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 (5.1, 5.2)	03/2018

----------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----------

- 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 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. (5.1).
- 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 (5.2).

----------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: 03/2018

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.

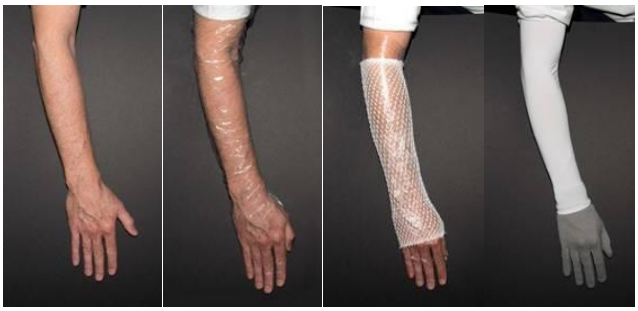
At the visit for light illumination before treatment, the actinic keratoses treated with the LEVULAN KERASTICK topical solution should be gently rinsed with water and patted dry.

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.

Step B - Administration of BLU-U Treatment:

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

Photoactivation of actinic keratoses treated with LEVULAN KERASTICK topical solution is accomplished with 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/cm^2 light dose. During light treatment, both patients and medical personnel should be provided with blue blocking protective eyewear, as specified in the BLU-U Blue Light Photodynamic Therapy Illuminator Operating Instructions. Please refer to the BLU-U Blue Light Photodynamic Therapy Illuminator 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 applying 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:
   a) The patient's nose should be no closer than 2" from the surface;
   b) The patient's forehead and cheeks should be no further than 4" from the surface;
   c) The sides of the patient's face and the patient's ears should be no closer than 2" from the BLU-U surface.

For patients with scalp lesions:

1. The knobs on either side of the BLU-U are loosened and the BLU-U is rotated to a horizontal position.
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:
   a) The patient's scalp should be no closer than 2" from the surface;
   b) The patient's scalp should be no further than 4" from the surface;
   c) The sides of the patient's face and the patient's ears should be no closer than 2" from the BLU-U surface.

For patients with upper extremity lesions:

1. The knobs on either side of the BLU-U Blue Light Photodynamic Therapy Illuminator are loosened and the light is rotated to a horizontal position.

2. The BLU-U Blue Light Photodynamic Therapy Illuminator is positioned around the upper extremity so the entire surface area to be treated lies between 2" and 4" from the BLU-U surface. A table may be used to support the upper extremities during light treatment.

3 DOSAGE FORM AND STRENGTHS

For topical solution: 354 mg of aminolevulinic acid hydrochloride as a powder in a plastic applicator device. Upon mixture, LEVULAN KERASTICK is a topical solution containing 20% aminolevulinic acid hydrochloride (ALA HCl) by weight.

4 CONTRAINDICATIONS

The LEVULAN KERASTICK for topical solution plus blue light illumination using the BLU-U Blue Light Photodynamic Therapy Illuminator is contraindicated in patients with:

- Cutaneous photosensitivity at wavelengths of 400-450 nm *[see Warnings and Precautions (5.1)]*
- Porphyria or known allergies to porphyrins *[see Warnings and Precautions (5.1)]*
- Known sensitivity to any of the components of the LEVULAN KERASTICK.

5 WARNINGS AND PRECAUTIONS

5.1 Photosensitivity

After LEVULAN KERASTICK topical solution has been applied, the treatment site will become photosensitive and patients should avoid exposure of the photosensitive treatment sites to sunlight or bright indoor light (e.g., examination lamps, operating room lamps, tanning beds, or lights at close proximity) for 40 hours. Exposure may result in a stinging and/or burning sensation and may cause erythema and/or edema of the lesions.

Therefore, before exposure to sunlight, patients should protect treated lesions from the sun by wearing a wide-brimmed hat or similar head covering of light-opaque material, and/or a long-sleeved shirt and/or gloves. Sunscreens will not protect against photosensitivity reactions caused by visible light. It has not been determined if perspiration can spread the LEVULAN KERASTICK topical solution outside the treatment site to the eye or surrounding skin.

Application of LEVULAN KERASTICK topical solution to perilesional areas of photodamaged skin of the face, scalp or upper extremities may result in photosensitization. Upon exposure to activating light from the BLU-U, such photosensitized skin may produce a stinging and/or burning sensation and may become erythematous and/or edematous in a manner similar to that of actinic keratoses treated with LEVULAN KERASTICK Photodynamic Therapy. Because of the potential for skin to become photosensitized, the LEVULAN KERASTICK topical solution should be used by a qualified health professional to apply drug to no more than 5mm of perilesional skin surrounding the target actinic keratosis lesions.

If for any reason the patient cannot return for blue light treatment during the prescribed period after applying LEVULAN KERASTICK topical solution, the patient should call the doctor. The patient should also continue to avoid exposure of the photosensitized lesions to sunlight or prolonged or intense light for at least 40 hours. If stinging and/or burning is noted, exposure to light should be reduced.

5.2 Irritation

The LEVULAN KERASTICK topical solution contains alcohol and is intended for topical use only. 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 Coagulation Defects

The LEVULAN KERASTICK for topical solution has not been tested on patients with inherited or acquired coagulation defects.

6 ADVERSE REACTIONS

The following adverse reactions are discussed in greater detail in the other sections of the labeling:

- Increased Photosensitivity *[see Warnings and Precautions (5.1)]*
- Irritation *[see Warnings and Precautions (5.2)]*
- Coagulation defects *[see Warnings and Precautions (5.3)]*

6.1 Clinical Trial Experience:

Because clinical trials are conducted under widely varying conditions, adverse reaction rate observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

In clinical trials, no non-cutaneous adverse events were found to be consistently associated with LEVULAN KERASTICK photodynamic therapy.

Photodynamic Therapy Response: The constellation of transient local symptoms of stinging and/or burning, itching, erythema and edema as a result of LEVULAN KERASTICK photodynamic therapy (PDT) was observed in all clinical trials for actinic keratoses treatment. Stinging and/or burning subsided between 1 minute and 24 hours after the BLU-U Blue Light Photodynamic Therapy Illuminator was turned off, and appeared qualitatively similar to that perceived by patients with erythropoietic protoporphyria upon exposure to sunlight. There was no clear drug dose or light dose dependent change in the incidence or severity of stinging and/or burning.

Local skin reactions at the application site were observed in 99% of subjects treated with LEVULAN KERASTICK topical solution and BLU-U Blue Light Photodynamic Therapy Illuminator. The most common local adverse reactions (incidence $\geq$ 10%) were application site stinging/burning, erythema, edema, scaling/crusting, hypo/hyperpigmentation, itching, erosion, oozing/vesiculation/crusting, dryness.

In the trials for face and scalp lesions, severe stinging and/or burning at one or more lesions during light treatment was reported by at least 50% of subjects. Severe stinging and/or burning also occurred during light treatment in 9% of subjects receiving treatment for upper extremity lesions. The majority of subjects reported that all lesions treated exhibited at least slight stinging and/or burning. In trials of the face and scalp, the sensation of stinging/burning appeared to reach a plateau at 6 minutes into the treatment. Less than 3% of subjects receiving treatment for face or scalp lesions discontinued light treatment because of stinging/burning. No subjects discontinued light treatment in the trial for upper extremity lesions.

In trials for the face or scalp lesions, 99% of the active treatment group and 79% of the vehicle group experienced erythema shortly after treatment. In the trial for the upper extremity lesions, 99% of LEVULAN KERASTICK topical solution treatment group and 52% of the vehicle group experienced erythema on visit Days 2-3. Approximately 35% of LEVULAN KERASTICK topical solution group had edema, while edema occurred in ≤1% of the vehicle group. Both erythema and edema resolved to baseline or improved by 4 weeks after therapy for face or scalp. Edema resolved by 4 weeks and erythema resolved to baseline by 8 weeks for upper extremities.

