Approved Professional Information for Medicines for Human Use:

AMOFUN 5 %

PROFESSIONAL INFORMATION

SCHEDULING STATUS

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1. NAME OF THE MEDICINE

AMOFUN 5 % Solution (Nail lacquer)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

AMOFUN 5 % Solution (Nail lacquer)

Each Solution contains amorolfine hydrochloride equivalent to amorolfine 5 % w/v (50 mg /mL amorolfine base).

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

AMOFUN 5 % Solution for Nail Lacquer.

It is clear, colourless to pale yellow solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Onychomycoses caused by dermatophytes, yeasts and moulds.

Only little experience is available in cases where the nail matrix was involved.

4.2 Posology and method of administration

Posology

Onychomycoses

Nail Lacquer: To be applied to affected finger or toenails once or twice weekly.

The patient should apply the nail lacquer as follows:

1. Before the first application of AMOFUN 5 %, it is essential that the affected areas of nail (particularly the nail surfaces) should be filed down as thoroughly as possible using a disposable nail file supplied. The surface of the nail should then be cleansed and degreased using an alcohol-soaked swab (as supplied). Cosmetic nail lacquer may be applied at least 10 minutes after AMOFUN 5 % application.

   Before repeating application of AMOFUN 5 %, the affected nails should be filed down again as required, and must always first 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 the applicator supplied, apply the nail lacquer to the entire surface of the affected nails and allow it to dry for approximately 3-5 minutes.

   For each nail to be treated, dip the applicator into the nail lacquer without wiping off any of the lacquer on the bottle neck.

   After use, clean the applicator with the same pre-soaked swab used before for nail cleansing.

   Keep the bottle tightly closed.

3. When working with organic solvents (thinners, white spirit, etc.) wear impermeable gloves in order to protect the AMOFUN 5 % on the nails.

Treatment should be continued without interruption until the nail is regenerated and the affected areas are finally cured. The required duration of treatment depends essentially on intensity and localization of the infection and on growth rate of the nails,
but in general, it is six months for fingernails and nine to twelve months for toenails.

Clinical experience indicates that cure is achieved after six months in approximately 50 % of distal onychomycosis cases in which less than 80 % of the nail surface was affected. Mycological cure was achieved in 60-80 % of cases.

Special populations

Elderly population

There are no specific dosage recommendations for use in elderly patients.

Paediatric population

Owing to a lack of clinical experience to date, children should not be treated with AMOFUN 5 %.

4.3 Contraindications

- Hypersensitivity to amorolfine hydrochloride or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

AMOFUN 5 % should not be applied on the skin around the nail.

Avoid contact of the lacquer with eyes, ears and mucous membranes.

Use of artificial nails should be avoided during treatment with AMOFUN 5 %.

After applying AMOFUN 5 %, an interval of at least 10 min should be respected before application of anycosmetic nail lacquer. Before repeat application of AMOFUN 5 %, the cosmetic nail lacquer should beremoved 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 bestopped immediately and medical advice should be sought.

Remove the product carefully by using a nail remover solution. The product should not be reapplied.

Paediatric population

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

4.5 Interaction with other medicines 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

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.

Fertility

No experience exists with fertility and the use of AMOFUN 5 % should therefore be avoided during pregnancy.

4.7 Effects on ability to drive and use machines

Not relevant.

4.8 Undesirable effects

Adverse drug reactions are nail disorders (e.g. nail discoloration, broken nails, brittle nails) skin burning sensation, contact dermatitis, erythema, pruritis, urticaria and blister may occur. These reactions can also be linked to the onychomycosis itself. The table below shows all adverse drug reactions (ADRs) observed during clinical trials and postmarket spontaneous reports with amorolfine hydrochloride.

System Organ Class	**Frequency**		
	Frequent	**Less Frequent**	**Not known**
Immune system disorders			Hypersensitivity (systemic allergic reaction)*
Skin and subcutaneous tissue disorders		Nail disorder, nail discoloration, onychoclasis (broken nails), onychorrhexis (brittle nails), skin burning sensation	Erythema*, pruritus*, contact dermatitis*, urticaria*, blister*

* Post-marketing experience

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8

4.9 Overdose

No systemic signs of overdose are expected following topical application of AMOFUN 5 %.

In case of accidental oral ingestion, appropriate symptomatic measures should be taken if needed.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and Class: A.13.9.2 - Fungicides

Pharmacotherapeutic group: Other antifungals

ATC Code: D01AE16

AMOFUN 5 %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 or Pityrosporum,

Dermatophytes:

*Trichophyton, *Microsporum, *Epidermophyton

Moulds:

*Hendersonula, *Alternaria, *Scopulariopsis, Scytalidium

Dematiacea:

*Cladosporium, Fonsecaea, Wangiella

*in onychomycosis

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

Absorption

Amorolfine from the nail lacquer penetrates and diffuses through the nail plate and effective concentrations accumulate in the nail bed where access to fungi is critical. Systemic absorption of the active ingredient is very low with this type of application. Following prolonged topical use of amorolfine nail lacquer there is no indication of drug accumulation in the body.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethanol, anhydrous

Ethyl acetate

Eudragit RL 100 (Ammonio Methacrylate Copolymer Type A)

n-Buthl acetate

Triacetin

6.2 Incompatibilities

Not applicable

6.3 Shelf life

36 months

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

AMOFUN 5 % is available in five fill volumes, 2,5 mL, 3 mL, 5 mL, 7,5 mL (5 mL + 2,5 mL bottle) and 10 mL (2 X 5 mL bottle) contained in amber glass (Type I or Type III) bottles with HDPE caps with TFE/EPE/PTFE liner and with tamper evident ring.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements

7. HOLDER OF CERTIFICATE OF REGISTRATION

Austell Pharmaceuticals (Pty) Ltd

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8. REGISTRATION NUMBER

54/13.8.2/0172

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

14 March 2023

10. DATE OF REVISION OF THE TEXT