SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Loceryl Curanail 5% w/v Medicated Nail Lacquer

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Loceryl 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

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 Loceryl 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. Before repeat application of Loceryl Curanail 5% nail lacquer, the

affected nails should be filed down again as required, following cleansing with a cleaning pad to remove any remaining lacquer.

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

2. With one of the reusable applicators supplied, 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 Loceryl 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. 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.

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

Paediatric population
Due to the lack of clinical experience available, Loceryl 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
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 and destroyed nail plate 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 cosmetic nail lacquer or artificial nails shall be used. When organic solvents are used impermeable gloves shall be used otherwise amorolfine nail lacquer will be removed.

4.5 Interaction with other medicinal products and other forms of interaction
No interaction studies have been performed.

Use of nail varnish or 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 unless clearly necessary.

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
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

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.
Website: www.mhra.gov.uk/yellowcard

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

Loceryl 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: 1.25ml
3ml

All packs contain cleaning swabs and nail files.

Not all pack sizes may be marketed.

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

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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

13/10/2015