The application of LEVULAN KERASTICK topical solution to perilesional skin resulted in stinging, burning, erythema and edema similar to treated actinic keratoses *[see Warnings and Precautions (5.1)]*.

Other Localized Cutaneous Adverse Experiences: Table 2 depicts the incidence and severity of cutaneous adverse events in trials for the face and scalp.

TABLE 2 Post-PDT Cutaneous Adverse Events – ALA-018/ALA-019 For the Face and Scalp								
	FACE				SCALP			
	LEVULAN KERASTICK Topical Solution + PDT (n=139)		Vehicle + PDT (n=41)		LEVULAN KERASTICK Topical Solution + PDT (n=42)		Vehicle + PDT (n=21)	
Degree of Severity	Mild/ Moderate	Severe	Mild/ Moderate	Severe	Mild/ Moderate	Severe	Mild/ Moderate	Severe
Scaling/Crusting	71%	1%	12%	0%	64%	2%	19%	0%
Pain	1%	0%	0%	0%	0%	0%	0%	0%
Tenderness	1%	0%	0%	0%	2%	0%	0%	0%
Itching	25%	1%	7%	0%	14%	7%	19%	0%
Edema	1%	0%	0%	0%	0%	0%	0%	0%
Ulceration	4%	0%	0%	0%	2%	0%	0%	0%
Bleeding/Hemorrhage	4%	0%	0%	0%	2%	0%	0%	0%
Hypo/hyper-pigmentation	22%		20%		36%		33%	
Vesiculation	4%	0%	0%	0%	5%	0%	0%	0%
Pustules	4%	0%	0%	0%	0%	0%	0%	0%
Oozing	1%	0%	0%	0%	0%	0%	0%	0%
Dysesthesia	2%	0%	0%	0%	0%	0%	0%	0%
Scabbing	2%	1%	0%	0%	0%	0%	0%	0%
Erosion	14%	1%	0%	0%	2%	0%	0%	0%
Excoriation	1%	0%	0%	0%	0%	0%	0%	0%
Wheal/Flare	7%	1%	0%	0%	2%	0%	0%	0%
Skin disorder NOS	5%	0%	0%	0%	12%	0%	5%	0%

Table 3 depicts the percentage of subjects with cutaneous adverse reactions by the most severe grade reported in course of the trial for the upper extremity lesions.

TABLE 3 Percentage of Subjects with Cutaneous Adverse Reactions by the Most Severe Grade Reported Post-Baseline – CP0108 For Upper Extremities						
	LEVULAN KERASTICK Topical Solution + PDT (N=135)			Vehicle + PDT (N=134)		
Degree of Severity	Minimal/ Mild	Moderate/ Severe	Total	Minimal/ Mild	Moderate/ Severe	Total
Edema	51%	4%	56%	7%	1%	8%
Erythema	35%	65%	100%	63%	12%	75%
Hyper-pigmentation	64%	9%	73%	57%	10%	66%
Hypo-pigmentation	46%	4%	50%	50%	5%	55%
Oozing/Vesiculation/ Crusting	36%	5%	41%	8%	2%	10%
Scaling and Dryness	65%	22%	87%	58%	7%	64%
Stinging/Burning	23%	73%	96%	23%	0%	23%

In the trial for upper extremity lesions, itching and scabbing occurred in 8% and 4%, respectively, of the subjects in the LEVULAN KERASTICK photodynamic therapy group. No subjects in the vehicle group reported itching or scabbing.

Common (≥2%, <10%) local cutaneous adverse reactions for face, scalp and upper extremities in the LEVULAN KERASTICK topical solution group included wheal, scabbing, pustules, ulceration, bleeding, tenderness and dysesthesia.

Uncommon (<2%) local cutaneous adverse reactions for face, scalp and upper extremities in the LEVULAN KERASTICK topical solution group were flaking, pain, peeling, perilesional pruritic rash, excoriation and blistering.

Common (≥2%, <10%) adverse reactions not limited to the application site for upper extremities and occurring more frequently in the LEVULAN KERASTICK topical solution group than in the vehicle group were sinusitis, squamous cell carcinoma, and squamous cell carcinoma of skin.

7 DRUG INTERACTIONS

There have been no formal studies of the interaction of LEVULAN KERASTICK 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 St. John's wort, griseofulvin, thiazide diuretics, sulfonylureas, phenothiazines, sulfonamides and tetracyclines might increase the photosensitivity reaction of actinic keratoses treated with LEVULAN KERASTICK topical solution *[see Warnings and Precautions (5.1)]*.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Limited available data with LEVULAN KERASTICK topical solution use in pregnant women are insufficient to inform a drug associated risk of adverse developmental outcomes. Animal developmental toxicology studies were not conducted with aminolevulinic acid. LEVULAN KERASTICK solution has low systemic absorption following topical administration, and the risk of maternal use resulting in fetal exposure to the drug is unknown *[see Clinical Pharmacology (12.3)]*.

The estimated background risk of major birth defects and miscarriage for the indicated population are unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

6.2 Lactation

Risk Summary

There are no data on the presence of LEVULAN KERASTICK topical solution in either human or animal milk, the effects on the breastfed infant or on milk production. The developmental and health benefits of

breastfeeding should be considered along with the mother's clinical need for LEVULAN KERASTICK topical solution and any potential adverse effects on the breastfeeding child from LEVULAN KERASTICK topical solution or from the underlying maternal condition.

8.4 Pediatric Use

The safety and effectiveness in pediatric patients below the age of 18 have not been established. Actinic keratosis is not a disease generally seen in the pediatric population.

8.5 Geriatric Use

Of the 512 subjects in Phase 3 clinical trials of LEVULAN KERASTICK topical solution, 63% (321/512) were 65 years old and over, while 24% (123/512) were 75 years old and over. No overall differences in safety or substantial differences in effectiveness were observed between these subjects and younger subjects, but greater sensitivity of some older individuals cannot be ruled out.

OVERDOSAGE

10.1 LEVULAN KERASTICK Topical Solution Overdose

In the event that the drug is ingested, monitoring and supportive care are recommended. The patient should be advised to avoid incidental exposure to intense light sources for at least 40 hours after ingestion. The consequences of exceeding the recommended topical dosage are unknown.

10.2 BLU-U Light Overdose

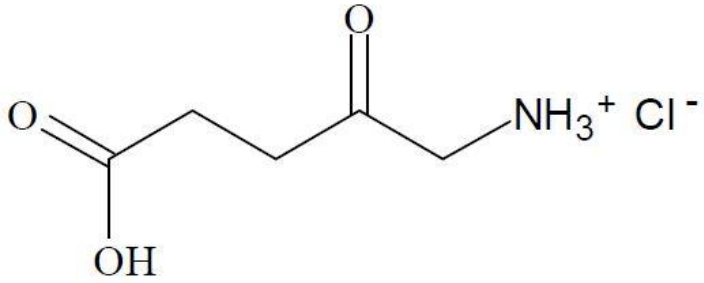
There is no information on overdose of blue light from the BLU-U Blue Light Photodynamic Therapy Illuminator following LEVULAN KERASTICK topical solution application.

11 DESCRIPTION

LEVULAN® KERASTICK® (aminolevulinic acid HCl) for topical solution, 20%, a porphyrin precursor, contains the hydrochloride salt of aminolevulinic acid (ALA), an endogenous 5-carbon aminoketone.

ALA HCl is a white to off-white, odorless crystalline solid that is very soluble in water, slightly soluble in methanol and ethanol, and practically insoluble in chloroform, hexane and mineral oil.

