SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Amorstad 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 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.

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. Twice weekly application may prove beneficial in some cases.

The patient should apply the nail lacquer as follows:

1. Before the first application of Amorstad 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 an alcohol cleaning pad. Before repeat application of Amorstad 5% w/v Medicated Nail Lacquer, the affected nails should be filed down again as required, following cleansing with a cleaning pad 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. Allow the nail lacquer to dry for 3-5 minutes. 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 Amorstad 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. 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.

Children

Amorstad 5% w/v Medicated Nail Lacquer is not recommended for use in children due to a lack of data on safety or efficacy.

Method of Administration

Cutaneous use.

4.3 Contraindications

Amorstad 5% w/v Medicated Nail Lacquer must not be reused by patients who have shown hypersensitivity to the treatment.

Hypersensitivity to the active substance amorolfine or to any of the excipients.

4.4 Special warnings and precautions for use

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 and destroyed nail plate should be referred to their doctor.

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

As no clinical data is available, amorolfine is not recommended in children.

4.5 Interaction with other medicinal products and other forms of interaction

There are no specific studies involving concomitant treatment with other topical medicines.

4.6 Fertility, Pregnancy and Lactation

Pregnancy

For Amorstad 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 amolorfine 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 Amorstad 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 amolorfine is negligible. Amorstad 5% w/v Medicated Nail Lacquer can be used during breast-feeding.

4.7 Effects on ability to drive and use machines

Amorstad 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 (≥1/10,000 to <1/1,000)	Nail disorder, nail discoloration, onychoclasis
	Very rare (<1/10,000)	Skin burning sensation, contact dermatitis

4.9 Overdose

Accidental oral ingestion

Amorstad 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: Antifungals for dermatological use, other antifungals for topical use

ATC code: D01AE16

Amorstad 5% w/v Medicated Nail Lacquer is a topical antifungal which contains the active ingredient amorolfine.

Its fungistatic and fungicidal efficacy 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 against the current or casual agents of onychomycoses:

- The yeasts:

** Candida albicans and other species of Candida.*

- The dermatophytes:

** Trichophyton rubrum, Trichophyton interdigitale and Trichophyton mentagrophytes, and other species of Trichophyton,*

** Epidermophyton floccosum,*

** Microsporum.*

- The moulds:

** Scopulariopsi.*

- The slightly sensitive moulds:

** Aspergillus, Fusarium, Mucorales*

- The dematiacea (black fungus):

** Hendersonula, Alternaria, Cladospirum.*

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 Amorstad 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 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

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 and other handling

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Chanelle Medical,

Loughrea,

Co. Galway,

Ireland.

8 MARKETING AUTHORISATION NUMBER(S)

PL 13931/0080

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

20/07/2011

10 DATE OF REVISION OF THE TEXT

20/07/2011