

Comparing Epionce® & Prevenge® MD

Clinical Assessment Results (Presented at 2008 AAD Annual Meeting Poster Exhibit No. P915)

INTRODUCTION

Epionce Intensive Nourishing Cream (INC) optimizes cutaneous permeability function and safely reverses chronic inflammation with mechanisms of action that differ from the Epionce Renewal product line. Intensive Nourishing Cream contains low concentrations of a modified prescription compound azelaic acid, which is comedolytic, anti-inflammatory, anti-dysplastic and broad spectrum anti-microbial. It also delivers ursolic acid, which aligns collagen and elastin fibers to reverse solar elastosis. Intensive Nourishing Cream has two peptides to stimulate cutaneous fibroblast synthesis of ceramide and cholesterol.

METHOD

A 12-week prospective controlled clinical trial of 10 middle-aged Caucasian and Hispanic women with photoaging grades II and III assessed reversal of extrinsic aging parameters with Epionce Intensive Nourishing Cream compared with Prevenge MD (Idebenone 1.0%) (PMD). This double-blind, split-face clinical trial was conducted by a nationally prominent contract research organization. Both Epionce Intensive Nourishing Cream and Prevenge MD were applied twice daily. In addition to the 6 major clinical parameters of extrinsic aging, reversal of dermal abnormalities were assessed by elasticity and recoil by an elastometer. Treatment of visible actinic keratoses and safety were also assessed.

RESULTS

The most important parameters for overall health of the skin include shallow wrinkles, laxity and dermal measurements. INC achieved statistically significant improvement ($p < 0.05$) over PMD and baseline for shallow wrinkles at both 6 and 12 weeks. INC also produced a trend toward statistically significant improvement ($p < 0.10$) of tactile roughness at both time points. INC also produced significant improvements ($p < 0.05$) compared to baseline of laxity and dyschromia with twice the improvement over PMD at 6 weeks. INC induced significant improvements in fine lines and clarity at 6 weeks. These improvements remained through 12 weeks. PMD produced no measurable dermal effects by elastometer. Conversely, INC produced a significant ($p < 0.05$) decrease in extensibility and increased in record which indicate improved dermal matrix. Results are shown in Tables 1 and 2.

Visible actinic keratoses responded to INC with complete resolution of 4 of 16 lesions with another 11 partially resolving; one had no response. PMD had no effect on 6 of 14, partial resolution of 7, but complete resolution of only one actinic keratosis. PMD induced mild to severe contact dermatitis in 27% of the panelists, with one panelist dropping out due to diffuse spreading of a rash. No INC panelists experienced reactions. This study strongly indicates the concept of barrier optimization and resolution of inflammation improves skin health to a much great degree than a potent anti-oxidant.

Comparing Epionce & Prevenge MD, cont.

Table 1 - Comparison of INC and PMD vs. Baseline

Clinical Parameter	Epionce Intensive Nourishing Cream (INC)				Prevenge MD (PMD)			
	Week 6		Week 12		Week 6		Week 12	
	%Δ	p value	%Δ	p value	%Δ	p value	%Δ	p value
Shallow Wrinkles	26.1	0.005*	31.3	0.005*	9.4	0.056**	9.9	0.044*
Tactile Roughness	40.6	0.001*	60.6	0.001*	28.8	0.006*	45.9	0.004*
Laxity	10.0	0.032*	18.4	0.006*	5.3	0.168	18.6	0.021*
Dyschromia	12.2	0.010*	8.9	0.246*	6.2	0.052**	9.4	0.132
Fine Line	7.5	0.022*	12.0	0.01*	8.6	0.121	12.1	0.04*
Clarity	34.9	--	47.6	--	28.1	--	42.2	--

% Δ = percent change from baseline * = stat. sig p value ($p < 0.05$) vs. baseline ** = trend of stat. sig ($p < 0.10$)

Table 2 - Comparison of INC vs. PMD

Clinical Parameter	Week 6	Week 12
	p value	
Shallow Wrinkles	INC p = 0.047*	INC p = 0.025*
Tactile Roughness	INC p = 0.09**	INC p = 0.09**
Laxity, Dyschromia, Fine Lines, Clarity	NS	NS

* stat. sig p value ($p < 0.05$) vs. baseline; ** trend of stat. sig ($p < 0.10$); NS (Not Significant)