The chemical name for ALA HCl is 5-amino-4-oxopentanoic acid hydrochloride (MW = 167.59). The structural formula is represented below:



The LEVULAN KERASTICK for topical solution applicator is a two-component system consisting of a plastic tube containing two sealed glass ampules and an applicator tip. One ampule contains 1.5 mL of solution vehicle comprising alcohol USP (ethanol content = 48% v/v), water, laureth-4, isopropyl alcohol, and polyethylene glycol. The other ampule contains 354 mg of aminolevulinic acid HCl as a dry solid. The applicator tube is enclosed in a protective cardboard sleeve and cap. The 20% topical solution is prepared just prior to the time of use by breaking the ampules and mixing the contents by shaking the LEVULAN KERASTICK applicator. "LEVULAN KERASTICK for topical solution" refers to the drug product in its unmixed state, "LEVULAN KERASTICK topical solution" refers to the mixed drug product (in the applicator tube or after application), and "LEVULAN KERASTICK" refers to the applicator only.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Following the application of LEVULAN KERASTICK topical solution, photosensitization occurs through the metabolic conversion of aminolevulinic acid to protoporphyrin IX (PpIX), a photosensitizer, which accumulates in the skin.

When exposed to light of appropriate wavelength and energy, the accumulated photoactive porphyrins produce a photodynamic reaction, resulting in a cytotoxic process dependent upon the simultaneous presence of oxygen. The absorption of light results in an excited state of porphyrin molecules, and subsequent spin transfer from photoreactive porphyrins to molecular oxygen generates singlet oxygen, which can further react to form superoxide and hydroxyl radicals. LEVULAN KERASTICK Photodynamic Therapy of actinic keratoses is the combination of photosensitization by application of the LEVULAN KERASTICK topical solution to the lesions and subsequent illumination with BLU-U Blue Light Photodynamic Therapy Illuminator.

12.2 Pharmacodynamics

ALA does not exhibit fluorescence, while PpIX has a high fluorescence yield. Time-dependent changes in surface fluorescence have been used to determine PpIX accumulation and clearance in actinic keratoses and perilesional skin after application of the LEVULAN KERASTICK topical solution in 12 subjects. Peak fluorescence intensity was reached in 11 ± 1 hr in actinic keratoses and 12 ± 1 hr in perilesional skin. The mean clearance half-life of fluorescence for lesions was 30 ± 10 hr and 28 ± 6 hr for perilesional skin. The fluorescence in perilesional skin was similar to that in actinic keratoses. Therefore, the LEVULAN KERASTICK topical solution should only be applied to the affected skin.

12.3 Pharmacokinetics

Two human pharmacokinetic (PK) studies were conducted in subjects with minimally to moderately thick actinic keratoses on the upper extremities, having at least 6 lesions on one upper extremity and at least 12 lesions on the other upper extremity. A single dose comprising of two topical applications of LEVULAN KERASTICK topical solution (each containing 354 mg ALA HCl) were directly applied to the lesions and occluded for 3 hours prior to light treatment.

The first PK study was conducted in 29 subjects and PK parameters of ALA were assessed. The baseline-corrected mean ± SD of the maximum concentration (C_{max}) of ALA was 249.9 ± 694.5 ng/mL and the median time to reach C_{max} (T_{max}) was 2 hr post dose. The mean ± SD exposure to ALA, as expressed by area under the concentration time curve (AUC_t) was 669.9 ± 1610 ng·hr/mL. The mean ± SD elimination half-life ($T_{1/2}$) of ALA was 5.7 ± 3.9 hr.

A second PK study was conducted in 14 subjects and PK parameters of ALA and PpIX were measured. The baseline-corrected PpIX concentrations were negative in at least 50% of samples in 50% (7/14) subjects and AUC could not be estimated reliably. The baseline-corrected mean ± SD of C_{max} for ALA and PpIX was 95.6 ± 120.6 ng/mL and 0.95 ± 0.71 ng/mL, respectively. The median T_{max} of ALA and PpIX was 2 hr post dose and 12 hr post dose, respectively. The mean AUC_t of ALA was 261.1 ± 229.3 ng·hr/mL. The mean ± SD $T_{1/2}$ of ALA was 8.5 ± 6.7 hr.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

No carcinogenicity testing has been carried out using ALA. No evidence of mutagenic effects was seen in four studies conducted with ALA to evaluate this potential. In the *Salmonella-Escherichia coli*/mammalian microsome reverse mutation assay (Ames mutagenicity assay), no increases in the number of revertants were observed with any of the tester strains. In the *Salmonella-Escherichia coli*/mammalian microsome reverse mutation assay in the presence of solar light radiation (Ames mutagenicity assay with light), ALA did not cause an increase in the number of revertants per plate of any of the tester strains in the presence or absence of simulated solar light. In the L5178Y TK± mouse lymphoma forward mutation assay, ALA was evaluated as negative with and without metabolic activation under the study conditions. PpIX formation was not demonstrated in any of these in vitro studies. In the in vivo mouse micronucleus assay, ALA was considered negative under the study exposure conditions. In contrast, at least one report in the literature has noted genotoxic effects in cultured rat hepatocytes after ALA exposure with PpIX formation. Other studies have documented oxidative DNA damage in vivo and in vitro as a result of ALA exposure.

No assessment of effects of ALA HCl on fertility has been performed in laboratory animals. It is unknown what effects systemic exposure to ALA HCl might have on fertility or reproductive function.

14 CLINICAL STUDIES

14.1 Actinic Keratoses of the Face or Scalp

LEVULAN KERASTICK for topical solution plus blue light at 6-10.9 J/cm^2, has been used to treat actinic keratoses of the face or scalp in 342 subjects in seven clinical trials. Phase 3 trials ALA-018 and ALA-019 were two, identically designed, multicenter, two-arm trials using LEVULAN KERASTICK topical solution plus illumination from the BLU-U Blue Light Photodynamic Therapy Illuminator for 1000 seconds (16 minutes and 40 seconds) for a nominal exposure of 10 J/cm^2. Subjects were excluded from these trials who had a history of cutaneous photosensitization, porphyria, hypersensitivity to porphyrins, photodermatosis, or inherited or acquired coagulation defects. A minimum of 4 and a maximum of 15 clinically typical, discrete, Grade 1 (slightly palpable actinic keratoses: better felt than seen), or Grade 2 (moderately thick actinic keratoses: easily seen and felt) target actinic keratoses were identified (see Table 5 for definitions). Target lesions on the face or on the scalp, but not on both locations in the same subject, received treatment. The subjects were randomized to receive treatment either with the LEVULAN KERASTICK topical solution plus BLU-U Blue Light Photodynamic Therapy Illuminator or vehicle plus BLU-U Blue Light Photodynamic Therapy Illuminator. Subjects were randomized at a 3 to 1 LEVULAN KERATICK topical solution to vehicle ratio. A total of 243 subjects were enrolled in two Phase 3 trials (ALA-018, ALA-019). Lesions were designated as cleared (complete response) if the lesion had completely cleared and adherent scaling plaques of actinic keratoses were no longer evident on the surface of the treated skin when palpated. The percentage of subjects in whom 75% or more of treated lesions were cleared, and the percentage of subjects in whom 100% of treated lesions were cleared (Complete Responders), for each trial 8 weeks after treatment are shown in Table 4.

