ORIGINAL ARTICLE

An innovative water-soluble biopolymer improves efficacy of ciclopirox nail lacquer in the management of onychomycosis

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Abstract

Background A new 8% ciclopirox-medicated nail lacquer (P-3051), based on a new technology, revealed superior properties in terms of affinity to keratin, nail permeation, and ease of use.

Objective This study aims to assess the efficacy and safety of P-3051 vs. the market 8% ciclopirox nail lacquer.

Methods This is a multicentre, randomized, three-arm, placebo-controlled, parallel groups, evaluator-blinded study. Overall, 467 patients with onychomycosis of at least one big toenail were randomized to receive P-3051, the reference drug or placebo in a 2 : 2 : 1 ratio for a 48-week treatment by daily application, followed by a 12-week follow-up.

Results The study satisfied its objective by demonstrating that P-3051 was both superior to placebo and non-inferior to reference in the complete cure rate after a 48-week active treatment period. Switching the non-inferiority to superiority hypothesis, the superiority of P-3051 vs. reference was nearly significant at week 48 (confirmed at week 52), and it was significant at week 60 (cure rate for P-3051 is 119% higher than reference; $P < 0.05$). Altogether, the results on primary endpoint exceed expectations; superiority test was performed also on secondary endpoints to confirm the superiority trend of the study. At the end of follow-up, percentages of patients who achieved the endpoint 'responder' in the P-3051 group were 66% higher than reference ($P < 0.05$), and those who achieved the endpoint 'decrease of diseased nail' were 40% higher ($P < 0.05$).

Conclusion Ciclopirox 8% hydrolacquer is more active than reference ciclopirox nail lacquer in the treatment of onychomycosis.

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Keywords

ciclopirox, hydroxypropyl chitosan, onychomycosis, water-soluble nail lacquer

Conflicts of interest

None declared.

Introduction

An original technology was developed by Polichem SA (Lugano, Switzerland) for delivery of actives to nails, based on hydroxypropyl chitosan (HPCH), a water-soluble semisynthetic biopolymer, which acts as a film-forming agent. A new 8% ciclopirox nail hydrolacquer (P-3051) based on this new technology revealed superior properties in terms of affinity to keratin, nail permeation, and ease of use.[1–3] In *in vitro* studies, it strengthened the efficacy of antimycotic agents.[3] In long-term treatment, it is expected to be acceptable to patients because of its simple (water rinsing) removal procedure and because it does not need nail filing.

The drug tested in this study, P-3051, is a new hydrolacquer based on hydroxypropyl chitosan technology, which contains 8% ciclopirox as the sole active compound. The content of active principle within the formulation is quantitatively identical to that of the market reference nail varnish formulation (Penlac® in the USA, corresponding to Batrafen® or Mycoster® in Europe). The main difference is the solubility in water of the film-forming agent