

Epionce Lytic Lotion and Lite Lytic Lotion Visibly Reduce Actinic Keratoses

Abstract

According to an independent, 16 week double-blind, controlled clinical study, visible facial non-hypertrophic actinic keratoses, not involving the nose, were reduced in severity by 75.5% while 61.9% completely resolved after daily use of Epionce® Lite Lytic Lotion and Lytic Lotion. No contact irritation, reaction or symptoms occurred during the trial period.

Introduction

Actinic keratoses (AKs) have been considered the precursor lesions of squamous cell carcinoma (SQCC), but have recently been reclassified as intraepithelial SQCC.¹ Although AKs are most commonly treated with destructive cryotherapy, several topical chemotherapeutic products have been introduced in the last three years. All but one induced a severe symptomatic transient inflammatory response, which limits physician prescribing and patient compliance. The Federal Drug Administration (FDA) approved Diclofenac (Solarz™) in the past two years for AK therapy. The mechanism is purely anti-inflammatory.

This summary details a prospective, controlled clinical trial using marketed cosmeceutical products to visibly reduce the severity and number of nonhypertrophic facial AKs. Epionce Lite Lytic and Lytic Lotions prevent the release and activation of proinflammatory factors in addition to dissolving scales and excessive stratum corneum without inducing an inflammatory reaction or symptoms. These two cosmeceuticals consist of blends of novel botanical extracts formulated in an elegant emollient base which contains delivery systems to maximize efficacy and minimize the risk of adverse reactions.

Patients

After signing an informed consent document, seven panelists with Fitzpatrick photo skin type I-III of ages 65-85 were enrolled. Panelists with primary or secondary facial dermatitis were excluded. Treatment consisted of a morning application of Epionce Lite Lytic Lotion and an Epionce Lytic Lotion evening application, for 16 weeks. Panelists did not apply sunscreen or other moisturizers during the trial, nor were they allowed to use systemic anti-inflammatory and chemotherapeutic medications.

Method

The number and severity of facial AKs were assessed by board certified dermatologist investigators. Indurated and/or hyperkeratotic lesions were treated by destructive surgery. Lesions on the nose and ears were not evaluated. Severity was assessed by the amount of scaling, erythema, lesional size and presence of symptoms with 0=none and 10=severe. Assessment occurred at time 0, week 8 and week 16.

The mean values of clinical severity of the lesions and the number of visible lesions were statistically compared to baseline using a paired t-test at the p=0.05 significance level. After cleansing with a non-medicated cleanser, the panelists applied a dime-sized amount over the entire face, sparing the upper eyelid. Development of a visible inflammatory reaction and symptoms during therapy were also documented at the follow-up visits.

Results

These novel cosmeceuticals produced statistically significant complete resolution of 61.9% of AKs (p=0.018) and a 75.5% reduction in lesional severity (p=0.003), a very statistically significant change. Statistically significant similar results, but with lower raw scores, were also documented at 8 week as exemplified in Table 1.

Discussion

The lifetime risk of conversion of an AK into squamous cell carcinoma is 6-10%, although 25% spontaneously remit.²⁻⁴ The incidence of AKs is increasing and is about 15-fold more common than non-melanoma skin cancer.¹ The latter now afflicts over 1 million Americans annually.⁵ Regular sunscreen use with a sun protection factor (SPF) of 17 and 29 have both been documented to reduce the number of AKs.^{6,7} Patient compliance with sunscreens is not as high as the dermatology community would like to see.

This blinded, prospective, controlled clinical study documented that novel marketed cosmeceuticals containing unique blends of botanicals and a naturally derived modified salicylate, in an emollient base, appear to effectively reduce the number and severity of visible actinic keratoses after 8 weeks of use. The mechanism of action of these products is keratolysis with prevention of release and binding of proinflammatory factors in the skin. The Epionce cosmeceuticals do not contain teas, soy, retinoids, vitamins, alpha hydroxy acids or traditional antioxidants. This clinical study strongly suggests that an Epionce skin care regimen can be expected to significantly reduce the incidence of actinic keratoses to an even greater extent if the patient adheres to the American Academy of Dermatology guidelines of daily use of an SPF 15 or higher sunscreen. Skin care regimens with this effectiveness are necessary to help stem the tide of the skin cancer epidemic.

References

1. Miller S, Moresi JM. Actinic Keratosis, Basal Cell Carcinoma and Squamous Cell Carcinoma. In: Bologna JL, Jorizzo JL, Rapini RP, (eds.) Dermatology. London: Mosby; 2003; 109:1676-94.
2. Glogau RG. The risk of progression to invasive disease. *J Am Acad Dermatol.* 2000; 42:523-4.
3. Marks R, Foley P, Goodman G, Hage BG, Selwood TS. Spontaneous remission of solar keratoses. *Br J Dermatol.* 1986;115:655.
4. Salache SJ. Epidemiology of actinic keratoses and squamous cell carcinoma. *J Am Acad Dermatol.* 2000; 42:54-7.
5. Greenlee RT, Hill-Harmon MB, Murray T, Thun M. Cancer Statistics 2001. *CA Cancer.* 2001; 51:15-36.
6. Naylor MF, Boyd A, Smith DW, et al. High sun protection factor (SPF) sunscreens in the suppression of actinic neoplasia. *Arch Dermatol.* 1995; 131: 120-5.
7. Thompson SC, Jolley D, Marks R. Reduction of solar keratoses by regular sunscreen use. *N Eng J Med.* 1993; 329:1147-51.

Table 1 - Clinical Severity and Lesion Counts

	Baseline	8 weeks		12 weeks	
		%Δ	p value	%Δ	p value
Severity	3.36	-51.5	0.006	-75.5	0.003
Lesion	3.71	-39.9	0.018	-61.9	0.018