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n-Docosanol Cream Is An Effective Topical Treatment of Recurrent Herpes Labialis. DAVID H. KATZ*, LIDAK Pharmaceuticals, La Jolla, CA, U.S.A, L. HABBEMA, Academisch Ziekenhuis Rotterdam Dijkzigt, Rotterdam, The Netherlands, K. DE BOULLE, Aalst, Belgium, G.A. RODERS, Brocades Pharma BV, Leiderdorp, The Netherlands.

n-Docosanol (trade-named LIDAKOL™), a 22 carbon-long saturated alcohol, has been shown to exert antiviral activity against herpes simplex virus and certain other lipid-enveloped viruses in tissue culture and animal studies. A recent study was conducted in the Netherlands and Belgium to examine the drug's clinical efficacy in a randomized, double-blind comparison between 10% *n*-docosanol cream and its corresponding vehicle placebo in 65 patients suffering from recurrent herpes labialis. The patients were instructed to self-initiate treatment with either *n*-Docosanol or placebo upon awareness of prodromal or other early symptoms of a herpetic outbreak. Patients were examined by investigator clinicians within 24 hours of initial application of test cream and were followed until lesions were completely healed. The study was designed around two major endpoints based on when treatment was initiated: **Early** treatment (i.e. initiated during the prodrome or erythema stage) was analyzed for effectiveness in aborting further evolution of an outbreak as well as for reduction of overall healing time. **Late** treatment (initiated at the papule stage or later) was scored for effects on overall healing time.

A total of 98 herpes episodes (48 treated with *n*-docosanol; 50 with placebo) were evaluated in the study. Included in this total were 22 "cross-over" treatment episodes (i.e. second outbreaks in the same patient who was then treated with the opposite test cream). In 20 early treatment episodes (n-docosonal = 13; placebo = 7), treatment with *n*-docosanol aborted further evolution of herpetic episodes in 70% (9/13) of such patients compared to around 25% (2/7) in the placebo group.

Moreover, in this early treatment cohort, a significantly reduced mean healing time resulted from treatment with *n*-docosanol (*n*-docosanol = 3.4 days; placebo = 6.6 days; $P = 0.05$). Combining the data from all treatment cohorts also resulted in a statistically significant ($P = 0.02$) reduction in mean overall healing time in *n*-docosanol-treated (5.7 days) versus placebo-treated (7.3 days) patients. In comparing effectiveness of early treatment with *n*-docosanol vs. all other treatment modalities, the difference was highly significant ($P = 0.0002$).

These studies suggest that *n*-docosanol is a promising new drug for the topical treatment of recurrent herpes labialis, and is particularly effective in significantly limiting both the progression and duration of an outbreak when applied at the early stages of symptoms. Further studies are being conducted to expand and verify these findings.