

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1 NAME OF THE MEDICINAL PRODUCT**

Amorolfine 5% w/v Nail Lacquer

### **2 QUALITATIVE AND QUANTITATIVE COMPOSITION**

1 ml contains 55.74 mg amorolfine hydrochloride (equivalent to 50 mg amorolfine).

For a full list of excipients, see section 6.1.

### **3 PHARMACEUTICAL FORM**

Medicated Nail Lacquer.

Clear, colourless to pale yellow solution.

### **4 CLINICAL PARTICULARS**

#### **4.1 Therapeutic indications**

Onychomycoses caused by dermatophytes, yeasts and moulds without nail matrix involvement.

#### **4.2 Posology and method of administration**

##### **Posology**

The nail lacquer should be applied to the affected finger or toe nails once weekly. Twice weekly application may prove beneficial in some cases.

The patient should apply the nail lacquer as follows:

1. Before the first application of Amorolfine 5% w/v Nail Lacquer, 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 pad (as supplied).

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

Before repeat application of Amorolfine 5% w/v 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. 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 Amorolfine 5% w/v 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.

### **Older people**

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 amorolfine 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.

When organic solvents are used impermeable gloves shall be used otherwise amorolfine nail lacquer will be removed

During the application of amorolfine artificial nails shall not 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.

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

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 482.53mg alcohol (ethanol) in 1ml, which is equivalent to 55.4% w/w

It may cause 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 unless clearly necessary.

#### 4.7 Effects on ability to drive and use machines

Amorolfine 5% w/v Nail Lacquer has no influence on the ability to drive and use machines.

#### 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 ( $\geq 1/10,000$ to $< 1/1,000$ )	Nail disorder, nail discoloration, onychoclasia (broken nails), onychorrhexis (brittle nails)
	Very rare ( $< 1/10,000$ )	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. Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search 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: Antifungals for dermatological use, other antifungals for topical use  
ATC code: D01AE16

Amorolfine 5% w/v 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 Amorolfine 5% w/v Nail Lacquer, there is no indication of drug accumulation in the body.

## 5.3 Preclinical safety data

There are no findings of relevance to the prescriber other than those mentioned elsewhere in the SPC.

# 6 PHARMACEUTICAL PARTICULARS

## 6.1 List of excipients

Eudragit RL 100 (Ammonio Methacrylate Copolymer Type A)  
Triacetin

Butyl acetate  
Ethyl acetate  
Ethanol, anhydrous

## **6.2 Incompatibilities**

Not applicable.

## **6.3 Shelf life**

2 years.

## **6.4 Special precautions for storage**

Stored below 30°C. Protect from heat. Keep bottle tightly closed and upright.

## **6.5 Nature and contents of container**

Amber glass (type I or type III) bottle with a HDPE cap, PTFE liner and tamper evident ring. Each pack may also contain cleansing swabs, spatulas and / or nail files, as required.

Pack size(s):

2.5 ml, 3 ml and 5 ml:

1 bottle packed with or without cleansing swabs, spatulas and / or nail files.

7.5 ml and 10 ml:

2 bottles packed with or without cleansing swabs, spatulas and / or 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.

#### **SUMMARY OF THE PRODUCT CHARACTERISTICS**

- 7. MARKETING AUTHORISATION HOLDER**  
Chanelle Medical Unlimited Company, Loughrea, Co. Galway, Ireland.

**8 MARKETING AUTHORISATION NUMBER(S)**

PL 13931/0049

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

20/07/2011

**10 DATE OF REVISION OF THE TEXT**

29/11/2023