TABLE 4 – Subject Responses at Week 8

	ALA-018		ALA-019	
	LEVULAN KERASTICK Topical Solution + PDT	Vehicle + PDT	LEVULAN KERASTICK Topical Solution + PDT	Vehicle + PDT
	Subjects with ≥ 75% of Actinic Keratosis Lesions Cleared			
Total No. Subjects	68/87 (78%)	6/29 (21%)	71/93 (76%)	8/32 (25%)
Subjects with Face Lesions	57/71 (80%)	2/21 (10%)	57/67 (85%)	7/19 (37%)
Subjects with Scalp Lesions	11/16 (69%)	4/8 (50%)	14/26 (54%)	1/13 (8%)
	Complete Responders			
Total No. Subjects	60/87 (69%)	4/29 (14%)	59/93 (63%)	4/32 (13%)
Subjects with Face Lesions	49/71 (69%)	2/21 (10%)	47/67 (70%)	4/19 (21%)
Subjects with Scalp Lesions	11/16 (69%)	2/8 (25%)	12/26 (46%)	0/13 (0%)

Because ALA-018 and ALA-019 had identical protocols, the combined results from the two trials are shown in the following tables. For actinic keratoses with a variety of thicknesses (excluding very thick, Grade 3 actinic keratoses which were not studied in the Phase 3 trials), LEVULAN KERASTICK topical solution plus

BLU-U Blue Light Photodynamic Therapy Illuminator is more effective than vehicle plus BLU-U Blue Light Photodynamic Therapy Illuminator, but as shown in Table 5, the percentage of lesions with complete responses at 8 weeks after treatment with LEVULAN KERASTICK topical solution plus blue light illumination was lower for those lesions that were thicker at baseline. Efficacy of LEVULAN KERASTICK topical solution plus BLU-U Blue Light Photodynamic Therapy Illuminator on higher grade lesions was not studied in the Phase 3 clinical efficacy trials.

TABLE 5 Lesions Complete Responses at Week 8 for Different Lesion Grades

Lesion Grade	LEVULAN KERASTICK Topical Solution + PDT	Vehicle + PDT
Grade 1 (slightly palpable actinic keratoses: better felt than seen)	666/756 (88%)	122/302 (40%)
Grade 2 (moderately thick actinic keratoses: easily seen and felt)	495/632 (78%)	52/199 (26%)
Grade 3 (very thick and/or hyperkeratotic actinic keratoses)	0	0

Those subjects who were not Complete Responders at Week 8 had retreatment of the persistent target lesions at Week 8. Among the subjects undergoing retreatment, efficacy results seen at 12 weeks after the initial treatment, i.e., at 4 weeks after the second treatment, are shown in Table 6.

TABLE 6 Complete Responders at Week 12, Among Subjects Receiving Two Treatments

	LEVULAN KERATICK Topical Solution + PDT	Vehicle + PDT
Total No. Subjects	24/56 (43%)	2/49 (4%)
Subjects with Face Lesions	21/40 (53%)	2/31 (6%)
Subjects with Scalp Lesions	3/16 (19%)	0/18 (0%)

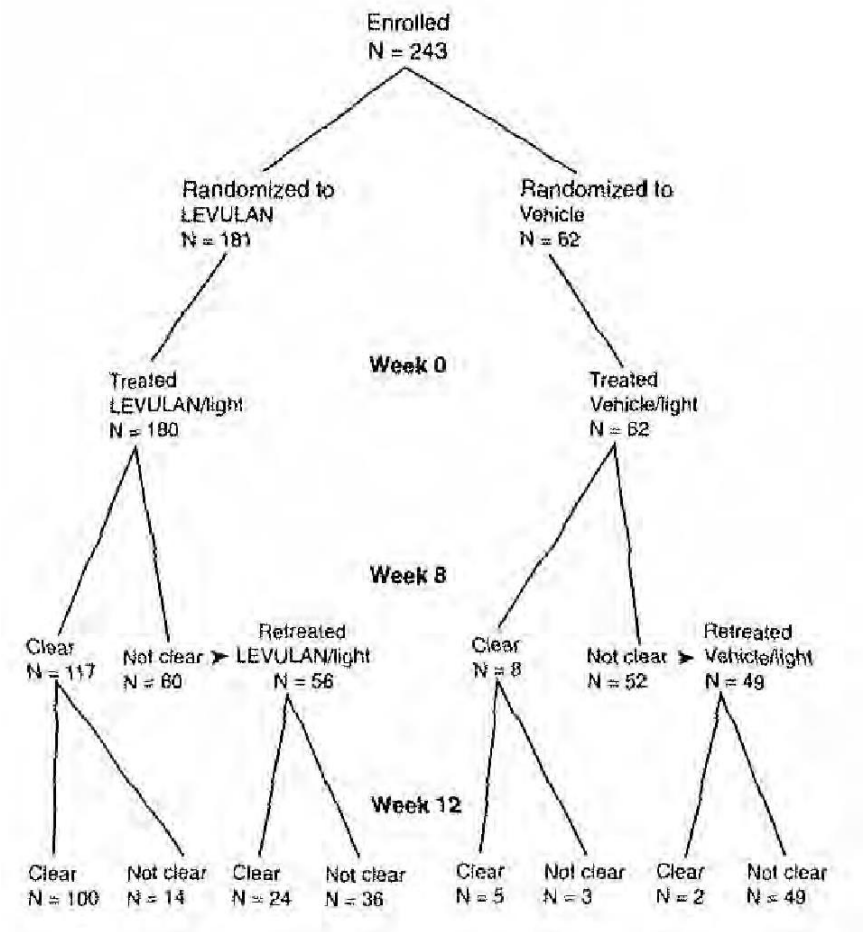
The efficacy results seen at 12 weeks after treatment, which include the results at 12 weeks for those subjects who received a single treatment as well as the results at 12 weeks for those subjects who received a second treatment at week 8, are shown in Table 7.

TABLE 7 Subject Responses at Week 12, Among Subjects Who Received One or Two Treatments

	LEVULAN KERASTICK Topical Solution + PDT	Vehicle + PDT
	Subjects with $\geq$ 75% of Actinic Keratosis Lesions Cleared	
Total No. Subjects	158/180 (88%)	12/61 (20%)
Subjects with Face Lesions	127/138 (92%)	8/40 (20%)
Subjects with Scalp Lesions	31/42 (74%)	4/21 (19%)
	Complete Responders	
Total No. Subjects	129/180 (72%)	7/61 (11%)
Subjects with Face Lesions	108/138 (78%)	5/40 (13%)
Subjects with Scalp Lesions	21/42 (50%)	2/21 (10%)

Among Complete Responders at Week 8, 93% (in ALA-018) and 83% (in ALA-019) maintained complete response at Week 12. Among subjects with scalp lesions, the percentage of subjects with 100% of actinic keratosis lesions having complete response declined from Week 8 (55%) to Week 12 (50%), because there were more subjects with scalp lesions with 100% of actinic keratosis lesions cleared at Week 8 who had a recurrence of a lesion by Week 12 than there were subjects with scalp lesions who had retreatment of persistent lesions at Week 8 and who then achieved 100% of actinic keratosis lesions cleared by Week 12. Subjects did not receive follow-up past 12 weeks after the initial treatment.

Subject outcomes recorded in the two Phase 3 trials are depicted in the following flowchart, in which Complete Responders are designated clear. Seven subjects in the active treatment arm and three subjects in the vehicle treatment arm withdrew or were lost to follow-up. Three subjects in the active treatment arm were treated at baseline but did not return for evaluation until Week 12. One subject in the active treatment arm and two in the vehicle treatment arm who were not clear at Week 8 did not receive retreatment.



