

Abstract of Our Published Clinical Study Results

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Topical treatment for acute phase Peyronie's disease utilizing a new gel, H-100: a randomized, prospective, placebo-controlled pilot study.

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Abstract

Safety and efficacy of topically applied gel H100™ composed of Nicardipine, superoxide dismutase and emu oil for treatment of acute phase Peyronie's disease (PD) was evaluated. Twenty-two patients (PD <12 months duration) were studied in a prospective, randomized, double-blind, placebo-controlled study. Eleven patients received H100™ and 11 patients received placebo for 3 months. All 22 patients then received H100™ for the final 3 months. Flaccid-stretched penile length, degree of penile curvature, pain level and side effects were assessed monthly. H100™ showed significant improvement in all PD parameters at 6 months: mean stretched penile length increase (22.6%, $P=0.0002$), mean curvature reduction (40.8%, $P=0.0014$), and mean pain level reduction (85.7%, $P=0.004$). Placebo group showed no significant improvement except for mean stretched penile length increase (6.8%, $P=0.009$). Crossover patients from placebo to H-100 showed significant improvement in all parameters: mean stretched penile length increase (17.5%, $P=0.000007$), mean curvature reduction (37.1%, $P=0.006$), and mean pain level reduction (40%, $P=0.17$). Treatment was well tolerated. A self-limited rash was the only side effect in three patients. Statistically significant improvements in flaccid-stretched penile length, curvature and pain suggest that H100™ is a safe and possibly effective non-invasive, topically applied treatment for acute phase Peyronie's Disease.

The study size was relatively small, but its design was done under the guidance of Dr. Larry Levine, a world expert in Peyronie's Disease. Due to H100™'s mechanism of action, the study only included acute phase patients with developing disease.

Based on our study, maximum benefit was seen after six months of treatment with H100™, though many patients noted improvement after three months of treatment. (1)

A skin rash in the area of application is the only known side effect or adverse reaction in about 10% of patients with H100™ use.

No compounded medication is reviewed by the FDA for safety and efficacy.

Important Note: H100™ gel is only meant to be applied topically as directed for treatment of Peyronie's disease. It is not intended for any other use. Do NOT take it

orally, by injection or through any other method of delivery. For best results, always follow prescribing directions carefully.

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