

## **SUMMARY OF PRODUCT CHARACTERISTICS**

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

Amorolfine 5% w/v Medicated Nail Lacquer

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

1 ml of Amorolfine 5% w/v Medicated Nail Lacquer 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**

Amorolfine 5% w/v Medicated Nail Lacquer 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:

Before the first application of Amorolfine 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 the nail file supplied. The surface of the nail should then be cleansed and degreased using a cleaning swab (as supplied). Before repeat application of Amorolfine 5% w/v Medicated Nail Lacquer, the affected nails

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

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

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 Amorolfine lacquer on the nails.

Amorolfine 5% w/v 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 twelvemonths (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.

### **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.

Use of nail varnish or artificial nails should be avoided during treatment.

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

No interactions studies have been performed.

#### 4.6 Fertility, pregnancy and lactation

For Amorolfine 5% w/v Medicated Nail Lacquer no clinical data on exposed pregnancies are available. Reproductive toxicology studies showed no evidence of teratogenicity in laboratory animals, but embryotoxicity was observed at high oral doses of amorolfine. Considering the low systemic exposure of amorolfine at the proposed clinical use, adverse effects on the fetus are not expected, however, as a precautionary measure it is preferable to avoid the use of Amorolfine 5% w/v Medicated Nail Lacquer during pregnancy.

##### Breastfeeding

No effects on the suckling child are anticipated since the systemic exposure of the breast-feeding women to amorolfine is negligible. Amorolfine 5% w/v Medicated Nail Lacquer can be used during breast-feeding.

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

Amorolfine 5% w/v Medicated 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
Skin and subcutaneous tissue disorders	Rare ( $\geq 1/10,000$ to $\leq 1/1,000$ )	Nail disorder, nail discoloration, onychoclasia, onychorrhexis
	Very rare ( $< 1/10,000$ )	Skin burning sensation
	Not known (cannot be estimated from the available)	Contact dermatitis

	data)	
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#### **4.9 Overdose**

##### *Accidental oral ingestion*

Amorolfine 5% w/v Medicated Nail Lacquer is for topical use. In the event of accidental oral ingestion, an appropriate method of gastric emptying may be used.

## **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.

### **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 Medicated Nail Lacquer, 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 stopped with HDPE cap with a Teflon liner

Pack Sizes:

2.5ml, 3ml, 5ml

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**

MG Pharma,  
24, rue Erlanger  
75016 PARIS,  
France

**8 MARKETING AUTHORISATION NUMBER(S)**

PL 36143/0001

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

01/11/2012

**10 DATE OF REVISION OF THE TEXT**

21/07/2014