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

----------RECENT MAJOR CHANGES----------

Indications and Usage (1)	03/2018
Dosage and Administration (2)	03/2018
Warnings and Precautions (5.2, 5.3)	03/2018
Warnings and Precautions (5.1)	04/2018

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

LEVULAN KERASTICK for topical solution, a porphyrin precursor, plus blue light illumination using the BLU-U Blue Light Photodynamic Therapy Illuminator is indicated for photodynamic therapy (treatment) of minimally to moderately thick actinic keratoses of the face or scalp, or actinic keratoses of the upper extremities (1).

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

- LEVULAN KERASTICK photodynamic therapy is a two-stage process for administration by a health care provider (2.1).
- Apply the drug product to the target lesions (2.1).
- Illuminate with blue light using the BLU-U® Blue Light Photodynamic Therapy Illuminator after the incubation time of (2.2):
  - 14 to 18 hours for scalp or face
  - 3 hours for upper extremities, with occlusion
- LEVULAN KERASTICK photodynamic therapy may be repeated a second time for lesions that have not completely resolved after 8 weeks (2.1).
- For topical use only (2.1).
- See full prescribing information for complete dosage and administration instruction.
- See BLU-U user manual for detailed lamp safety and operating instructions (2.2).

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

After mixture, topical solution contains 20% aminolevulinic acid hydrochloride (ALA HCl) by weight in a plastic applicator device (3).

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

- Cutaneous photosensitivity at wavelengths of 400-450 nm (4)
- Porphyria or known allergies to porphyrins (4)
- Sensitivity to any of the components of the LEVULAN KERASTICK (4)

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

- Transient amnestic episodes have been reported during postmarketing use of Levulan Kerastick in combination with BLU-U Blue Light Photodynamic Therapy Illuminator. Inform patients and their caregivers that Levulan Kerastick in combination with PDT may cause transient amnestic episodes. Advise them to contact -the healthcare provider if the patient develops amnesia after treatment (5.1)
- 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 (5.2).
- The LEVULAN KERASTICK for topical solution should be used by a qualified health professional. To avoid unintended photosensitivity, LEVULAN KERASTICK topical solution should be applied to no more than 5 mm of perilesional skin surrounding each target actinic keratosis lesion. (5.2).
- Irritation may be experienced if this product is applied to eyes or mucus membranes. Do not apply to the eyes or to mucous membranes. Excessive irritation may be experienced if this product is applied under occlusion longer than 3 hours (5.3).

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

The most common local adverse reactions (incidence ≥ 10%) were erythema, edema, stinging/burning, scaling/crusting, itching, erosion, hypo/hyperpigmentation, oozing/vesiculation/crusting, scaling and dryness. (6.1).

To report SUSPECTED ADVERSE REACTIONS, contact Sun Dermatology at 877-533-3872 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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

Concomitant use of other known photosensitizing agents such as St. John's wort, griseofulvin, thiazide diuretics, sulfonylureas, phenothiazines, sulfonamides and tetracyclines might increase the photosensitivity reaction (7).

See 17 for PATIENT COUNSELING INFORMATION

Revised: 04/2018

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 Illuminator is indicated for the treatment of minimally to moderately thick actinic keratoses of the face, scalp, or upper extremities.

DOSAGE AND ADMINISTRATION

2.1 Preparation and Administration Overview

After mixing, the LEVULAN KERASTICK 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 lesions on the scalp, face or upper extremities; multiple lesions can be treated within a treatment region, but multiple treatment regions should not be treated simultaneously.

The recommended treatment frequency is: one application of the LEVULAN KERASTICK topical solution and one dose of illumination per treatment region per 8-week treatment session. Each individual LEVULAN KERASTICK applicator should be used for only one patient.

LEVULAN KERASTICK photodynamic therapy for actinic keratoses is a two-stage process involving application of the LEVULAN KERASTICK topical solution to the target lesions and then illumination with blue light using the BLU-U Blue Light Photodynamic Therapy Illuminator after 3 hours for upper extremity lesions or after 14-18 hours for face or scalp lesions.

TABLE 1 Schedule for LEVULAN KERASTICK Photodynamic Therapy		
LEVULAN KERASTICK topical solution application	Time window[1] for Blue Light Illumination for face or scalp	Time window[2] for Blue Light Illumination for upper extremities
6 am	8 pm to Midnight	9 am
7 am	9 pm to 1 am	10 am
8 am	10 pm to 2 am	11 am
9 am	11 pm to 3 am	12 Noon
10 am	Midnight to 4 am	1 pm
11 am	1 am to 5 am	2 pm
12 pm	2 am to 6 am	3 pm
1 pm	3 am to 7 am	4 pm
2 pm	4 am to 8 am	5 pm
3 pm	5 am to 9 am	6 pm
4 pm	6 am to 10 am	7 pm
5 pm	7 am to 11 am	8 pm
6 pm	8 am to Noon	9 pm
7 pm	9 am to 1 pm	10 pm
8 pm	10 am to 2 pm	11 pm
9 pm	11 am to 3 pm	12 Midnight
10 pm	Noon to 4 pm	1 am

[1] The incubation time is 14-18 hours for actinic keratosis lesions on the face or scalp.
[2] The incubation time is 3 hours for actinic keratosis lesions on the upper extremities.