An open-label trial enrolled 110 subjects with 4 to 10 clinically typical, discrete actinic keratoses on the face or scalp, but not both locations. The target lesions were treated with the LEVULAN KERASTICK topical solution plus BLU-U Blue Light Photodynamic Therapy Illuminator. Any treated lesions that were not clear

at Month 2 (Week 8) were re-treated. Subjects were followed monthly for 12 months. Lesions were designated as cleared if the lesion had completely cleared and adherent scaling plaques of actinic keratoses were no longer evident on the surface of the treated skin when palpated. The percentages of subjects in whom 100% of treated lesions were cleared (Complete Responders) by month, starting at Month 3 (Week 12), are shown in Figure 4. Of the 72 subjects with 100% of treated lesions cleared (Complete Responders) at Month 3, 53% had a recurrence by Month 12. A total of 748 individual lesions were treated; 539 were treated once and 209 were treated twice. At Month 3, 624 lesions (83%) were cleared. From Month 3 through Month 12 of the trial, 476 lesions (64%) remained clear. See Figure 5. Of the 624 treated lesions determined cleared at Month 3, 24% had recurred by Month 12, while 5% were lost to follow-up and their recurrence status is unknown.

Figure 4
Percent of Subjects With 100% of Treated Lesions Cleared (Complete Responders) by Month (N=110 Subjects)

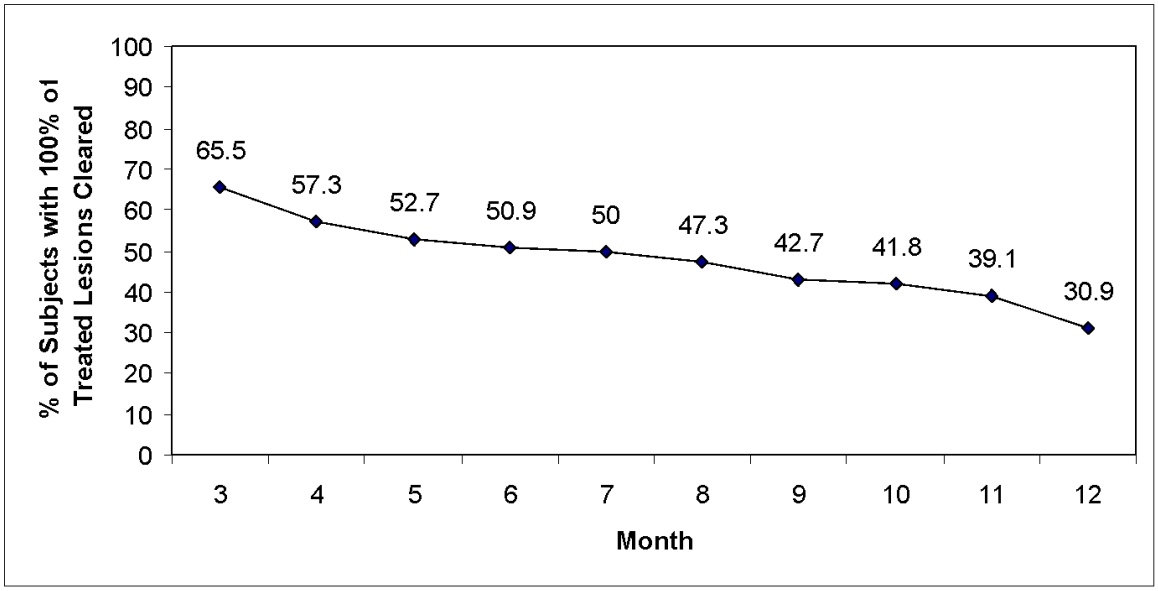
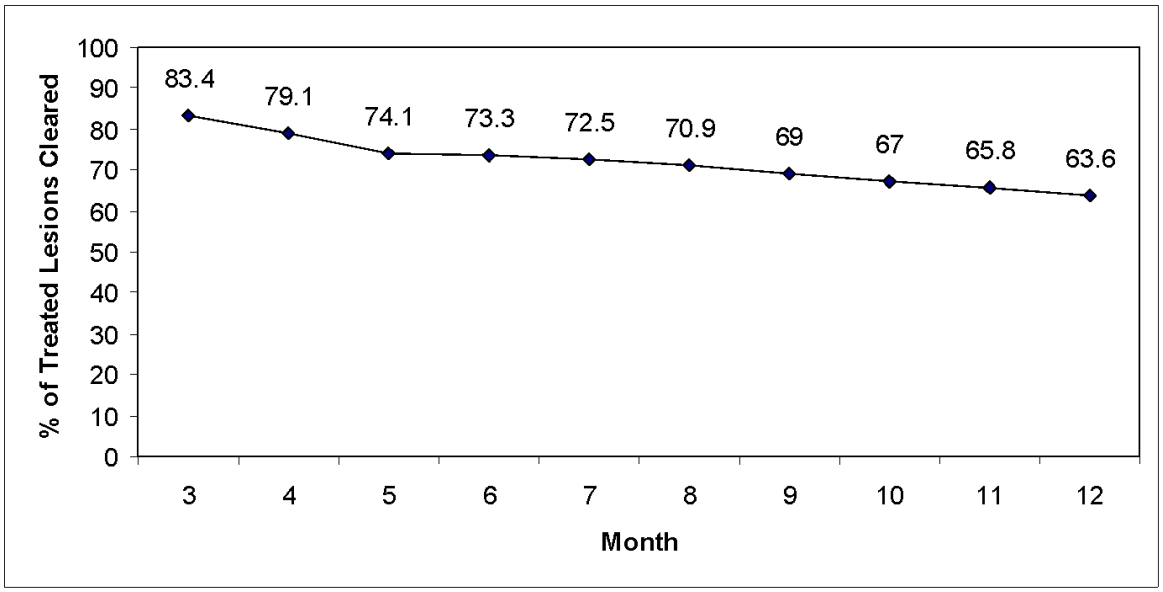


Figure 5
Percent of Lesions Cleared at Month 3 and Remaining Clear Through Month 12 (N=748 Lesions)



14.2 Actinic Keratoses of the Upper Extremities:

The safety and efficacy of LEVULAN KERASTICK topical solution plus BLU-U Blue Light Photodynamic Therapy Illuminator at 10J/cm^2 to treat actinic keratoses of the upper extremities has been evaluated in a multicenter randomized, parallel-group, evaluator-blinded, vehicle-controlled trial of 269 subjects.

In this trial (CP0108), 269 subjects with 4 -15 mild to moderate actinic keratoses on the upper extremities (dorsal hand/forearm area between the elbow and the base of the fingers) were treated with LEVULAN KERASTICK topical solution and BLU-U Blue Light Photodynamic Therapy Illuminator. Subjects ranged from 45 to 90 years of age (mean 68 years) and 90% had Fitzpatrick Skin Type I, II or III. No subjects had Fitzpatrick Skin Type V or VI. Approximately 70% of subjects were male and all subjects were Caucasian.

