

- 1. NAME OF THE MEDICINAL PRODUCT**  
Care Antifungal 5% w/v Medicated Nail Lacquer

## **2 QUALITATIVE AND QUANTITATIVE COMPOSITION**

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

For the full list of excipients, see section 6.1.

## **3 PHARMACEUTICAL FORM**

Medicated Nail Lacquer.

Clear, colourless to pale yellow solution.

### **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**

#### **Posology**

##### ***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 Care Antifungal 5% w/v Medicated 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. The surface of the nail should then be cleansed and degreased using an alcohol cleaning pad. Cosmetic nail lacquer may be applied at least 10min after amorolfine 5% nail lacquer application. Before repeat application of Care Antifungal 5% w/v Medicated 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 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 Care Antifungal 5% w/v Medicated 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 Care Antifungal 5%w/v Medicated Nail Lacquer is not recommended for patients below the age of 18 years.

#### 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**

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.

During the application of amorolfine no artificial nails shall be use. After applying amorolfine 5% nail lacquer, an interval of at least 10min 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 possible 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 nail remover solution. The product should not be reapplied.

### **4.5 Interaction with other medicinal products and other forms of interaction**

#### Pregnancy

Experience with amorolfine use during pregnancy 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. Amorolfine 5 % nail lacquer should not be used during pregnancy.

#### Breast-feeding

Experience with amorolfine use during lactation is limited. It is unknown whether amorolfine is excreted in human milk. Amorolfine 5 % nail lacquer should not be used during lactation.

### 4.6 Fertility, Pregnancy and Lactation

#### Pregnancy

Experience with amorolfine use during pregnancy 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. Amorolfine 5 % nail lacquer should not be used during pregnancy.

#### Breast-feeding

Experience with amorolfine use during lactation is limited. It is unknown whether amorolfine is excreted in human milk. Amorolfine 5 % nail lacquer should not be used during lactation.

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

Not applicable.

### 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
<b>Immune system disorder</b>	<b>Not known (cannot be estimated from available data)*</b>	<b>Hypersensitivity (systemic allergic reaction)*</b>
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
	Not known (cannot be estimated from the available data)*	Erythema*, pruritus*, contact dermatitis*, urticarial*, 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 the Yellow Card Scheme. Website: [www.mhra.gov.uk/yellowcard](http://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.

#### 5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antifungals for dermatological use, other antifungals  
for topical use ATC code: D01AE16

Care Antifungal 5% w/v Medicated Nail Lacquer is a topical antimycotic.

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 < 2 µg/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 Antinomyces, 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 Care Antifungal 5% w/v Medicated 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 SmPC.

## 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**

3 years.

## **6.4 Special precautions for storage**

Store 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. >

Not all pack sizes may be marketed.

## **6.6 Special precautions for disposal**

No special requirements.

**7      MARKETING AUTHORISATION HOLDER**

Thornton & Ross Limited  
Linthwaite  
Huddersfield  
HD7 5QH  
UK

**8      MARKETING AUTHORISATION NUMBER(S)**

PL 00240/0381

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

20/07/2011

**10     DATE OF REVISION OF THE TEXT**

27/03/2020