Human Trials

Investigator-initiated clinical trials

(NY-based podiatrist, USA 2006)

50 patient trial (including 15 patients with Type 2 diabetes) on subjects with tinea and/or mild (Class 1) to severe (Class 4) onychomycosis. 90-day treatment with 8% AMYCOT® lotion (equivalent to the current dose in nailKALM®) resulted in an improvement of at least one full class in 88% of infected fungal nails.[1]

(Hamburg-based specialist, Germany 2006)

10 patient trial on subjects with tinea and/or onychomycosis. After 14 days treatment there was a 42% improvement in nails, and positive fungal cultures reduced from 96% (baseline) to 18%.[2]

(Drs. MG & AM Freeman, Australia, 2011, Australian College of Dermatology)

7 out of 10 Onychomycosis subjects had complete cure with nailKALM® after 3 months treatment. An additional subject had complete cure after 6 months treatment.[3]

(Singapore-based podiatrist 2020)

Retrospective observational study on 109 subjects with various fungal infections who were treated for 90 days. Of the 76 subjects with onychomycosis or nail damage, 33% had complete remission, 9% had an excellent response (90-99% improvement), 30% had a good response and 3% had a fair response. 9% had a poor response or worsening of the disease. Outcome was unknown in 16% of patients.[4]

Phase II Clinical Trial (ACUNOVA India 2010/12)

A randomised, double-blind, placebo controlled, parallel, single centre, efficacy and safety study on 28 subjects with tinea (14) and onychomycosis (10) showing significant efficacy over placebo with overall mycological cure rate of 92% against combined tinea/onychomycosis (severe to very severe) infections. Onychomycosis subjects (5/5) treated with nailKALM® had 100% mycological and clinical cure rates while none of the subjects receiving placebo were cured (0/5) after 3 months treatment and another 3 months follow-up.[5]

Patient results achieved in 90 days

Before topical treatment twice daily with AMYCOT® lotion, (8% active w/w) the fungal infection covered two thirds of the nail. 4 weeks after the start of the treatment, a scraping was taken and no live fungi were present.

2 months after treatment ceased, the damaged nail had grown out and been replaced with a new, healthy nail.[6]

Before treatment *2 months after treatment*

FOOTNOTES:

1. Data in file
2. Data in file
3. Freeman AM and Freeman MG. nailKALM® (Arthrospira maxima) for the treatment of dermatophyte nail infections. Australasian Journal of Dermatology 2011; 52 Suppl 1: 25.
4. Data in file
5. Parekh M et al. (2017) A pilot single centre, double blind, placebo controlled, randomised, parallel study of Calmagen® dermaceutical cream and lotion for the topical treatment of tinea and onychomycosis. BMC Complement Altern Med 17: 464
6. Data in file

"I can swear by nailKALM®. Having used many expensive and toxic preparations over many years, never with any real resolution!"

– J.K.

"I had a nail fungal infection for more than 10 years. I can swear by nailKALM®, having used a number of expensive and toxic preparations over many years, without any real resolution. I have tried most of the available treatments. I even went through the medical program, including fungal culture by my GP to allow Authority PBS access to the expensive oral treatment. 3 months later, there was little improvement and I gave up."

– GOOGLE REVIEW

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To order nailKALM® or to receive further information and a sample pack, contact Yana Gotmaker at ygotmaker@nailkalm.com.au or phone +61 414 235 960

nailKALM® is distributed by Dermedy Pty Ltd.
246 Esplanade, Brighton Victoria 3186 Australia

