

**Evaluation of the Efficacy and Safety of
Diclofenac Sodium 3% Gel in the Treatment of
AK Lesions Post Cryosurgery: Prospective,
Double-Arm, Multi-Center, Open Label,
Phase IV Study**

Lead Investigators:

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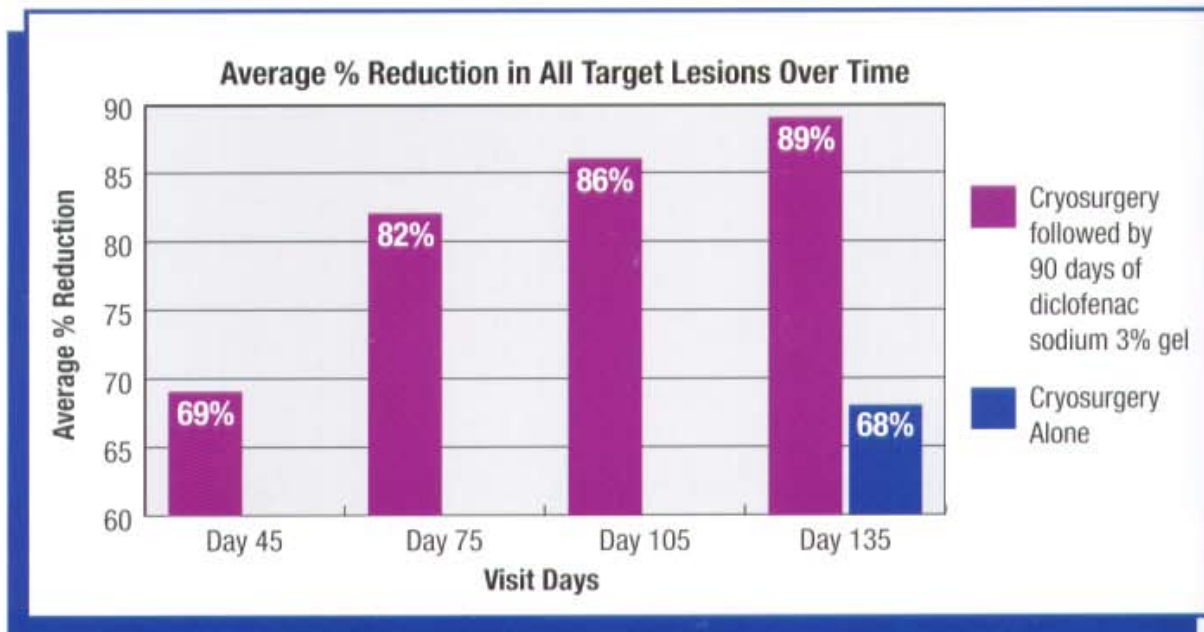
Rx Only
SOLARAZE[®] GEL
Diclofenac Sodium-3%

TREAT THE FIELD

New Multi-Center Study Proves That Cryosurgery Followed by SOLARAZE® Gel (diclofenac sodium-3%) is More Effective than Cryosurgery Alone

