

EMTRIX® Fungal Nail Treatment

Summary of published clinical studies supporting the efficacy of Emtrix®

Emtrix (K101) is an effective and clinically proven topical treatment for nails affected by fungal nail infection or psoriasis. Efficacy and safety in patients with nail fungus has been demonstrated in several studies including more than 500 patients. This summary covers mode of action and three published studies supporting the efficacy and safety of Emtrix. For full publications see www.emtrix.com.

Mode of Action

Propylene glycol has humectant properties and is used similarly to glycerol in topical moisturising preparations¹. Urea promotes hydration and is mainly applied topically in the treatment of ichthyosis and hyperkeratotic skin disorders¹. Lactic acid is used in topical formulations, particularly cosmetics, for its softening and conditioning effect on the skin². Lactate and urea are natural humectants and constituents of the "natural moisturising factor" within the stratum corneum³. The principal intended action of *K101 Nail Solution* exploits the keratolytic properties of the combination of ingredients to facilitate gentle sloughing of damaged and unsightly nail tissue and to increase hydration, thereby promoting normal healing of unguinal surface lesions.

Low pH in skin and nails is important for antimicrobial protection against both pathogenic fungi and bacteria⁴. The action of the relatively acidic pH of *K101 Nail Solution* (approximately pH 4) contributes to its efficacy. The pH of the formulation is controlled in the product specification with acceptance criteria of pH 3.5 to 5.0 for a 50% aqueous solution.

In vitro studies have characterised the physical antifungal action of K101 Nail Solution; establishing that there is a purely physical basis to such action⁵. Observed structural changes (physical degradation of the cell wall and cell membrane leads to increased permeability thus giving rise to osmotic changes and collapse) following treatment with K101 Nail Solution imply an unspecific physical mode of action.

1. Martindale: The Complete Drug Reference; 37th Edition; 2011
2. Handbook of Pharmaceutical Excipients; 5th Edition; 2006
3. Bikowski J; *Cutis*; 68(5 Suppl): 3-11; December 2001
4. Schmid-Wendtner MH, Korting HC; The pH of the Skin Surface and its Impact on the Barrier Function; *Skin Pharmacol Physiol* 2000; 19: 296-302.
5. Hultenby K, Chryssanthou E, Klingspor L, Rensfeldt K, Strömbeck L and Faergemann J; The effect of K101 Nail Solution on *Trichophyton rubrum* and *Candida albicans* growth and ultrastructure; *Mycoses* 2014 doi: 10.1111/myc.12211.

EMTRIX[®] Fungal Nail Treatment

Journal of Cosmetics, Dermatological Sciences and Applications, 2011, 1, 59-63

doi:10.4236/jcda.2011.13010 Published Online August 2011 (<http://www.SciRP.org/journal/jcda>)

Early and Visible Improvements after Application of K101 in the Appearance of Nails Discoloured and Deformed by Onychomycosis

Jan Faergemann, Sören Gullstrand, Kjell Rensfeldt

Department of Dermatology, Sahlgrenska University Hospital, Gothenburg, Sweden; Möllevångens Husläkargrupp, Malmö,

Sweden; Moberg Derma AB, Bromma, Sweden.

ABSTRACT

Onychomycosis is a fungal infection of the nails of the fingers and toes and is difficult to cure. A previous 24-week, placebo-controlled study demonstrated that a solution containing propylene glycol, urea and lactic acid (K101) was well-tolerated and effective in the treatment of onychomycosis. Patients who received K101 judged that their condition had improved from Week 2 of treatment onwards. The aim of the current study was to further evaluate and document early visible effects on nail appearance after application of topical K101 in an 8-week baseline-controlled study in 75 patients. Patients graded the appearance of their nail compared with baseline using a four-point scale. Compared with baseline, 91.8% (67/73; 95% confidence interval (CI): 83.0%, 96.9%) of the patients experienced at least some improvement in their target nail after 8 weeks of treatment. At Week 2, the proportion showing some improvement was 76.7% (56/73; 95% CI: 65.4%, 85.8%) with this number increasing to 87.7% (64/73; 95% CI: 77.9%, 94.2%) at Week 4. Proportions of patients reporting less thickened, less discoloured, less brittle and softer nails increased over the course of the study. No safety issues were identified. In conclusion, K101 provided early visible improvements in nails affected by onychomycosis.



BEFORE TREATMENT



2 WEEKS



4 WEEKS



8 WEEKS

Mycoses, 2012, 55, 532-540

Treatment of distal subungual onychomycosis with a topical preparation of urea, propylene glycol and lactic acid: results of a 24-week, double-blind, placebo-controlled study

L. Emtestam, T. Kaaman and K. Rensfeldt

Department of Dermatology & Venereology, Karolinska University Hospital, Stockholm, Sweden, Mykolab, Stockholm, Sweden and Moberg Derma AB, Bromma, Sweden

ABSTRACT

Onychomycosis is difficult to cure as this requires eradication of the primary infection and protection of new areas of growth from reinfection. A new topical treatment (K101) has been developed. The aim of this study was to assess the efficacy, safety and tolerability of K101 treatment of distal subungual onychomycosis. This was a 24-week (plus 2-week washout), multicentre, randomised, double-blind, placebo-controlled study in 493 patients with distal subungual onychomycosis (K101, n = 346; placebo, n = 147), stratified according to degree of nail involvement. More patients with 50% nail involvement achieved the primary endpoint (mycological cure after 26 weeks) in the K101 group (27.2%) than placebo (10.4%; P = 0.0012). Proportions for patients with 51–75% involvement were 19.1% for K101 and 7.0% for placebo (not significant). More patients applying K101 than placebo judged that their condition had improved from week 2 (P = 0.0148) to week 24 (P = 0.0004). No safety issues were identified. K101 provides early visible improvements in nail appearance and a clinically meaningful antifungal activity.

EMTRIX[®] Fungal Nail Treatment

Mycoses 2014, Vol 57:630-638

The effect of K101 Nail Solution on *Trichophyton rubrum* and *Candida albicans* growth and ultrastructure

Kjell Hultenby, Erja Chryssanthou, Lena Klingspor, Kjell Rensfeldt, Louise Strömbeck and Jan Faergemann

Department of Laboratory Medicine, Karolinska Institutet, Stockholm, Sweden, Department of Clinical Microbiology, Karolinska University Hospital and Karolinska Institutet, Stockholm, Sweden, Moberg Pharma AB, Bromma, Sweden and Department of Dermatology, Sahlgrenska University Hospital, Gothenburg, Sweden.

ABSTRACT