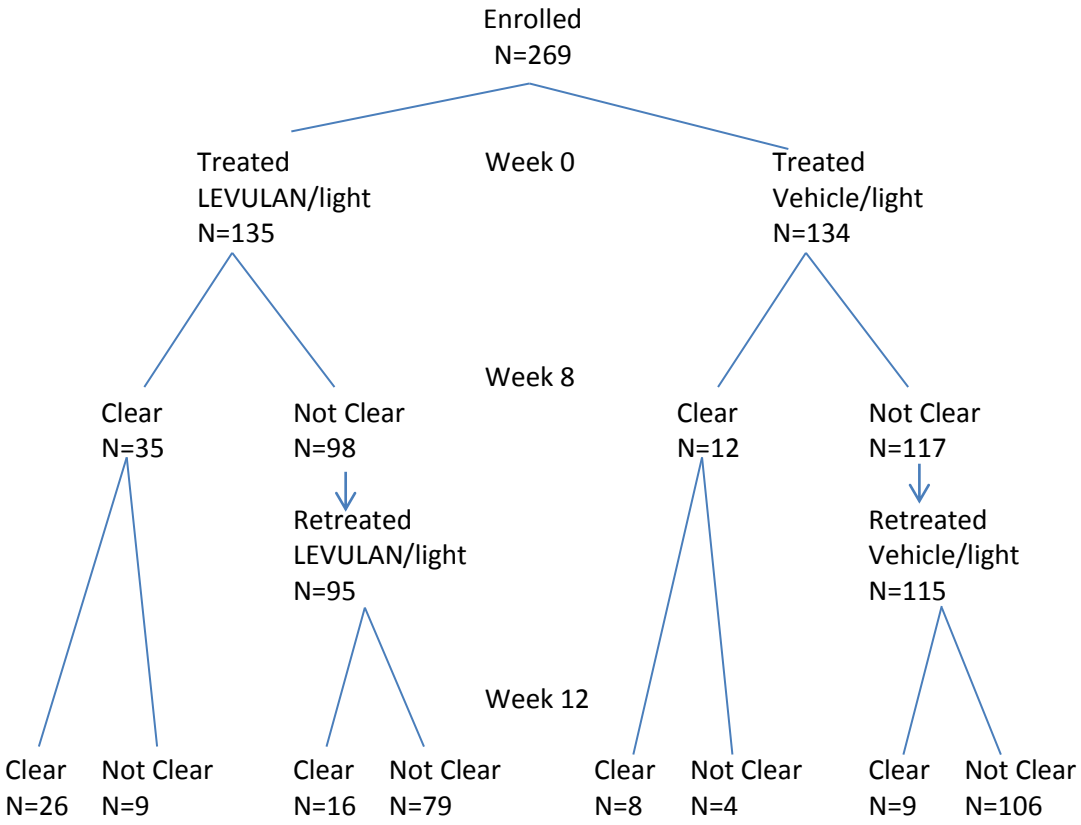
Subjects were randomized to treatment in a 1:1 ratio to receive either LEVULAN KERASTICK topical solution or vehicle. Treatment was applied to 4-15 lesions on one dorsal hand/forearm on each subject, and occluded for the three-hour incubation period before treatment with 10 J/cm^2 blue light delivered at 10 mW/cm^2. Treatment was repeated at Week 8 if any actinic keratosis lesions were present in the treatment area.

The primary endpoint was the proportion of subjects with complete clearance of all actinic keratosis lesions in the treatment area 12 weeks after initial treatment. The results of the trial are presented in Table 8.

Table 8 – Number and Percentage of Subjects with Actinic Keratosis of the Upper Extremities Achieving Complete Clearance at Week 12

	LEVULAN KERASTICK Topical Solution + PDT	Vehicle + PDT
CP0108	42/135 (31%)	17/134 (13%)

Subject outcomes recorded in the trial of the upper extremities are depicted in the following flowchart.



Subjects who achieved complete clearance at Week 12 entered a 12-month follow-up period. Subjects who received LEVULAN KERASTICK topical solution with blue light and achieved complete clearance at Week 12 in CP0108A had a recurrence rate of 58% (22/38) at 12 months, where recurrence was defined as the presence of at least one previously treated lesion in the treatment area at any visit during the 12-month follow-up period.

16 HOW SUPPLIED/STORAGE AND HANDLING

16.1 How Supplied

The LEVULAN KERASTICK for topical solution, 20%, is supplied in packs of 6 applicators. Each LEVULAN KERASTICK applicator is for single use and 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 354 mg of aminolevulinic acid HCl. The applicator is covered with a protective cardboard sleeve and cap.

16.2 Product Package – NDC Number

Carton of 6 LEVULAN KERASTICK for topical solution, 20% applicators 67308-101-06

16.3 Storage

Store between 20° - 25 °C (68° - 77 °F); excursions permitted to 15°- 30 °C (59° - 86 °F) [See USP Controlled Room Temperature]. The LEVULAN KERASTICK topical solution should be used immediately following preparation (dissolution). Solution application must be completed within 2 hours of preparation. An applicator that has been prepared must be discarded 2 hours after mixing (dissolving) and a new LEVULAN KERASTICK applicator used, if needed.

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Patient Information).

Photosensitivity

Advise patients that after LEVULAN KERASTICK topical solution has been applied, the treatment site will become photosensitive and that they should avoid exposure of the photosensitive treatment sites to sunlight or bright indoor light (e.g., examination lamps, operating room lamps, tanning beds, or lights at close proximity) for 40 hours. Exposure may result in a stinging and/or burning sensation and may cause erythema and/or edema of the lesions *[see Warnings and Precautions (5.1)]*.

Advise patients to protect treated lesions from the sun by wearing a wide-brimmed hat or similar head covering of light-opaque material, and/or a long-sleeved shirt and/or gloves. Advise patients sunscreens will not protect against photosensitivity reactions caused by visible light. It has not been determined if perspiration can spread the LEVULAN KERASTICK topical solution outside the treatment site to the eye or surrounding skin *[see Warnings and Precautions (5.1)]*.

If for any reason the patient cannot return for blue light treatment during the prescribed period after applying LEVULAN KERASTICK topical solution, advise patients to call the doctor. Advise patient to continue to avoid exposure of the photosensitized lesions to sunlight or prolonged or intense light for at least 40 hours. If stinging and/or burning is noted, exposure to light should be reduced *[see Warnings and Precautions (5.1)]*.

Advise patients to avoid certain medications that may enhance the phototoxic reaction to PDT *[see Drug Interactions (7)]*.

Common Adverse Reactions

Inform patients that treatment with LEVULAN KERASTICK topical solution plus BLU-U Blue Light Photodynamic Therapy Illuminator may result in sensitivity to light, skin irritation and local skin reactions including erythema, edema, stinging/burning, scaling, crusting, oozing, vesiculation, wheal, scabbing, pustules, ulceration, itching, erosion, hypo/hyperpigmentation, bleeding, tenderness, dysesthesia, and dryness.

Manufactured by:

DUSA Pharmaceuticals, Inc.®, a Sun Pharma company
25 Upton Drive
Wilmington, MA 01887

LAB-0530AW, Revision: C

Marketed by:

Sun Dermatology
Princeton, NJ
1-877-533-3872

Revised: 03/2018

PATIENT INFORMATION
LEVULAN® KERASTICK® (LEV-you-lan KER-rah-stick)
(aminolevulinic acid HCl)
for topical solution, 20%

Important: LEVULAN KERASTICK is for use as an in-office treatment. LEVULAN KERASTICK treatment is given by a healthcare provider only and is not for use at home.

What is LEVULAN KERASTICK?

LEVULAN KERASTICK is a prescription medicine used on the skin (topical) with blue light treatment (BLU-U Blue Light Photodynamic Therapy or PDT) for the treatment of minimally to moderately thick actinic keratoses (AK's) of the face, scalp, or upper arms.

It is not known if LEVULAN KERASTICK is safe and effective in children under 18 years of age.

Who should not receive LEVULAN KERASTICK treatment?

Do not receive LEVULAN KERASTICK treatment if you:

- are allergic to aminolevulinic acid HCl or to any of the ingredients in LEVULAN KERASTICK. See the end of this leaflet for a complete list of ingredients in LEVULAN KERASTICK.
- have porphyria or are allergic to porphyrins
- have a skin sensitivity to blue light

Before receiving LEVULAN KERASTICK treatment, tell your healthcare provider about all of your medical conditions, including if you:

- have blood clotting problems
- are pregnant or plan to become pregnant. It is not known if LEVULAN KERASTICK will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if LEVULAN KERASTICK passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby during LEVULAN KERASTICK treatment.

Tell your healthcare provider about all of the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. LEVULAN KERASTICK and other medicines may affect each other causing side effects.

