

New Study Confirms Long-Term Benefits for Common, Precancerous Skin Condition Affecting 10 Million Americans; Good News for Those Who Have Spent a Lot of Time in the Sun

A new study published in the June issue of *Dermatologic Surgery* offers good news for those who have spent a lifetime in the sun. Led by an investigator at the University of Minnesota, the study showed prescription Aldara (imiquimod) cream, 5% delivers long-term treatment benefits for the treatment of a precancerous skin condition known as actinic keratosis or AK. According to the American Academy of Dermatology, more than 10 million Americans suffer from AK, which typically appears as rough, red, scaly patches on the skin. AK has the potential to develop into squamous cell carcinoma (SCC), the second leading cause of death from skin cancer in the United States.

The study results confirm Aldara cream is effective in lowering the chance of AK from reappearing in the previously treated area. In fact, a majority of patients (nearly 75 percent) treated with Aldara cream three times a week, and nearly 60 percent treated two times per week, remained completely clear of AK for 12 to 18 months after initial treatment. These results are significant for patients because AK treatment and management is a lifelong process, due to the extensive sun damage that accumulates over a lifetime. Because Aldara cream reduces the number and frequency of new or recurrent AK, an additional benefit may be a decreased number of physician visits and treatments needed for this potentially serious condition.

"These results validate the importance of treating AK with the future in mind. We know that those who have had AK lesions have a much higher chance of developing other ones, and Aldara cream gives AK patients a treatment option with long-term benefits," said Dr. Peter K. Lee, Department of Dermatology, University of Minnesota.

Many Americans understand the harmful effects of sun exposure; however, according to a recent national survey conducted by Harris Interactive, they still lack awareness of AK. The survey found that only one in five people had heard of AK (or actinic keratosis), and of those who had heard of AK, many (61 percent) were not familiar with the characteristics associated with the condition.

About Aldara Cream

Early last year, the U.S. Food and Drug Administration approved Aldara cream as a topical prescription for treatment of certain types (clinically typical, nonhyperkeratotic, nonhypertrophic) of AK on the face or scalp dosed two times a week. Aldara cream also is approved for treatment five times a week of biopsy-confirmed, primary superficial basal cell carcinoma (sBCC), a type of nonmelanoma skin cancer. The first immune response modifier (IRM) approved for AK, Aldara cream works with the body to stimulate the skin's immune response to reveal and clear visible and previously undetectable AK lesions.

In AK clinical studies, the most common side effects involved skin reactions in the application area. These included redness, swelling, erosions, weeping, scabbing, itching and burning. Most skin reactions were rated mild to moderate.

In sBCC clinical studies, the most frequently reported adverse reactions were local skin reactions, including flaking/scaling, induration, edema, erythema, scabbing/crusting, erosion, and itching and burning at the application site. These local skin reactions generally decrease in intensity or resolve after cessation of Aldara cream therapy. Overall, only 2 percent of patients discontinued therapy due to local skin/application-site

reactions.

Exposure to sunlight (including sunlamps) should be avoided or minimized during use of Aldara cream because of concern for heightened sunburn susceptibility. Patients should be warned to use protective clothing (hat) when using Aldara cream.

About Actinic Keratosis

Actinic keratosis appears as rough, red, scaly patches or crusts on the skin. AK lesions usually measure less than one-quarter inch in diameter and more than 80 percent of lesions occur on the upper limbs, head and neck. Individuals with fair skin, light hair and light-colored eyes are at greatest risk for AK. Because AK is caused by a lifetime of sun exposure, it can take years to develop. The condition usually appears first in older people, although cases have been reported in people in their 40s.

Common AK treatments include cryotherapy (freezing), excisional surgery, electrodesiccation (burning) and curettage, lasers, topical chemotherapy and photodynamic therapy.

About Superficial Basal Cell Carcinoma

According to the American Cancer Society, more than 1 million new cases of nonmelanoma skin cancer occur in the United States each year. Basal cell carcinoma (BCC) affects an estimated 800,000 Americans each year, and there are four types of BCC comprised of superficial, nodular, pigmented, ulcerating or sclerosing types.

Individuals with fair skin, blond or red hair and blue or green eyes, and those living in sunny climates are at the greatest risk for developing sBCC. Usually, sBCC develops on sun-exposed areas of the body. Superficial BCC can appear as red, finely wrinkled, scaly patches that occasionally have a fine, pearly border.

Common treatments for sBCC include surgical excision, cryosurgery (freezing), curettage (scraping) and electrodesiccation (burning).

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About the Survey

This online survey was conducted in the U.S. between March 22 and 25, 2005, among a nationwide cross section of 1,041 adults (aged 45 or over). Figures for age, sex, race/ethnicity, education, income and region were weighted where necessary to align with population proportions. Propensity score weighting was also used to adjust for respondents' propensity to be online. Though this online sample is not a probability sample, in theory, with probability samples of this size, one could say with 95 percent certainty that the results have a sampling error of plus or minus 3 percentage points for the overall sample.

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