NAIL DISORDERS

AN AQUEOUS, PEELABLE, ACIDIFYING NAIL POLISH VERSUS 5% AMOROLFINE FOR THE TOPICAL TREATMENT OF ONYCHOMYCOSIS

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Introduction and Objective: Onychomycosis is a fungal nail infection, frequently caused by dermatophytes, which occurs in 2-14% of Western adults. The present study was set-up to evaluate efficacy and safety of an aqueous, peelable nail polish, which acidifies the nail environment, versus a 5% amorolfine nail lacquer for topical treatment of mild to moderate onychomycosis.

Materials and Methods: 102 adults were randomized in this open, prospective, blinded trial. Clinical efficacy was evaluated at baseline and days 30, 60, 120, and 180, respectively. All patients underwent microbiological testing (at baseline and study end). Primary objective of this trial was the change in % healthy nail surface at day 180.

Results: The % healthy surface between baseline and day 180 increased with 11.8% in the test product group and 13.2% in the amorolfine group, which was statistically comparable. Both treatments resulted in significant ($p < 0.05$) improvement after 180 days (versus baseline) for nail dystrophy, discoloration, nail thickening, and healthy aspect but effects were more pronounced with the test product. Clinical performance was further confirmed by the frequency of patients with onychomycosis improvement or success at the end of the study: 96.0% (test product) versus 79.6% (amorolfine). Microbiological results and improved quality of life further confirmed clinical performance. Both treatments were well tolerated and appreciated for their properties and efficacy.

Conclusions: Clinical results confirmed clinical performance of daily acidification of the nail, as reflected by 1) a comparable increase of percentage of healthy nail surface following treatment with test product versus amorolfine, 2) the overall improvement of other onychomycosis-related parameters, 3) user convenience, and 4) absence of side effects. These data indicate that an aqueous, acetic acid-based,