential risk is unknown. Studies in animals have shown reproductive toxicity at high oral doses; it is unknown whether amorolfine is excreted in human milk. Amorolfine should not be used during pregnancy and/or lactation.

4.7 Effects on ability to drive and use machines

Not relevant

4.8 Undesirable effects

Adverse drug 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.

System Organ Class	Frequency	Adverse drug reaction
Immune system disorders	Unknown frequency*	Hypersensitivity (systemic allergic reaction)*
Skin and subcutaneous tissue disorders	Rare (≥ 1/10000, < 1/1000)	Nail disorder, nail discoloration, onychoclasis (broken nails), onychorrhexis (brittle nails)
	Very rare (< 1/10000)	Skin burning sensation
	Unknown frequency*	Erythema*, pruritus*, contact dermatitis*,

		urticaria*, blister*

*post-marketing experience

Reporting of suspected adverse reactions

Reporting suspected adverse reaction after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at https://yellowcard.mhra.gov.uk/ or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

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

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

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic Group: Other antifungals for topical use ATC code: D01AE16

Curanail 5% nail lacquer is a topical antimycotic. Amorolfine belongs to a new chemical class, and its fungicidal action is 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 < 2mcg/ml) in vitro against

yeasts:	Candida, Cryptococcus, Malassezia
dermatophytes:	Trichophyton, Microsporum, Epidermophyton
moulds:	Hendersonula, Alternaria, Scopulariopsis
dematiacea:	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 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 Curanail 5% Nail Lacquer, there is no indication of drug accumulation in the body.

5.3. Pre-clinical Safety Data

None stated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ammonio methacrylate copolymer A, triacetin, butyl acetate, ethyl acetate, ethanol absolute.

6.2 Incompatibilities

Not applicable.

6.3. Shelf-Life

3 years.

6.4 Special precautions for storage

Store below 30°C.
Protect from heat.
Keep bottle tightly closed after use.

6.5 Nature and contents of container

Amber glass type I bottle with screw thread and plastic screw closure.

Or

Amber glass type III bottle with screw thread and plastic closure with integrated applicator.

Pack Size: 3 ml

The pack contains cleaning swabs and nail files.

6.6 Special precautions for disposal and other handling

No special requirements.

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

7 MARKETING AUTHORISATION HOLDER

Galderma (U.K.) Limited,

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8. MARKETING AUTHORISATION NUMBER(S)

PL 10590/0049

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

07/04/2006

10 DATE OF REVISION OF THE TEXT

06/04/2023