SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Amorolfin Apofri 5%, medicated nail lacquer

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml nail lacquer contains amorolfine hydrochloride corresponding to 50 mg amorolfine.

Excipient with known effect: 1 ml contains 482.3 mg ethanol.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Medicated nail lacquer

A clear colourless solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Treatment of onychomycosis without matrix involvement.

4.2 Posology and method of administration

Posology
Amorolfin Apofri should be applied to the affected nails once a week.

Method of administration
Cutaneous use.

Before the first application of Amorolfin Apofri 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. The surface of the nail should then be cleansed and degreased using an alcohol cleansing pad or a swab impregnated with nail varnish remover. Before repeat application of Amorolfin Apofri the affected nails should be filed down again as required, following cleaning with a cleansing pad or a swab impregnated with nail varnish remover to remove any remaining lacquer.

Amorolfin Apofri medicated nail lacquer is effective in moderately extensive onychomycosis.

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.

4.3 Contraindications

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.

Dependning on the lack of clinical safety and efficacy, children and adolescents below the age of 18 years should not be treated with Amorolfin Apofri medicated nail lacquer.

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

Patients working with organic solvents (thinners, white spirit, etc.) shall use impermeable gloves, otherwise amorolfine nail lacquer will be removed.

During the treatment of Amorolfin Apofri, no cosmetic nail lacquer or artificial nails shall be used.

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 482.3 mg alcohol (ethanol) per ml. Ethanol may cause a burning sensation on damaged skin.

This product is flammable. Keep away from heat and open flame.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

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 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 (see section 5.3). 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 (≥1/10,000 <1/1,000)	Nail disorder, nail discoloration, onychoclasis, onychorrhexis
	Very rare (<1/10,000)	Skin burning sensation

	Not known (cannot be estimated from the available data)	Erythema, pruritus, contact dermatitis, urticaria, blister

Reporting of suspected adverse reactions
Reporting suspected adverse reactions 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 national reporting system listed in (to be completed nationally)*

4.9 Overdose

No systemic signs of overdose are expected following topical application of Amorolfin Apofri 5% medicated nail lacquer. In case of accidental oral ingestion, appropriate symptomatic measures should be taken, if necessary, e.g. appropriate method for gastric emptying.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other antifungals for topical use. ATC Code: D01AE16

Amorolfin Apofri is a topical antimycotic with a broad spectrum, containing amorolfine. Amorolfine´s effect is fungicidal or fungicide due to fungal spieces. The content of ergosterol in the cell membrane is reduced, and at the same time unusual sterically nonplanar sterols accumulate. 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.

Amorolfine has clinical effect against onychomycosis caused by: Dermatophytes: *Trichophyton rubrum* and *Trichophyton mentagrophytes.* Yeasts: *Candida albicans.* Against the following fungi, effect is shown *in vitro*, but clinical effect is not documented*:* Dermatophytes: *Microsporum*, *epidermophyton.* Dermatiacea: *Cladosporium.*

5.2 Pharmacokinetic properties

Amorolfine from nail lacquer penetrates through the nail. Low plasma concentrations have been measured, but systemic effect cannot be expected at the recommended dose.

Following long-term use, there is no indication of drug accumulation in the body.

5.3 Preclinical safety data

Amorolfin Apofri was considered irritant to the skin and to possess skin-sensitising potential when tested in animals.

In toxicological studies, systemic effects were only observed at high exposures/at exposures significantly higher than clinical exposures. These effects are therefore considered to be of no clinical relevance.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethanol, anhydrous

Ammonio methacrylate copolymer (Type A)
Ethyl acetate
Butyl acetate
Triacetin

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Keep the bottle tightly closed.

6.5 Nature and contents of container

Glass bottle (Ph. Eur. Type I or type III) with plastic cap (HPDE) with Teflon liner.

Pack sizes: 2.5 ml, 3 ml, 5 ml

All packs contain 30 nail files, 10 spatulas and 30 swabs.

The swabs are impregnated with 70% isopropyl alcohol.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements.

7. MARKETING AUTHORISATION HOLDER

Evolan Pharma AB
Box 120
182 12 Danderyd
Sweden

8. MARKETING AUTHORISATION NUMBER(S)

<[To be completed nationally]>

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation : <[To be completed nationally]>
Date of latest renewal: <[To be completed nationally]>

10. DATE OF REVISION OF THE TEXT

May 2023