

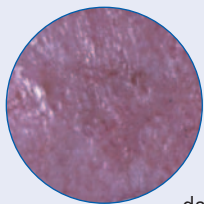
# actinic keratoses

aminolevulinic acid HCl

Your dermatologist is treating you with Levulan® Kerastick® (aminolevulinic acid HCl) for Topical Solution, 20%, which is part of a unique photodynamic therapy (PDT) system to treat your actinic keratoses (AKs). This brochure has been designed to help give you a better understanding of this unique system and how it is used. It will answer some of the most commonly asked questions about the Levulan PDT system, and about the importance of treating AKs promptly and effectively.

*If you have any further questions, be sure to ask your dermatologist.*

## **What are actinic keratoses?**



Actinic keratoses (AKs) are rough, scaly patches on the skin, caused by excessive exposure to the sun, that can sometimes progress into dangerous skin cancers. More than 5 million Americans live with these lesions, and far too many people ignore them, leaving them untreated. This can have serious consequences. Doctors estimate that 40% of squamous cell carcinomas, the second leading cause of skin cancer deaths in the United States, begin as

AKs. And without performing a skin biopsy, it can be almost impossible for a doctor to distinguish an AK from a squamous cell carcinoma.

*For this reason, 3 major medical groups— the American Cancer Society, The Skin Cancer Foundation, and the American Academy of Dermatology—all recommend that people with AKs seek treatment for them immediately.*

## **How do AKs become squamous cell carcinomas?**

AKs sometimes can become larger and thicker. Doctors call this “hyperkeratotic.” These enlarged lesions may then progress to squamous cell carcinomas. Patients may notice increased redness, tenderness, itching, and burning. However, these symptoms can be the same for either AKs or squamous cell carcinomas. This is what makes distinguishing between the two so difficult without a biopsy.

Left untreated, squamous cell carcinomas may become larger, go deeper into the skin, and eventually spread to other parts of the body. This results in thousands of skin cancer deaths each year, many of which could be prevented.

# actinic keratoses

## ***How likely are AKs to become squamous cell carcinomas?***

It is impossible to predict if an AK will evolve into a squamous cell carcinoma, or at which point it will happen.

Many doctors believe that AKs and squamous cell carcinomas are really the same condition at different stages of a continuing process. This process begins with minor cell damage and, over time, ultimately results in the cell becoming cancerous. These doctors believe that AKs occur in the early stages of the process; squamous cell carcinomas occur in the final stage.

One thing, however, is certain: a significant percentage of AKs develop into squamous cell carcinomas. Estimates range from 10% to as high as 20% over a 10-year period.

## ***Is there anything I can do to prevent AKs in the future?***

Long-term exposure to the sun is the single most significant cause of AKs, so the best defense against them is a comprehensive sun protection program. This includes wearing protective clothing and a wide-brimmed hat, avoiding the sun at midday when ultraviolet rays are strongest, staying in the shade as much as possible, and wearing a broad-spectrum sunscreen with a sun protection factor (SPF) of at least 15.

## **Levulan® Kerastick®**

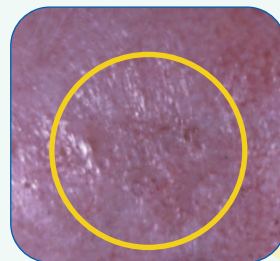
(aminolevulinic acid HCl) for Topical Solution, 20%

## ***What is the Levulan PDT system?***

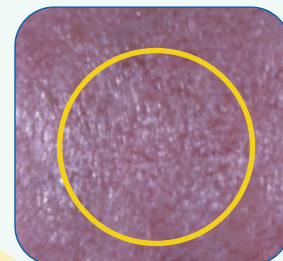
The Levulan PDT system is an advanced 2-step treatment for minimally to moderately thick AKs (AKs that have not yet become enlarged and thick) of the face or scalp. The system is unique because it's the only one that uses light to destroy AKs.

## ***How effective is it?***

The Levulan PDT system has been proven effective in clinical testing. Eight weeks after treatment, it had *cleared 100% of AKs* in about 2/3 patients. The system more effectively cleared AKs of the face than those of the scalp. Clinical studies did not examine what happened to completely cleared AKs more than 12 weeks after treatment.