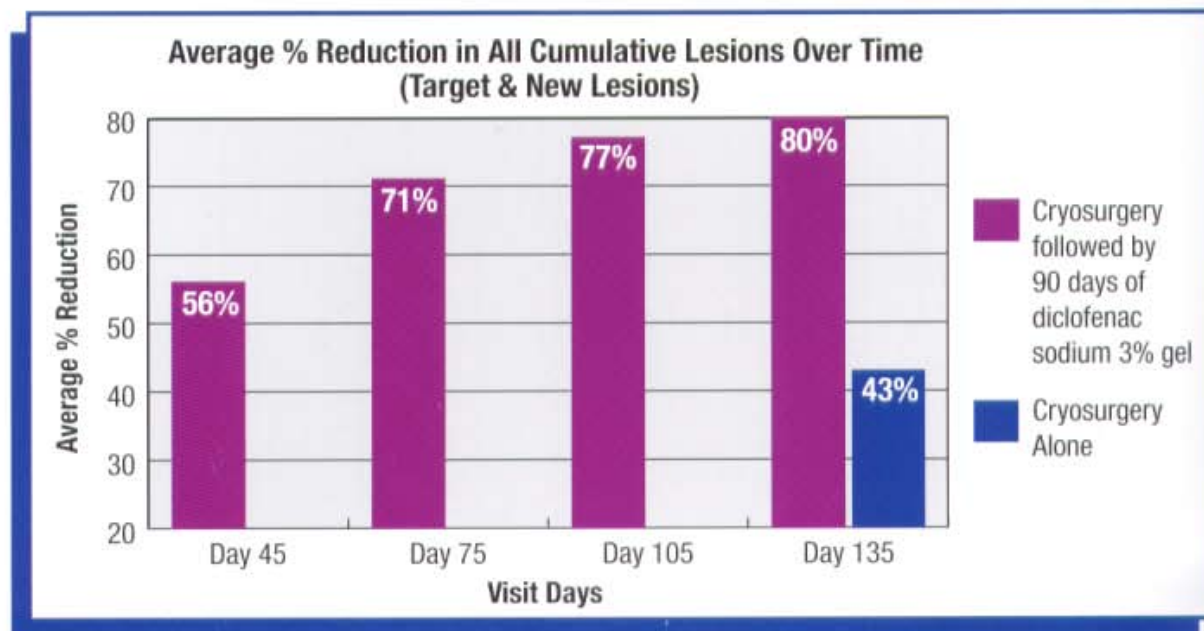
89% clearance of all target lesions

over time with cryosurgery followed by SOLARAZE® Gel vs. 68% with cryosurgery alone



80% clearance of all cumulative lesions

over time with cryosurgery followed by SOLARAZE® Gel vs. 43% with cryosurgery alone



SUN AVOIDANCE IS INDICATED DURING SOLARAZE® Gel THERAPY. As with other NSAIDs, anaphylactoid reactions may occur in patients without prior exposure to diclofenac. Diclofenac sodium should be given with caution to patients with the aspirin triad. In clinical trials, the most common adverse reactions involved the skin, and included contact dermatitis, rash, dry skin and exfoliation. The majority of these reactions were mild to moderate, and resolved upon discontinuation of therapy. SOLARAZE® Gel should not be applied to open skin wounds, infections, or exfoliative dermatitis. Please see full Prescribing Information enclosed.

Before[†]



After[†]



[†] Photographs are unretouched images of the same patient depicting results achieved after cryosurgery with two weeks healing, followed by 90 day treatment with SOLARAZE[®] Gel. Individual results may vary.

SOLARAZE[®] Gel is indicated for the topical treatment of actinic keratosis (AK).

SUMMARY POSTER PRESENTED
The American Academy of Dermatology
Washington, D.C., February 2007

STUDY CONCLUSIONS

- Sequential treatment of SOLARAZE® Gel post cryosurgery is more effective than cryosurgery alone

89% clearance of all target lesions

over time with cryosurgery followed by SOLARAZE® Gel vs. 68% with cryosurgery alone

80% clearance of all cumulative lesions

over time with cryosurgery followed by SOLARAZE® Gel vs. 43% with cryosurgery alone

- The SOLARAZE® Gel safety profile demonstrated in this study is similar to the safety data reported in previous studies*

STUDY DESIGN

Multi-Center, Open Label, Phase IV, Prospective, Double-Arm Study

- 714 patients diagnosed with one or more AK lesions were enrolled in 82 centers throughout the USA
- 521 patients were evaluated—244 received Solaraze® Gel post cryosurgery and 277 received cryosurgery alone
- The Solaraze® Gel following cryosurgery group started treatment 15 days after cryosurgery and applied it twice daily for 90 days

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SOLARAZE® GEL
Diclofenac Sodium-3%



* A total of 52 adverse events (10%) were reported in the study. 48 occurred in the cryosurgery followed by diclofenac sodium 3% gel arm. 36 were reported as product related: contact dermatitis (19), redness & itching (5), irritation (5), pain/burning sensation (5), dry skin (2). 18 events were reported as severe, 12 as moderate, 4 as mild, and intensity was not reported for 2.

This study was funded through a grant provided by Doak Dermatologics, a subsidiary of Bradley Pharmaceuticals, Inc.

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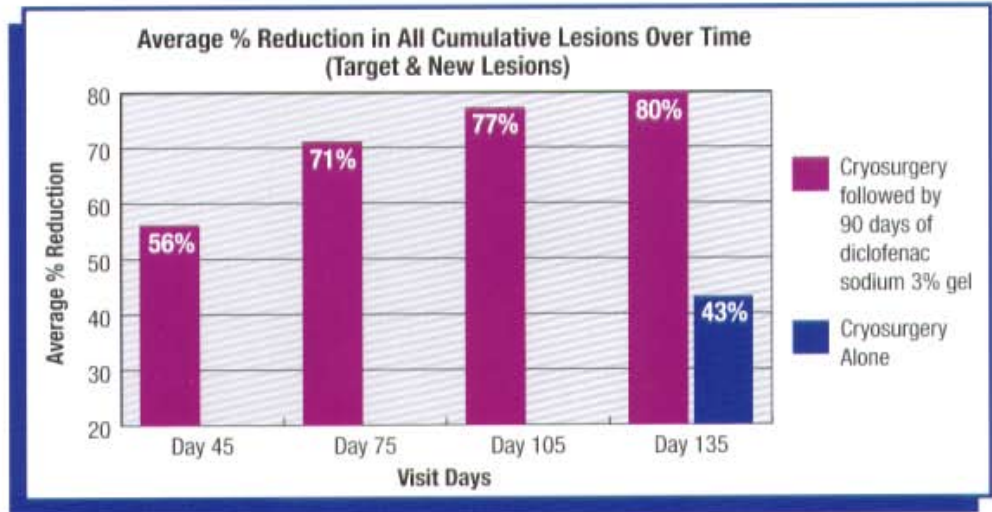