If for any reason the patient cannot be given BLU-U Blue Light Photodynamic Therapy Illuminator treatment during the prescribed time after applying LEVULAN KERASTICK topical solution, 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. Advise the patient to wear appropriate protective apparel (e.g., wide-brimmed hat, long sleeve shirt, gloves) 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. Advise the patient to reduce light exposure if the sensations of stinging and/or burning are experienced.

LEVULAN KERASTICK photodynamic therapy may be repeated a second time for lesions that have not completely resolved 8 weeks after the initial treatment.

2.2 Dosage and Administration Instructions

Step A – Treatment of Actinic Keratoses with LEVULAN KERASTICK Topical Solution

Preparation of Lesions

Actinic keratoses targeted for treatment should be clean and dry prior to applying the LEVULAN KERASTICK topical solution.

Preparation of LEVULAN KERASTICK topical solution

The LEVULAN KERASTICK applicator consists of a plastic tube containing two sealed glass ampules and an applicator tip. One ampule contains 1.5 mL of solution vehicle. The other ampule contains aminolevulinic acid HCl as a dry solid. LEVULAN KERASTICK topical solution is prepared by crushing the glass ampoules and mixing the contents together.

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

Figure 1: Manual Preparation:

1. Hold the LEVULAN KERASTICK applicator with cap point up. Crush the bottom ampule containing the solution vehicle by applying finger pressure to Position A on the cardboard sleeve.
2. 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. Shake the LEVULAN KERASTICK applicator gently for at least 30 seconds to completely dissolve the drug powder in the solution vehicle.

Figure 2: Optional Kerastick Krusher Preparation:

1. Open the Kerastick Krusher and properly position one LEVULAN KERASTICK applicator into the Krusher making sure to orient the LEVULAN KERASTICK label “A” with the Krusher “A”. Firmly seat the LEVULAN KERASTICK applicator 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 applicator from the Krusher and shake the LEVULAN KERASTICK applicator gently for at least 30 seconds to completely dissolve the drug powder in the solution vehicle.

The LEVULAN KERASTICK topical solution must be used within two (2) hours of activation. If the solution is not completely applied within 2 hours of the activation, discard the applicator. If needed, use a new LEVULAN KERASTICK applicator.

Application of LEVULAN KERASTICK topical solution

Application of LEVULAN KERASTICK topical solution to Face or Scalp Lesions:

Following solution admixture, remove the cap from the LEVULAN KERASTICK applicator. 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. Once the initial application has dried, apply again in the same manner.

Do not apply the LEVULAN KERASTICK topical solution to the periorbital area or allow it to contact ocular or mucosal surfaces.

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 Blue Light Photodynamic Therapy Illuminator treatment. The patient should be advised to reduce light exposure if the sensations of stinging and/or burning are experienced.

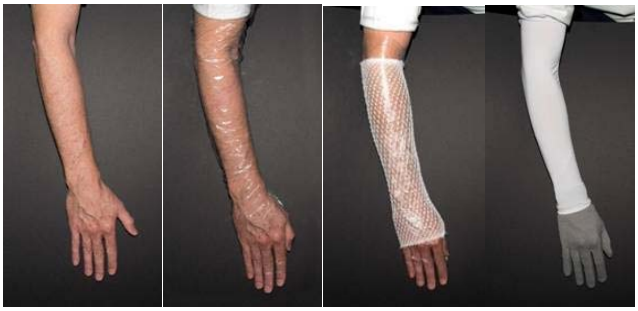
At the visit for light illumination before treatment, the actinic keratoses treated with the LEVULAN KERASTICK topical solution should be gently rinsed with water and patted dry.

For Lesions on the Upper Extremities**:**

Following solution mixture, remove the cap from the LEVULAN KERASTICK applicator. 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.

Occlude the upper extremity with low density polyethylene plastic wrap and hold in place with an elastic net dressing.

Figure 3: Method of Occlusion for Upper Extremities



The patient should wear a long-sleeved shirt and/or gloves or other protective apparel to shade the treated actinic keratoses from sunlight or other bright light sources until BLU-U Blue Light Photodynamic Therapy Illuminator treatment. Photosensitization of the treated lesions will take place over the next 3 hours. The actinic keratoses should not be washed during this time. Remove the occlusive dressing prior to light treatment and gently rinse the treated area(s) with water and pat dry before light illumination.

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