AUSTRALIAN MADE

nailKALM®

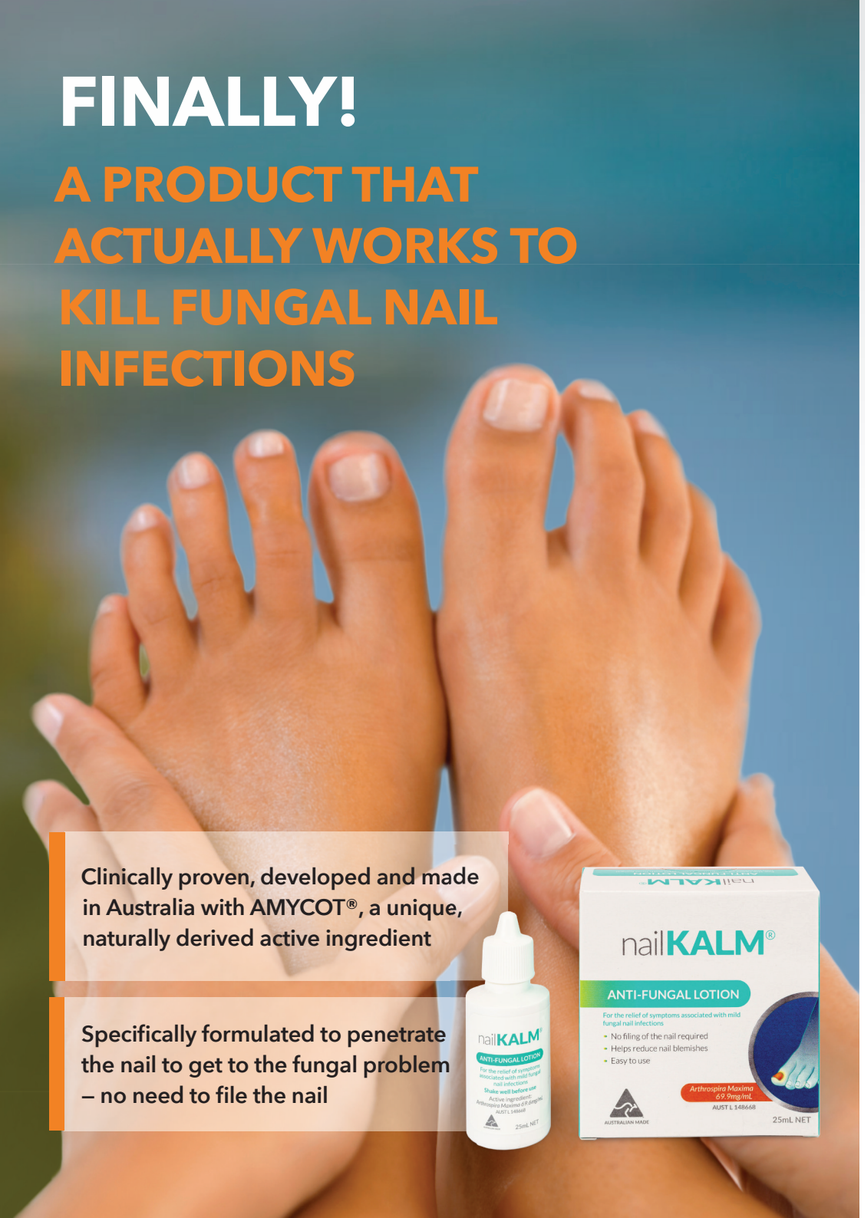
CLINICALLY PROVEN TO RELIEVE FUNGAL NAIL INFECTIONS

- Naturally derived, non-toxic active ingredient
- Kills nail fungus
- Penetrates the nail
- Soothes irritation

Amycot 8% (69.6 mg/g *Arthrospira maxima* powder)

FINALLY!

A PRODUCT THAT ACTUALLY WORKS TO KILL FUNGAL NAIL INFECTIONS



Clinically proven, developed and made in Australia with AMYCOT®, a unique, naturally derived active ingredient

Specifically formulated to penetrate the nail to get to the fungal problem – no need to file the nail

AMYCOT®

AN OPTIMAL FUSION OF SCIENCE AND NATURE

AMYCOT® is a powerful bioactive derived from a specific type of blue-green algae, one of the earliest forms of life on the planet. These algae have built in defences against fungi, bacteria and other microbes.

The blue-green algae from which AMYCOT® is derived has also been used for hundreds of years as a part of human diets and today is considered a superfood and dietary supplement. There have been no reported safety issues from its use as a food source.

AMYCOT® is a naturally derived and biological-based active with no toxicity reported to humans

- Using a patented technology that is protected around the globe, AMYCOT® is a unique formulation derived from blue-green algae
- AMYCOT® has broad spectrum anti-fungal and anti-microbial activity and is the active ingredient of nailKALM®, which has been specifically formulated to deliver a highly potent anti-fungal action
- AMYCOT®'s efficacy has been validated in multiple clinical trials
- nailKALM® holds an Australian Therapeutic Good Administration (TGA) listing
- Market safety data shows nailKALM® is extremely safe with no side effects
- nailKALM® is Australian made.

FUNGICIDAL NOT FUNGISTATIC

POTENT ANTI-FUNGAL ACTIVITY

An in vitro efficacy trial was conducted by ConMac, an independent TGA licensed testing laboratory, comparing the efficacy of AMYCOT® to other anti-fungal products already on the market. The trials confirmed that AMYCOT-containing preparations were at least as effective as other marketed products against fungi and yeast in vitro. It should be noted that in vitro results do not always translate to clinical results, indeed AMYCOT® clinical results to this stage show greater clinical efficacy than the marketed products.

Another study performed by NTS Ventures demonstrated that AMYCOT® can penetrate human nails, and can prevent the growth of common nail fungi on the untreated side of the nail. In treatment terms, this means nailKALM® is effective without nail filing or removal.

AMYCOT®'s fungicidal activity was demonstrated using Scanning Electron Microscopy (SEM) A vigorous, predatorial fungus, Trichoderma Viride, was grown and then sprayed with AMYCOT®. SEM photos (Figures 1–3) taken before spraying and 1 and 5 days after spraying demonstrate graphic evidence of the rapid and complete destruction of fungi by AMYCOT®.

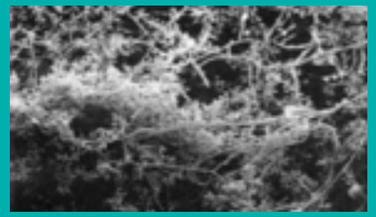


Figure 1: Photo showing normal growth morphology of Trichoderma Viride.

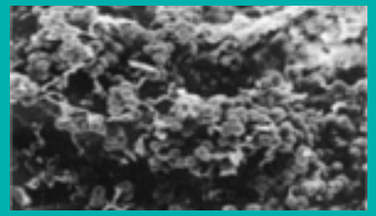


Figure 2: AMYCOT® digestion of Trichoderma Viride after 24 hours showing complete digestion of the fungal cell wall leading to the formation of inert protoplasts.

Figure 3: AMYCOT® digestion of Trichoderma Viride after 5 days showing that all that is left is a mass of dry cytoplasmic matter.