*Before treatment*



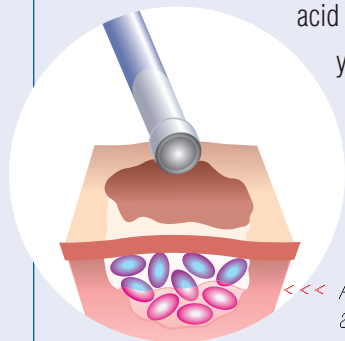
*4 weeks posttreatment*

# the Levulan PDT system

## How does the Levulan PDT system work?

### Step 1

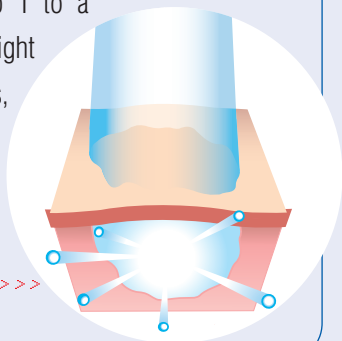
The first step in the Levulan PDT system is when your dermatologist applies Levulan® Kerastick® (amino-levulinic acid HCl) for Topical Solution, 20% to individual AKs on your skin. This unique solution is an acid that occurs naturally in your body; it makes the AKs more sensitive to light. This application prepares them for step 2 in the Levulan treatment.



<<< Application of solution and absorption by treated cells

### Step 2

After waiting 14 to 18 hours, you return to your dermatologist's office. The dermatologist then exposes the AKs treated in step 1 to a special blue light. This light then destroys these AKs, whether they are precancerous or not.



Blue light illumination and destruction of treated cells >>>

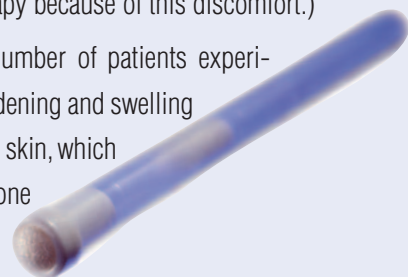
## Are there any precautions I should take during the treatment?

Because step 1 makes the treated areas more sensitive to light, it is important that you avoid bright light during the 14 to 18 hours between step 1 and step 2. Sunscreens will not protect these treated areas. Stay out of sunlight or bright indoor light, and wear light-protecting clothing such as a wide-brimmed hat.

## What will I experience during treatment?

During step 2 (the blue light therapy), at least half of the patients in the clinical studies felt a stinging and/or burning in the treated areas. Usually, this improved immediately after treatment and ended within 24 hours. (Less than 3% of patients discontinued therapy because of this discomfort.)

After treatment, a small number of patients experienced some temporary reddening and swelling of the AKs and surrounding skin, which generally was completely gone by 4 weeks after treatment.



Photos courtesy of DUSA Pharmaceuticals, Inc.®



24 hours posttreatment



4 weeks posttreatment

## ***Is there anything my doctor should know before I begin treatment?***

Your doctor should be told:

- If you have porphyria or known allergies to porphyrins
- If you are allergic to any of the system's components
- The names of any medications you are presently taking
- If you are pregnant or nursing
- Photosensitivity
- If you have inherited or acquired blood-clotting defects, as Levulan Kerastick Topical Solution has not been tested on patients with these conditions

*Ask your doctor for more product information.*

## ***Your next treatment is scheduled for***

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(scheduled date/time of treatment)

---

(physician's name)

---

(physician's address)

---

(city) (state) (zip)

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(physician's phone number)

***Remember to take the precautions discussed in this brochure to help reduce the chance of future AKs.***

***Contact your doctor immediately if new lesions occur.***

**DUSA<sup>®</sup>** **Levulan<sup>®</sup> Kerastick<sup>®</sup>**  
(aminolevulinic acid HCl) for Topical Solution, 20%

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MKT-1221 RevD

**For Patients With Actinic Keratoses**



## **Levulan<sup>®</sup> Kerastick<sup>®</sup>** **Photodynamic Therapy System**



**Levulan<sup>®</sup> Kerastick<sup>®</sup>**

(aminolevulinic acid HCl)  
for Topical Solution, 20%

**Levulan<sup>®</sup> is the only FDA approved ALA**

**Call DUSA at 877-533-3872 or www.dusapharma.com**