



*Have a Voice in Your Choice<sup>®</sup>!*

**BLU-U<sup>®</sup> Blue Light Photodynamic Therapy**

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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.

**LEVULAN<sup>®</sup>  
KERASTICK<sup>®</sup>**  
(aminolevulinic acid HCl)  
for Topical Solution, 20%



**BLU-U<sup>®</sup>**  
Blue Light Photodynamic Therapy  
Illuminator Model 4170

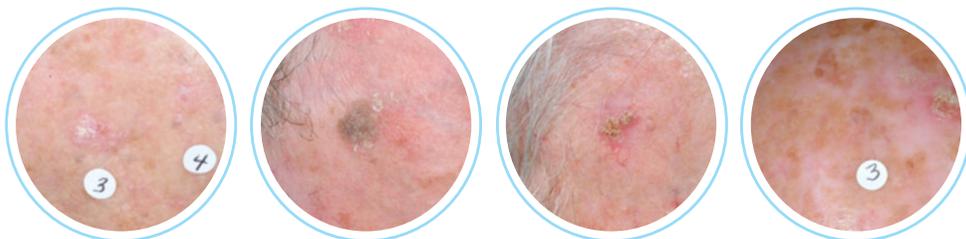
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## About Actinic Keratoses

Up to 58 million Americans have actinic keratosis (AK). An AK has 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. 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 sun exposed areas such as the face, scalp or ears, and can range in color from skin toned to reddish brown. They can be as small as a pinhead or larger than a quarter.



## 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

## Levulan Kerastick and Blu-U:

Levulan® Kerastick® for Topical Solution, 20% plus blue light illumination using the BLU-U® Blue Light Photodynamic Therapy Illuminator is indicated for the treatment of minimally to moderately thick Actinic Keratosis of the face or scalp.

LEVULAN KERASTICK and BLU-U PDT, a 2-part treatment, is unique because it uses a light activated drug therapy to destroy AKs. 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.

### **\*Important Safety Information**

LEVULAN KERASTICK should not be used by patients who have skin photosensitivity, or known allergies to porphyrins, a group of disorders that result from a buildup of natural chemicals that produce porphyrin in your body and in patients with know sensitivity to any of the components of the LEVULAN KERASTICK for Topical Solutions.



### Step 1: Application of LEVULAN KERASTICK Topical Solution

- LEVULAN KERASTICK will be uniformly applied to your AK lesion.
- Your provider will direct you to wait the recommended time, per the label, in order to allow the solution to penetrate the targeted cells.
- Avoid exposing the treated lesions to sunlight or bright light for at least 40 hours after application of LEVULAN KERASTICK Topical Solution. Examples include household lights at close range or engaging in outdoor sports or recreation. Sunscreens will not protect against photo sensitivity reactions caused by visible light during this time.



## Step 2: BLU-U light treatment

- › Before your BLU-U light treatment, the AKs to be treated should be gently rinsed and patted dry.
- › Your treatment with the BLU-U will take approximately 17 minutes.
- › Protective eyewear should be worn during your BLU-U treatment.
- › The BLU-U does not emit UVA or UVB light.

### **\*Important Safety Information**

The most common side effects include scaling/crusting, skin discoloration, itching, stinging and/or burning, redness and swelling. 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.

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# What to expect before, during and after treatment

## Before treatment starts

- › Be sure to tell your physician if you are taking any oral medications or using any topical prescription or nonprescription products on your face or scalp.
- › Bring adequate sun-protective items with you to your appointments such as a wide-brimmed hat or umbrella.

## During BLU-U treatment

The BLU-U blue light is of low intensity and will not heat the skin. However, during the light treatment, you may experience sensations of burning, tingling, stinging, or prickling of the treated AKs. The sensation of stinging and/or burning appears to reach a plateau at 6 minutes into the BLU-U light treatment. These feelings of discomfort should improve at the end of the BLU-U treatment and should subside as early as 1 minute after BLU-U treatment, but may take up to 24 hours after the BLU-U is turned off. Following treatment, the AKs, and to some degree the surrounding skin, may redden. Swelling and scaling may also occur. However, these effects are temporary and should completely resolve by 4 weeks after treatment. In clinical trials, less than 3% of patients discontinued light treatment due to stinging and/or burning.

## After treatment

- › Avoid exposure of your photosensitive treatment sites to sunlight or bright light for at least 40 hours after the application of LEVULAN KERASTICK Topical Solution.
- › Sunscreens will not protect against photo sensitivity reactions caused by visible light. Moisturizers may be applied as needed.



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## The convenience of an in office treatment

- › A 2-step treatment procedure that is completed within 24 hours
- › Low downtime \*
- › A qualified healthcare professional will administer the treatment
- › No prescription to fill
- › No daily medication to remember
- › Flexible treatment for a range of AKs on face and scalp
  - Appropriate for either a few or multiple minimally to moderate thick AKs
- › Results include:
  - Recovery beginning right after your treatment with BLU-U blue light ends
  - No scarring reported in clinical trials

### **\*Important Safety Information**

Patients should avoid exposure of the photo sensitive treatment sites to sunlight or bright light for at least 40 hours after the application of LEVULAN KERASTICK Topical Solution. Exposure may result in a stinging and/or burning sensation and may cause redness or swelling of the lesions. Sunscreens will not protect against photo sensitivity reactions caused by visible light.

## Important Safety 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 use LEVULAN KERASTICK?

LEVULAN KERASTICK should not be used by patients who have skin photo sensitivity, or known allergies to porphyrins, a group of disorders that result from a buildup of natural chemicals that produce porphyrin in your body, and in patients with known sensitivity to any of the components of the LEVULAN KERASTICK for Topical Solutions.

LEVULAN KERASTICK has not been tested on patients with inherited or acquired coagulation defects. It is possible that concomitant use of other known photo sensitizing agents might increase the photo sensitivity 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 nonprescription 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, skin discoloration, itching, stinging and/or burning, redness and swelling. 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 photo sensitive treatment sites to sunlight or bright light for at least 40 hours after the application of LEVULAN KERASTICK Topical Solution. Exposure may result in a stinging and/or burning sensation and may cause redness or swelling of the lesions. Sunscreens will not protect against photo sensitivity reactions cause by visible light.

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