HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use Levulan® Kerastick® safely and effectively. See full prescribing information for Levulan® Kerastick®.

Levulan® Kerastick® (aminolevulinic acid HCl) for Topical Solution, 20%
Initial U.S. Approval: 1999

----------INDICATIONS AND USAGE----------

The LEVULAN KERASTICK for Topical Solution, a porphyrin precursor, 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 (1).

----------DOSAGE AND ADMINISTRATION ----------

Photodynamic therapy for actinic keratoses with LEVULAN KERASTICK for Topical Solution is a two stage process involving a) application of the product to the target lesions with LEVULAN KERASTICK Topical Solution, followed 14 to 18 hours later by b) illumination with blue light using the BLU-U® Blue Light Photodynamic Therapy Illuminator. Treated lesions that have not completely resolved after 8 weeks may be treated a second time with LEVULAN KERASTICK for Topical Solution Photodynamic Therapy (2).

----------DOSAGE FORMS AND STRENGTHS ----------

Solution containing 20% aminolevulinic acid hydrochloride (ALA.HCl) by weight in a plastic applicator device (3).

----------CONTRAINDICATIONS----------

Cutaneous photosensitivity at wavelengths of 400-450 nm (4).

----------WARNINGS AND PRECAUTIONS ----------

- Avoid exposure of the photosensitive actinic keratoses to sunlight or bright indoor light prior to blue light treatment. Protect treated lesions from sunlight exposure. Sunscreens will not protect the patient against photosensitivity reactions (5.1).
- The LEVULAN KERASTICK for Topical Solution should be used by a qualified health professional to apply drug only to actinic keratoses and not perilesional skin (5.2).
- Do not apply to the eyes or to mucous membranes. Excessive irritation may be experienced if this product is applied under occlusion (5.2).

----------ADVERSE REACTIONS ----------

Adverse reactions occurring during clinical trials with an incidence ≥ 2% were erythema, edema, stinging/burning, scaling/crusting, hypo/hyperpigmentation, itching/pruritus, erosion, wheal/flare, vesiculation, ulceration, bleeding/hemorrhage, pain, pustules, tenderness, scabbing and dysesthesia (6).

To report SUSPECTED ADVERSE REACTIONS, contact DUSA Pharmaceuticals, Inc. at (877) 533-3872 or FDA at (800) FDA-1088 or www.fda.gov/medwatch

----------DRUG INTERACTIONS ----------

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, however, possible that concomitant use of other known photosensitizing agents such as griseofulvin, thiazide diuretics, sulfonylureas, phenothiazines, sulfonamides and tetracyclines might increase the photosensitivity reaction of actinic keratoses treated with LEVULAN KERASTICK Topical Solution (7).

See 17 for PATIENT COUNSELING INFORMATION

Revised: 03/2010

Full Prescribing Information: Contents*

*Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

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

2 DOSAGE AND ADMINISTRATION

LEVULAN KERASTICK for Topical Solution 20% is intended for direct application to individual lesions diagnosed as actinic keratoses and not to perilesional skin. This product is not intended for application by patients or unqualified medical personnel. Application should involve either scalp or face lesions, but not both simultaneously. The recommended treatment frequency is: one application of the LEVULAN KERASTICK Topical Solution and one dose of illumination per treatment site per 8-week treatment session. Each individual LEVULAN KERASTICK for Topical Solution should be used for only one patient. Photodynamic therapy for actinic keratoses with LEVULAN KERASTICK for Topical Solution is a two stage process involving a) application of the product to the target lesions with LEVULAN KERASTICK Topical Solution, followed 14 to 18 hours later by b) illumination with blue light using the BLU-U Blue Light Photodynamic Therapy Illuminator. The second visit, for illumination, must take place in the 14-18 hour window following application. Patients in clinical trials usually received application in the late afternoon, with illumination the following morning.

TABLE 1 Schedule for LEVULAN KERASTICK and Blue Light Administration

LEVULAN KERASTICK Topical Solution Application	Time Window for Blue Light Illumination
6 am	8 pm to Midnight
7 am	9 pm to 1 am
8 am	10 pm to 2 am
9 am	11 pm to 3 am
10 am	Midnight to 4 am
11 am	1 am to 5 am
12 pm	2 am to 6 am
1 pm	3 am to 7 am
2 pm	4 am to 8 am
3 pm	5 am to 9 am
4 pm	6 am to 10 am
5 pm	7 am to 11 am
6 pm	8 am to Noon
7 pm	9 am to 1 pm
8 pm	10 am to 2 pm
9 pm	11 am to 3 pm
10 pm	Noon to 4 pm

Treated lesions that have not completely resolved after 8 weeks may be treated a second time with LEVULAN KERASTICK for Topical Solution Photodynamic Therapy.

Step A - LEVULAN KERASTICK for Topical Solution Application: Actinic keratoses

Preparation of lesions

Actinic keratoses targeted for treatment should be clean and dry prior to application of LEVULAN KERASTICK Topical Solution.

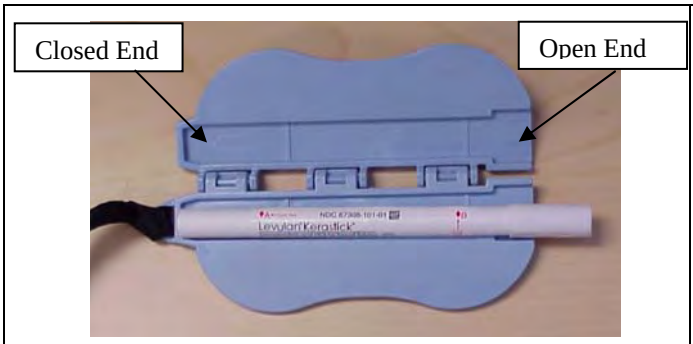
Preparation of LEVULAN KERASTICK

LEVULAN KERASTICK can be prepared either manually, or using the optional Kerastick Krusher. These methods are illustrated below.