How will I receive LEVULAN KERASTICK treatment?

- **LEVULAN KERASTICK treatment is received in 2 parts:**
  - Your healthcare provider will apply LEVULAN KERASTICK topical solution to your skin lesions. You should not wash the treated areas before you return to your healthcare provider for blue light treatment.
  - After the prescribed amount of time you will return to your healthcare provider for blue light treatment. Call your healthcare provider if you cannot return for blue light treatment during the prescribed time after LEVULAN KERASTICK topical solution has been applied. If you cannot return for blue light treatment, avoid sunlight and bright indoor light for at least 40 hours after LEVULAN KERASTICK topical solution has been applied.
- During blue light treatment, you will likely feel tingling, stinging, prickling, or burning of the treated areas.

What should I avoid during LEVULAN KERASTICK treatment?

After LEVULAN KERASTICK topical solution is applied to your skin you should avoid sunlight or bright indoor light (such as examination lights, operating room lights, tanning beds, or lights that are close to you) for 40 hours. During this time, the treated areas of your skin will become sensitive to light (photosensitive).

Exposure to light during this time may cause you to feel a burning or stinging sensation and may cause your treated lesions to become red or swollen. You should wear appropriate protective apparel such as a wide-brimmed hat, long sleeve shirt, and gloves to protect your treated skin from sunlight and other bright light.

Sunscreen will not protect the treated areas of your skin against sensitivity to light.

What are the possible side effects of LEVULAN KERASTICK?

LEVULAN KERASTICK may cause serious side effects, including:

- **Sensitivity to light (photosensitivity).** See, "What should I avoid during LEVULAN KERASTICK treatment?"
- **Skin irritation.** LEVULAN KERASTICK topical solution contains alcohol and may cause skin irritation if covered or bandaged for longer than 3 hours.

The common side effects of LEVULAN KERASTICK include:

- Local skin reactions including redness, swelling, stinging and burning, scaling, crusting, oozing, pustules, welts, scabbing, itching, erosion, changes in skin color, bleeding, tenderness, changes in the sense of touch, and dryness.

These are not all the possible side effects of LEVULAN KERASTICK.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General Information about LEVULAN KERASTICK

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. You can ask your pharmacist and healthcare provider for information about LEVULAN KERASTICK that is written for health professionals.

What are the Ingredients in LEVULAN KERASTICK?

Active ingredient: aminolevulinic acid HCl

Inactive ingredients: alcohol USP (ethanol content = 48% v/v), water, laureth-4, isopropyl alcohol, polyethylene glycol

Manufactured by:
DUSA Pharmaceuticals, Inc.®, a Sun Pharma company
25 Upton Drive
Wilmington, MA 01887

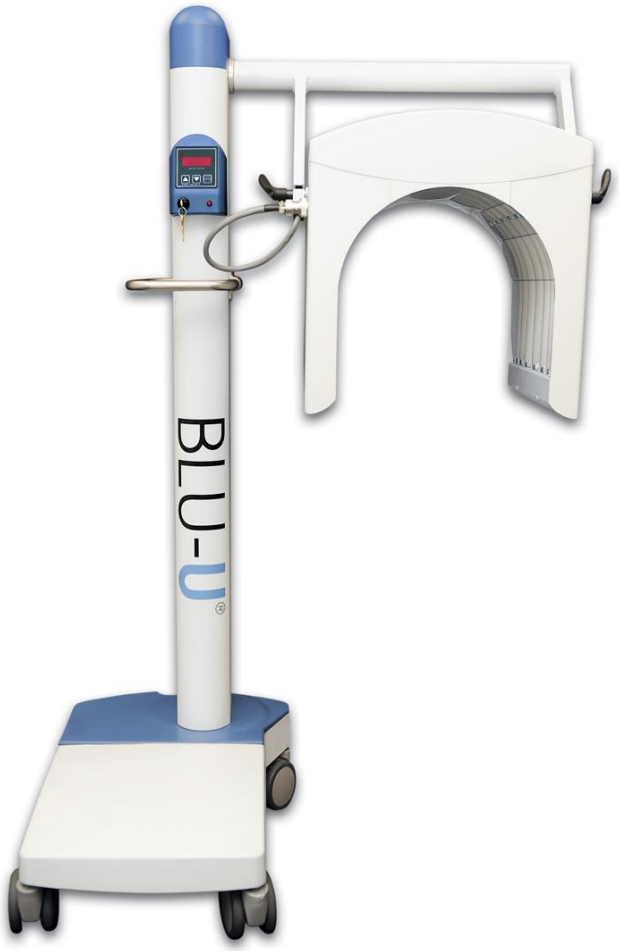
For more information call 1-877-533-3872
www.levulan.com

SUN
DERMATOLOGY

This Patient Information has been approved by the U.S. Food and Drug Administration. Revised: 03/2018

BLU-U® Blue Light Photodynamic Therapy Illuminator Model 4170

Operating Manual



SUN DERMATOLOGY

Operating Manual

OPERATING MANUAL
BLU-U® Blue Light Photodynamic Therapy Illuminator, Model 4170

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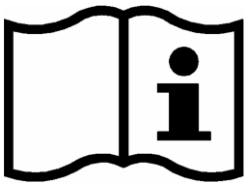
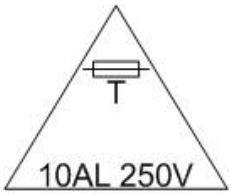
Symbols and Definitions:



Consult Operating Instructions

Caution, consult accompanying documents

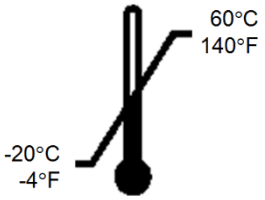
Mandatory, Follow Instructions



Indicates the Electrical Specification and Location of the Required Fuses

Prescription only

Warning, General



Indicates the Temperature Limitations for Storage and Transport

Non-Condensing

Indicates the % Humidity Limitations for Storage and Transport

Indicates Need to Wear Eye Protection

Contains or presence of Natural Rubber Latex

Warning, Dangerous voltage

Call for maintenance

Pushing prohibited

OPERATING MANUAL
BLU-U® Blue Light Photodynamic Therapy Illuminator, Model 4170

Indications for Use:

The **BLU-U®** Blue Light Photodynamic Therapy Illuminator Model 4170, in combination with the Levulan® Kerastick® (aminolevulinic acid HCl) for Topical Solution, 20%, is indicated for the treatment of minimally to moderately thick actinic keratoses (AK) of the face, scalp or upper extremities.

The **BLU-U®** Blue Light Photodynamic Therapy Illuminator Model 4170 is intended to provide phototherapeutic light to the body. The **BLU-U®** 4170 is generally indicated to treat dermatological indications. The **BLU-U®** 4170 is specifically indicated to treat moderate inflammatory acne vulgaris.

Cautions and Warnings:

	**WARNING:** The BLU-U® Blue Light Photodynamic Therapy Illuminator, in combination with the Levulan® Kerastick® for Topical Solution, 20% is indicated for the treatment of minimally to moderately thick actinic keratoses of the face, scalp or upper extremities. Do not use this device with other photosensitizing drugs. Refer to the Levulan® Kerastick® for Topical Solution, 20% Package Physician Insert for additional information. When using the BLU-U® for acne, do not use this device with photosensitizing drugs.
	**WARNING:** All personnel should read and understand the instructions in this manual before the system is used. Failure to do so may result in improper operation of the system.
	**WARNING:** Use only eyewear which blocks light with wavelengths of at least 500nm and shorter with an Optical Density (OD) of two or greater.
	**WARNING:** To avoid the risk of electrical shock, this equipment must only be connected to a supply mains with protective earth.
	**WARNING:** Never attempt to service the device when it is connected to a power source. Hazardous voltages inside the device may cause severe electrical shock. Disconnect the power cord before servicing.
	**WARNING:** Do not allow fluids to enter the device. Damage to the device may result.
	**CAUTION:** The device should not be serviced or opened except by qualified service technicians. Tampering by unqualified persons may cause damage to the unit or personal injury.
RxOnly	**CAUTION:** U.S. Federal law restricts this device to sale by or on the order of a physician or properly licensed medical practictioner.
	**CAUTION:** The patient goggles may contain natural rubber latex (NRL) which may cause allergic reactions.

