

HemCon Medical Technologies, Inc.

Mycosinate™ for the Treatment of Onychomycosis

Product Solution Meets Market Need

Over twenty million people in the U.S. suffer from onychomycosis or nail fungus.¹ The disease affects the nails of both hands and feet, making the nails malformed, thick and crumbly. Nail fungus is more prevalent in the elderly, those suffering from diabetes and patients previously taking antibiotics. These at-risk, growing patient populations are driving a global market worth \$4 billion.^{2,3}

Today, onychomycosis is treated with expensive oral drugs and creams that can have serious side effects and can take up to a year to treat. Cure rates are as low as 10-36% and relapse rates as high as 50%.⁴

Mycosinate the Solution for Onychomycosis

HemCon has developed an efficacious therapeutic, as evidenced through pre-clinical studies, for the treatment of onychomycosis. Mycosinate (formerly A31S) is a formulation containing a proprietary, synthetic, antimicrobial ingredient that is slowly released, penetrating the nail's surface to kill the fungus throughout the infected nail plate and bed, eradicating the fungal infection.

Product Description

The antifungal active in HemCon's Mycosinate differs from current solutions in several ways. First, the antifungal active has a very small molecular weight and size that allows it to easily penetrate through the nail to kill the fungal infection underneath. Second, the antimicrobial is continually released over a period of time to more effectively kill the fungal infection. Finally, Mycosinate is a highly potent broad spectrum antimicrobial that has successfully killed all microorganisms tested to date.

The Mycosinate active can be formulated into gels, lacquers and thin film delivery systems enabling many standard and novel methods of application.

Pre-Clinical Efficacy Results

The initial strategy has been to measure the *in vitro* efficacy of antifungal formulation of HemCon's Mycosinate formulation against two market leading topical commercial products and a placebo. Measurements were conducted using MedPharm's industry leading TurChub® agar based, distal finger nail model.

Each formulation was applied to full-thickness nails and doses were given at 0 h, 48 h and 96 h over the course of seven days. The study end points evaluated the production of areas of no growth of the organism under the full thickness nails. These Zone of Inhibitions (ZOI), therefore are a measure of a formulations ability to penetrate a nail and their subsequent ability to kill the *T. rubrum* fungal cells. The larger the ZOI produced, the more efficacious the formulation is against fungal cells.

The results showed that all formulations of Mycosinate had significant activity (<0.05) against *T. rubrum* when applied to the full thickness distal human nail. A "total kill" of the fungal organism was observed in the cells treated with this formulation as shown in Figure 1.



Figure 1: Mycosinate with a total fungal kill

The outcome of Product A tests showed limited efficacy against the test organism in the TurChub nail model. See Figure 2 for images taken at day seven.



Figure 2: Product A showing limited efficacy at day 7

Testing of commercially available Product B showed no activity against the organism in the TurChub nail model. As shown in the Figure 3 below, no zones of inhibition were observed.



Figure 3: Product B showing no efficacy at day 7

The Mycosinate placebo also showed no activity against the fungal organism, hence no placebo effect was observed.

From the results obtained in the full scale investigation, the formulations were ranked from highest to lowest efficacy: Mycosinate > Product A > Product B = Mycosinate placebo = Negative Control. This data is shown in Figure 4. As achieved by Mycosinate, the yellow zone indicates that the maximum zone of inhibition for the cell has been reached (e.g. total kill). Included are negative controls, whereby no formulation was added to the surface of the respective nail samples.

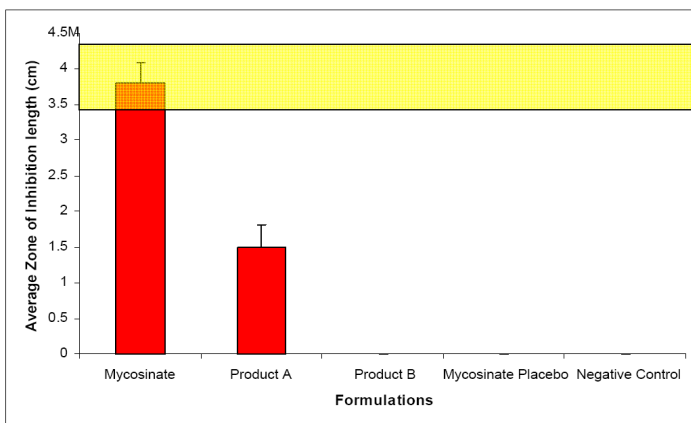


Figure 4: Final Efficacy Results

Time Based Efficacy Study Results

Further studies have determined the effectiveness of Mycosinate, administered once every 48 hours, on the kill of the microorganism *T. rubrum* through human nails at 3, 7, and 14 days. The model uses levels of ATP recovered from viable organisms as a biological marker to demonstrate the effectiveness of different formulations in reducing the viability of fungal cells where by the lower the amount of ATP recovered, the more efficacious the formulation is against fungal cells.

Mycosinate applications resulted in a complete kill of the infecting microorganism, with 0% viability, following 14 days of treatment. Cell viability was reduced to 52% and 5.3% following 3 and 7 days respectively. The results, shown in Figure 5, are normalized to untreated nails and formulation quenching.

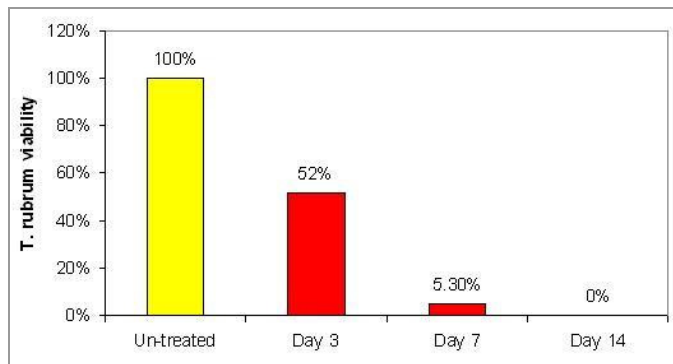


Figure 5: Mycosinate affect when applied once every 48 hrs

Safety Study Results

Human biocompatibility tests conducted by the National Institute of Health in Prague, have shown no skin irritation from Mycosinate formulations in twenty volunteers tested.

All components within the Mycosinate formulation are non irritant, non toxic and can be terminally sterilized.

Near Term Focus

The IND process for HemCon's Mycosinate product is currently underway. The initial clinical strategy is to commence with a Phase I safety and efficacy study which is scheduled to be complete in 2009. It is anticipated that the overall time to market will be much shorter compared to the typical drug development cycle with corresponding reductions in costs up until final drug application.

Revenue Opportunity

Physicians and consumers recognize the need for a safe, efficacious nail fungal solution. When compared against leading topical nail fungal products in pre-clinical studies, HemCon's Mycosinate has proven itself more efficacious, making it well positioned to become the leading solution. Against oral therapies, it offers patients significantly shorter treatment periods without the potential side effects. And since Mycosinate penetrates the nail and actively attacks the fungal source, we expect future studies to show low relapse rates.

Endnotes

¹ www.medpure.com

² Medpharm Article on Drug Delivery, Spring/Summer 2007, www.medpharm.co.uk.

³ NexMed and Arpida R&D independently reported the U.S. market value between \$1.5-\$2 billion.

⁴ www.medicinenet.com/fungal_nails and Medical Trial by Gupta et al., 2000

