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Pharmacodynamic of P-3074 (finasteride 0.25% topical solution) in subjects with androgenetic alopecia

M Caserini[1], R Palmieri[1], M Radicioni[2] and E Terragni[2] [1]*Polichem S.A., Lugano, Switzerland and* [2]*Cross Research S.A., Arzo, Switzerland*

A new proprietary topical formulation, P-3074, containing finasteride 0.25% as active ingredient and hydroxypropyl-chitosan (HPCH) as film-forming agent, was developed for androgenetic alopecia. The present study was aimed at investigating the pharmacodynamic profile of finasteride in terms of dihydrotestosterone (DHT) concentrations in the scalp and in serum after multiple topical application of P-3074 or oral finasteride intake in subjects with androgenetic alopecia. Eighteen healthy men were randomly allocated to P-3074 or oral treatment after providing written informed consent. Twelve volunteers applied P-3074 topical solution for 7 days: six subjects once daily (o.d.) in the morning and the others twice daily (b.i.d.) in the morning and in the evening. The third group of six volunteers was administered 1 mg oral finasteride once daily in the morning for 1 week. Scalp (vertex) biopsies were collected at baseline and 6 hours after last dose administration, while serum samples were collected at baseline, before last administration, and 6 and 12 hours after the last multiple dose. A marked decrease in scalp DHT levels was observed: by 47.22% with P-3074 b.i.d., from 1.91 (±0.54) to 1.01 ng ml^{-1} (±0.39), by 71.20% with P-3074 o.d., from 1.52 (±0.41) to 0.44 ng ml^{-1} (±0.08), and by 51.11% with the oral formulation, from 1.39 (±0.25) to 0.68 ng ml^{-1} (±0.34). Serum DHT was reduced by 69.3–74.0% with P-3074 b.i.d., 67.6–80.4% with P-3074 o.d., and 69.7–76.1% with the oral formulation. These results showed a similar inhibition of serum DHT after 1 week of finasteride administration with the three dose regimens and were consistent with the results obtained in a previous P-3074 PK study. These findings show that DHT concentration in the scalp, after 7-day treatment course of P-3074 o.d., was more reduced (about 40%) than after 1 mg oral finasteride administration for the same treatment period.