SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Amorolfin Mylan 5% w/v medicated nail lacquer

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml of <Product name> contains amorolfine hydrochloride corresponding to 50 mg amorolfine.

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Medicated nail lacquer

Clear, colourless, solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Treatment of onychomycosis without matrix involvement caused by dermatophytes, yeasts or moulds.

4.2 Posology and method of administration

Posology

<Product name> should be applied to the affected finger nails once or twice weekly or toe nails once weekly.
The patient should apply the nail lacquer as follows:

1. Before the first application of <Product name>, it is essential that the affected areas of nail (particularly the nail surfaces) should be filed down as thoroughly as possible using the nail file supplied. The surface of the nail should then be cleansed and degreased using a cleaning swab (as supplied).

Cosmetic nail lacquer may be applied at least 10 min after amorolfine 5% nail lacquer application.

Before repeat application of <Product name>, 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 cleansed with an alcohol soaked swap 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 spatulas supplied, apply the nail lacquer to the entire surface of the affected nails and allow it to dry. After use, clean the spatula with the same cleaning swab used before for nail cleaning. Keep the bottle tightly closed.

For each nail to be treated, dip the spatula 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 <Product name> lacquer on the nails.

<Product name> 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.

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

Paediatric population
There are no specific dosage recommendations for children owing to the lack of clinical experience available to date.

Method of administration

Cutaneous use

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

<Product name> should not be applied on the skin around the nail.
Avoid contact of the lacquer with eyes, ears and mucous membranes.
Owing to the lack of clinical experience available to date, children should not be treated with <Product name>.
During the application of <Product name> no artificial nails shall be used.
After applying <Product name>, an interval of at least 10 min should be respected before application of any cosmetic nail lacquer.
Before repeat application of <Product name>, 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 medicinal product contains 482.3mg ethanol in each mL. It may cause a burning sensation on damaged skin and should not be used near an open flame, lit cigarette or some devices (e.g. hairdryers) as it is flammable.

4.5 Interaction with other medicinal products and other forms of interaction

No interactions 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 (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 discolouration, 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 (≥1/10,000 to <1/1,000)	Nail disorder, nail discolouration, 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*

* post marketing experience

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 [To be completed nationally].

4.9 Overdose

No systemic signs of overdose are expected following topical application of <Product name>. 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

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 <Product name>, there is no indication of drug accumulation in the body.

5.3 Preclinical safety data

Systemic effects in non-clinical studies were observed only at exposures considered sufficiently in excess of the maximum human exposure indicating little relevance to clinical use.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethanol anhydrous
Ammonio methacrylate copolymer (type A)
Ethyl acetate
Butyl acetate
Triacetin

6.2 Incompatibilities

None.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Protect from heat. Keep bottle tightly closed after use.

6.5 Nature and contents of container

Amber glass type I or Type III bottle with HDPE tamper-proof cap with a Teflon liner, containing a clear, colourless solution.

Pack Sizes:
2.5 ml, 3 ml, 5 ml

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

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7. MARKETING AUTHORISATION HOLDER

[To be completed nationally]

8. MARKETING AUTHORISATION NUMBER(S)

[To be completed nationally]

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation :{ DD/MM/YYYY}
Date of latest renewal: {DD/MM/YYYY}

10. DATE OF REVISION OF THE TEXT

2023-04-13
[To be completed nationally]
{MM/YYYY}