

## Actinic Keratoses Fact Sheet

More than 58 million Americans have actinic keratoses (AKs).<sup>1</sup> AKs have the potential to progress to squamous cell carcinoma (SCC), the second most common skin cancer. While most AKs remain benign, approximately 10 percent develop into SCC within an average of two years.<sup>2</sup> Since there is no way to know ahead of time which ones will become cancerous, it is very important to seek a dermatologist's care. Frequent skin examinations are the key to early detection and prevention.

### What are Actinic Keratoses (AKs)?

AKs – often called “sun spots”— are rough-textured, dry, scaly patches on the skin caused by excessive exposure to ultraviolet light (UV) such as sunlight. They occur most often on the face, scalp, ears, neck, hands and arms and can range in color from skin toned to reddish brown. They can be as small as a pinhead or larger than a quarter.

### What do AKs look like?



Actinic Keratoses generally begin as rough spots of skin that may be easier felt than seen. Common complaints include a lesion that has increased in size or one that is raised, bleeding, poor in healing, discolored, or associated with discomfort such as pain or itching.

While a lesion may initially appear skin colored to pink, red, or brown, lesions on darker skin may be more pigmented. AKs may feel soft, rough, or “gritty,” but in any case, they feel different from the surrounding healthy skin. Since there are many clinical variants of AKs, it is best to consult a dermatologist if you suspect a lesion.

### **Who gets AKs?**

AKs are seen primarily in Caucasians with pale skin living in sunny climates. Areas of the skin with the most sun exposure, such as the head, neck, forearms, and hands account for more than 80 percent of AKs.

Actinic Keratoses develop as the result of years of sun exposure. Because the effect of sun exposure is cumulative, it is your lifetime exposure that increases your risk. Even if you didn't suntan much, years of just doing simple tasks outside can add up to significant amount of sun exposures. For example:

- Going out to the mailbox
- Playing an outdoor sport
- Walking the dog

Because AKs take a long time to develop, they generally appear after the age of 40. The American Academy of Dermatology estimates that 60 percent of persons apt to get Actinic Keratoses will indeed get at least one AK in their lifetime. Your risk of developing AKs increases if you have one or more of the risk factors.

### **What are some of the risk factors?**

- A history of cumulative sun exposure
- Fair skin
- Blond or red hair, in particular if combined with blue, hazel or green eyes
- A tendency to freckle or burn after sun exposure
- A weakened immune system

### **About DUSA Pharmaceuticals, Inc.**

DUSA is an integrated dermatology pharmaceutical company focused primarily on the development and marketing of its Levulan<sup>®</sup> PDT technology platform, and other dermatology products. Levulan<sup>®</sup> Kerastick<sup>®</sup> (aminolevulinic acid HCl) for Topical Solution, 20% in combination with DUSA's BLU-U<sup>®</sup> Blue Light Photodynamic Therapy Illuminator is currently approved for the treatment of minimally to moderately thick actinic keratoses (AKs) of the face or scalp. DUSA is based in Wilmington, MA.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or call 1-800-FDA-1088.

<sup>1</sup> American Academy of Dermatology. [www.aad.org](http://www.aad.org). Retrieved on 25 January 2008.

<sup>2</sup> Fuchs A, Marmur E. The Kinetics of Skin Cancer: Progression of Actinic Keratosis to Squamous Cell Carcinoma. *Dermatol Surg.* 2007;33:1099-1101.

## Levulan<sup>®</sup> PDT Fact Sheet

Levulan<sup>®</sup> Kerastick<sup>®</sup> (aminolevulinic acid HCl) for Topical Solution, 20% (Levulan Kerastick) plus blue light illumination using the BLU-U<sup>®</sup> Blue Light Photodynamic Therapy Illuminator (Levulan PDT) is indicated for the treatment of minimally to moderately thick actinic keratosis of the face or scalp. Actinic keratoses (AKs) are rough-textured, dry, scaly patches on the skin that can lead to skin cancer. Levulan PDT, a 2-part treatment, is unique because it uses a light activated drug therapy to destroy AKs.

So how does it work? Levulan Kerastick Topical Solution is applied to the AK. The solution is then absorbed by the AK cells where it is converted to a chemical that makes the cells extremely sensitive to light. When the AK cells are exposed to the BLU-U Blue Light Illuminator, a reaction occurs which destroys the AK cells.

Levulan PDT has a range of benefits that might be right for you. The 2-part treatment offers the following conveniences:

- No prescription to fill
- No daily medication to remember
- Treatment is administered by a qualified healthcare professional

The 2-part treatment can also fit your lifestyle:

- The 2-part, 2 office visit treatment is completed in a 24-hour period
- Low downtime\*
- Excellent cosmetic response<sup>1</sup>
- No scarring reported to date

\*Patients treated with Levulan PDT should avoid exposure of the photosensitized lesions to sunlight or prolonged or intense light for at least 40 hours.

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## **Important Risk Information**

### **What is Levulan Kerastick used for?**

The Levulan Kerastick for Topical Solution plus blue light illumination using the BLU-U Blue Light Photodynamic Therapy Illuminator is indicated for the treatment of minimally to moderately thick actinic keratoses of the face or scalp.

### **Who should NOT take Levulan?**

Levulan Kerastick should not be taken by patients who have cutaneous photosensitivity at wavelengths at 400-450 nm, porphyria, or known allergies to porphyrins, and in patients with known sensitivity to any of the components of the Levulan Kerastick for Topical Solution.

Levulan Kerastick has not been tested on patients with inherited or acquired coagulation defects. There have been no formal studies of the interaction of Levulan Kerastick for Topical Solution with any other drugs and no drug-specific interactions were noted during any of the controlled clinical trials. It is possible that concomitant use of other known photosensitizing agents might increase the photosensitivity reaction of actinic keratoses treated with the Levulan Kerastick. It is important to tell your physician if you are taking any oral medications or using any topical prescription or non-prescription products on your face or scalp. Tell your doctor if you are pregnant or nursing.

### **What are the possible side effects?**

The most common side effects include scaling/crusting, hypo/hyper-pigmentation, itching, stinging, and/or burning, erythema and edema. Severe stinging and/or burning at one or more lesions being treated was reported by at least 50% of patients at some time during the treatment.

### **What precautions should be taken?**

Patients should avoid exposure of the photosensitive treatment sites to sunlight or bright indoor light prior to and at least 40 hours after blue light treatment. Exposure may result in a stinging and/or burning sensation and may cause erythema or edema of the lesions. Sunscreens will not protect against photosensitivity reactions caused by visible light.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or call 1-800-FDA-1088.

<sup>1</sup>Data on file; DUSA Pharmaceuticals, Inc.®