SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Amorolfine hydrochloride 5% w/v nail lacquer

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

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

Excipient(s) with known effect
1 ml contains 0.61 ml ethanol.

For the 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

Treatment of mild cases of distal and lateral subungual onychomycoses caused by dermatophytes, yeasts and moulds limited up to 2 nails.

Consideration should be given to official guidance on the appropriate use of antifungal agents.

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 supplied. The surface of the nail should then be cleansed and degreased using an alcohol cleaning pad, as supplied. Cosmetic nail lacquer may be applied at least 10 min 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 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 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 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.

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.

Excipients
This medicinal product contains 0.61 ml alcohol (ethanol) in each ml. It may cause burning sensation on damaged skin.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

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 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	Not known (cannot be estimated from the available data)*	Hypersensitivity (systemic allergic reaction)*
Skin and subcutaneous tissue disorders	Rare (≥ 1/10,000 to < 1/1,000)	Nail disorder, nail discolouration, onychoclasis (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*, 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 the Yellow Card Scheme. Website: www.mhra.gov.uk/yellowcard or search for 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 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 *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 % 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

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):
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

Genus Pharmaceuticals Limited (trading as Genus Pharmaceuticals)
Linthwaite
Huddersfield
HD7 5QH
UK

8 MARKETING AUTHORISATION NUMBER(S)

PL 06831/0273

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

20th July 2011

10 DATE OF REVISION OF THE TEXT

20/11/2020