Manual Preparation:

<table>
<tr>
<td> 
1. Hold the LEVULAN KERASTICK so that the applicator cap is pointing up.</td>
<td> 
2. Crush the bottom ampule containing the solution vehicle by applying finger pressure to Position A on the cardboard sleeve.</td>
</tr>
<tr>
<td> 
3. Crush the top ampule containing the ALA HCl powder by applying finger pressure to Position B on the cardboard sleeve. To ensure both ampules are crushed continue crushing the applicator downward, applying finger pressure to Position A.</td>
<td> 
4. Holding the LEVULAN KERASTICK between the thumb and forefinger, point the applicator cap away from the face, shake the LEVULAN KERASTICK gently for at least 30 Seconds to completely dissolve the drug powder in the solution vehicle. Do not press on the end cap while shaking.</td>
</tr>
</table>

Optional Kerastick Krusher Preparation:



1. Open the Kerastick Krusher and properly position one LEVULAN KERASTICK into the Krusher making sure to orient the LEVULAN KERASTICK label “A” with the Krusher “A”. Firmly seat LEVULAN KERASTICK against the closed end of the Krusher (cap should be at open end).

2. Once positioned properly, close and firmly press the top and bottom handles together until the top and bottom handles touch one another along their length. A distinct crushing sound is made during this process. Ensure Krusher handles meet.

3. Remove the LEVULAN KERASTICK from the Krusher.

4. Holding the LEVULAN KERASTICK between the thumb and forefinger, point the applicator cap away from the face, shake the LEVULAN KERASTICK gently for at least 30 Seconds to completely dissolve the drug powder in the solution vehicle. Do not press on the end cap while shaking.

Application of solution

Following solution admixture, remove the cap from the LEVULAN KERASTICK Topical Solution. The dry applicator tip should be dabbed on a gauze pad until uniformly wet with solution. Apply the solution directly to the target lesions by dabbing gently with the wet applicator tip. Enough solution should be applied to uniformly wet the lesion surface, including the edges without excess running or dripping. The effect of LEVULAN KERASTICK Topical Solution on ocular tissues is unknown. LEVULAN KERASTICK Topical Solution should not be applied to the periorbital area or allowed to contact ocular or mucosal surfaces. Once the initial application has dried, apply again in the same manner. The LEVULAN KERASTICK Topical Solution must be used immediately following preparation (dissolution) due to the instability of the activated product. If the solution application is not completed within 2 hours of activation, the applicator should be discarded and a new LEVULAN KERASTICK for Topical Solution used.

Photosensitization of the treated lesions will take place over the next 14-18 hours. The actinic keratoses should not be washed during this time. The patient should be advised to wear a wide-brimmed hat or other protective apparel to shade the treated actinic keratoses from sunlight or other bright light sources until BLU-U treatment. The patient should be advised to reduce light exposure if the sensations of stinging and/or burning are experienced.

If for any reason the patient cannot be given BLU-U treatment during the prescribed time after LEVULAN KERASTICK Topical Solution application, he or she may nonetheless experience sensations of stinging and/or burning if the photosensitized actinic keratoses are exposed to sunlight or prolonged or intense light at that time. The patient should be advised to wear a wide-brimmed hat or other protective apparel to shade the treated actinic keratoses from sunlight or other bright light sources until at least 40 hours after the application of LEVULAN KERASTICK Topical Solution. The patient should be advised to reduce light exposure if the sensations of stinging and/or burning are experienced.

Step B - Administration of BLU-U Treatment 14 to 18 hours after application

LEVULAN KERASTICK for Topical Solution is not intended for use with any device other than the BLU-U Blue Light Photodynamic Therapy Illuminator. Use of LEVULAN KERASTICK Topical Solution without subsequent BLU-U illumination is not recommended.

At the visit for light illumination, the actinic keratoses to be treated should be gently rinsed with water and patted dry. Photoactivation of actinic keratoses treated with LEVULAN KERASTICK Topical Solution is accomplished with BLU-U illumination from the BLU-U Blue Light Photodynamic Therapy Illuminator. A 1000 second (16 minutes 40 seconds) exposure is required to provide a 10 J/cm2 light dose. During light treatment, both patients and medical personnel should be provided with blue blocking protective eyewear, as specified in the BLU-U Operating Instructions. Please refer to the BLU-U Operating Instructions for further information on conducting the light treatment. Patients should be advised that transient stinging and/or burning at the target lesion sites occurs during the period of light exposure.

If blue light treatment with the BLU-U Blue Light Photodynamic Therapy Illuminator is interrupted or stopped for any reason, it should not be restarted and the patient should be advised to protect the treated lesions from exposure to sunlight or prolonged or intense light for at least 40 hours after application of the LEVULAN KERASTICK Topical Solution.

For patients with facial lesions:

1. The BLU-U Blue Light Photodynamic Therapy Illuminator is positioned so that the base is slightly above the patient's shoulder, parallel to the patient's face.

2. The BLU-U is positioned around the patient's head so the entire surface area to be treated lies between 2" and 4" from the BLU-U surface:

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