

New drug now available for actinic keratosis

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A new topical gel now available by prescription significantly decreases the amount of time needed to treat actinic keratosis, a skin condition that is a common precursor to skin cancer, according to a multi-center trial led by researchers at Mount Sinai School of Medicine. The gel, called ingenol mebutate, is applied to the skin for just a few days, making it quicker and even more effective as current therapies require weeks to months to apply. The Phase III study results of the trial are published in the March 15, 2012 issue of the *The New England Journal of Medicine*.

Actinic keratoses are premalignant skin lesions very common in fair-skinned individuals who always burn and rarely tan. It is the most common precursor to sun-related squamous-cell carcinoma, the second most common type of [skin cancer](#).

Current [topical medications](#) to treat actinic keratosis often causes [skin irritation](#) and result in many patients not completing the full [treatment regimen](#). Topical gels are used as an alternative treatment to cryosurgery, a method of freezing lesions using [liquid nitrogen](#) as the cooling solution, to destroy the precancerous skin lesions. Cryosurgery is the most common form of treatment, but is only practical in treating areas with single lesions, not multiple lesions.

"The shorter application period is what makes ingenol mebutate a breakthrough in the treatment of actinic keratosis," said Mark Lebwohl, MD, lead study author and Professor and Chair of the Department of Dermatology at Mount Sinai School of Medicine. "Many patients find it difficult to stick with the current regimen. The shorter period is a more effective option for patients who don't want a treatment that interferes with their everyday lives for weeks or even months."

Ingenol mebutate is derived from the active ingredient in the sap of the plant *Euphorbia peplus*, which has long been used as a traditional remedy for common skin lesions. The study found patients require just two to three days of application with results comparable or improved to rates of current

actinic keratosis clearance. The shorter treatment period also results in 98 percent of patients completing the full treatment regimen.

Researchers studied two cohorts; 547 patients with actinic keratoses on the face or scalp and 458 patients with actinic keratoses on the trunk or extremities. About half of each group received ingenol mebutate with the other half receiving a placebo. The first group applied treatment at a .015 percent concentration for three days and the second at a .05 percent concentration for two days. At the end of the evaluation period, 42 percent of the first group that received ingenol mebutate and 34 percent of the second group showed complete clearance of actinic keratosis, compared to about 4 and 5 percent, respectively, of the placebo groups.

The approval of ingenol mebutate was announced at the 2012 The American Academy of Dermatology's Annual Meeting and is currently available for prescription under the name Picato®.

Provided by The Mount Sinai Hospital

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