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Study Proves Cryosurgery Followed by 90 Days of Treatment with SOLARAZE® Gel is More Effective than Cryosurgery Alone

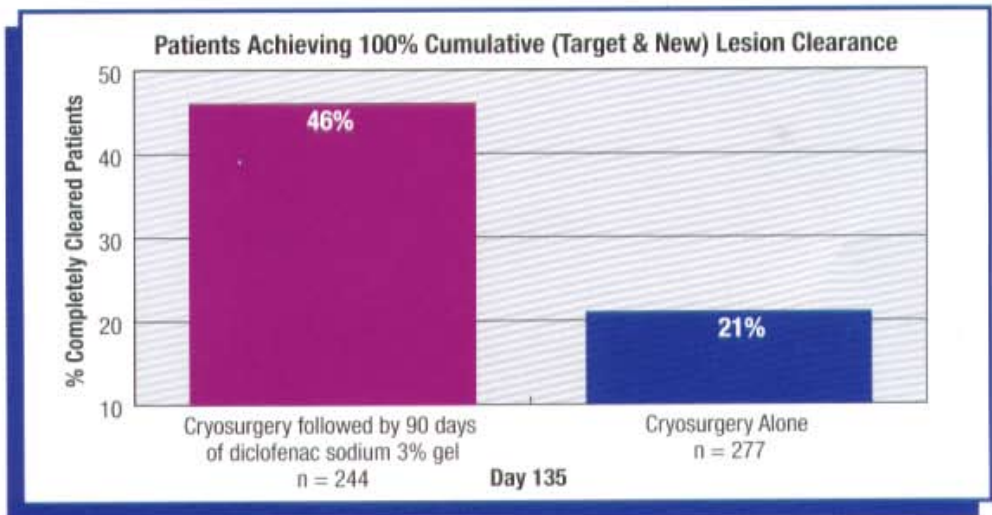
80% clearance of all cumulative lesions

over time with cryosurgery followed by 90 days of treatment with SOLARAZE® Gel vs. 43% with cryosurgery alone



46% of patients

treated with cryosurgery followed by 90 days of treatment with SOLARAZE® Gel achieved 100% cumulative lesion clearance



SOLARAZE® Gel is indicated for the topical treatment of actinic keratoses (AK).

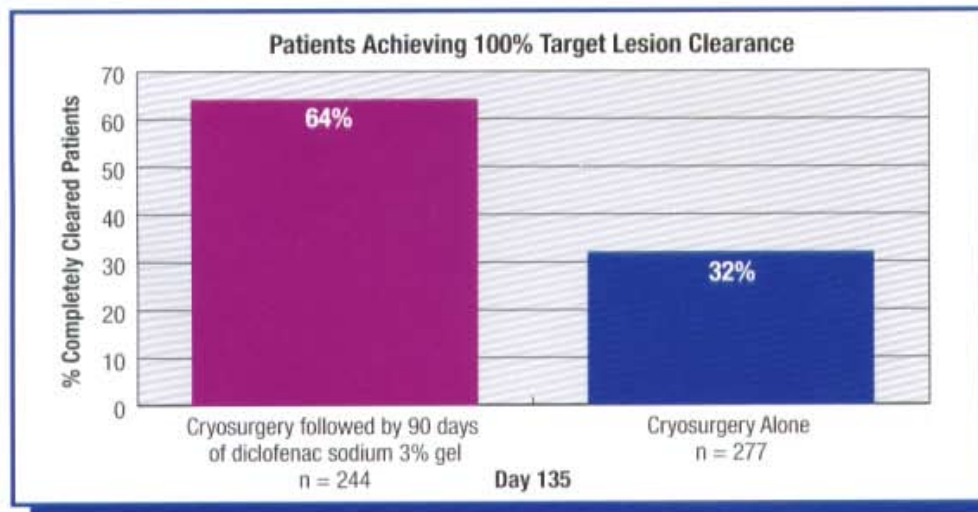
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powered by ^{Rx Only} **SOLARAZE® GEL**
Diclofenac Sodium-3%

Cryosurgery Alone



89% clearance of all target lesions over time with cryosurgery followed by 90 days of treatment with SOLARAZE® Gel vs. 68% with cryosurgery alone



64% of patients treated with cryosurgery followed by 90 days of treatment with SOLARAZE® Gel achieved 100% target lesion clearance

patients without prior exposure to diclofenac. Diclofenac sodium should be given with caution to patients with the aspirin triad. The majority of these reactions were mild to moderate, and resolved upon discontinuation of therapy. SOLARAZE® Gel