	If there are any concerns about NRL allergies, the physician or medical practitioner should check the medical product (patient goggles) label to determine if the product of interest contains NRL.
	**WARNING:** When transporting or moving the device, take caution by making sure the device is in the transport position and utilize the handle to move the device.
	**CAUTION:** This electronic device may interfere with other electronic devices. If there is any interference, move the device to another part of the room.

Product Specifications:

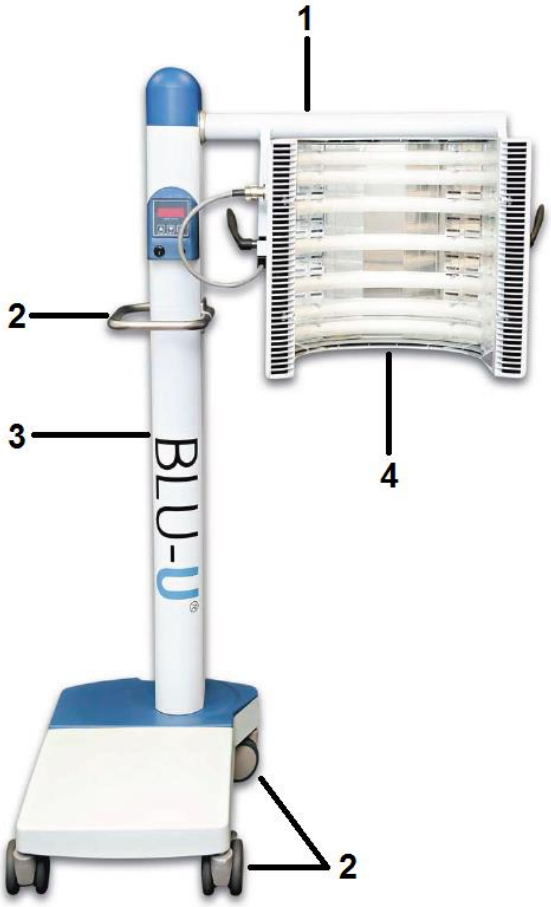
The **BLU-U®** is an electrical Class I device designed for indoor use only. It has been tested to and is compliant with IEC 60601-1:2005.

The **BLU-U®** is listed as a Group Risk 1 Lamp Classification per IEC 60601-2-57 and IEC 62471.

The **BLU-U®** is compliant with the IEC 60601-1-2 (CISPR 11, Group 1, Class A) requirements for EMC emissions. General specifications are listed below.

Power cord	3-conductor hospital grade electrical cord
Power requirements	120/220 - 240 VAC; 60/50 Hz; 2.5/1.5 A
Footprint (light unit + stand)	Width Open: 92.7 cm (36.5 inches) Closed: 49.5 cm (19.5 inches) Depth Open: 67.31 cm (26.5 inches) Closed: 80.1 cm (31.5 inches) Height Minimum: 130.8 cm (51.5 inches) Maximum: 167.6 cm (66.0 inches)
Overall dimensions of the light unit	Width: 52.71 cm (20.75 inches) Depth: 47.63 cm (18.75 inches) Height: 38.74 cm (15.25 inches)
Weight (light unit + stand)	70 kg (155 lbs.)
Operating Temperature Range	20 – 30° C (68 – 86° F)
Spectral Irradiance (E_s)	1.78 E-05
Maximum Power Output	10 J/cm^2 @ 1,000 seconds
Maximum Output Variation	417 nm ±5 nm

Product Diagram:



① Adjustable height positioning of the unit for treatment flexibility.

② Large casters and post handle for easier mobility.

③ A pivoting post for compact storage and easy movement within the treatment facility.

④ Seven (7) continuous wave linear fluorescent lamps.

Description:

The **BLU-U®** is a compact light source designed to provide a uniform distribution of blue light to areas of the patient's face, scalp or upper extremities for the use stated above. It is comprised of 7 horizontally mounted U-shaped fluorescent tubes within a plastic chassis. The tubes are covered by a polycarbonate shield, which directs cooling airflow within the unit and significantly minimizes the risk of glass-patient contact in the event of tube breakage.

The **BLU-U®** is mounted on a floor-stand, which permits rapid positioning as well as adjustment for patient height. The control panel is also affixed to the floor stand.

The **BLU-U®** has a built-in power output monitoring and diagnostic system, which illuminates a neon light to inform the user of the system's status.

The **BLU-U®** has a system timer used to set the light dose delivered to the patient.

The **BLU-U®** is rated for short-time operation.

Controls:

Controls for the **BLU-U®** are located on the floor stand.

Caution – Use of controls or adjustments or performance of procedures other than those specified herein could result in improper operation of the system.

Main Power Switch:

The **Main Power Switch** is a two-position rocker switch, labeled "**I**" and "**0**," located next to the electrical cord.

I	=	ON
0	=	OFF

Push the **Main Power Switch** to "**I**" to turn on power to the system.
Push the **Main Power Switch** to "**0**" to disconnect all electrical components within the **BLU-U®** from the AC line.

Key Switch:

The **Key Switch** is the "ON/OFF" switch for the **BLU-U®** and requires a special key to operate.

➔ Remove the key and store it securely whenever the unit is not in use, to prevent unauthorized use of the **BLU-U®**.

Turn the **Key Switch** to "**I**" to turn on power to the **BLU-U®** control electronics. This activates the **Timer** so that the prescribed exposure time can be entered. When activated, the timer will remember and display the last treatment time setting.

Note:
When the Key Switch is turned off, it should not be turned back on again for at least thirty (30) seconds to ensure that the control electronics have properly powered down and reset.

Timer:

The system **Timer** is used to control the operation of the fluorescent tubes. Use the Timer to:

- Set the exposure time,
- Initiate light exposure,
  and after the set exposure time has elapsed,
- Automatically turn off the tubes.

The following buttons control operation of the Timer:

BUTTON	FUNCTION / OPERATION
Time Select 	**The Time Select buttons are used to set the exposure time**. Depress the ↑ (up arrow) button to increase time. Depress the ↓ (down arrow) button to decrease time. When first depressed, these buttons change the displayed reading slowly; if they remained depressed, the display changes quickly. Depressing and releasing these buttons quickly makes small adjustments to the displayed time.
Start/Stop	**The Start/Stop button toggles between the *running* and *stopped* states of the Timer and Tubes.**

	After the exposure time has been set, depress this button once to turn on the tubes and initiate the **Timer** countdown sequence. Depress it a second time to turn off the tubes and stop the **Timer**.

Note:
If the light treatment for actinic keratoses of the face, scalp or upper extremities is interrupted, see the Levulan® Kerastick® for Topical Solution, 20% package physician insert for further details before proceeding.

If the light treatment for acne is interrupted, reset and continue treatment.

Indicator Lights:

Indicator lights for the **BLU-U®** are located on the control panel on the floor stand.

INDICATOR	FUNCTION / OPERATION
System Status Indicator	The Indicator light, located near the **Timer**, indicates system status. At the beginning of each light treatment, the **System Status Indicator** flashes three (3) times to indicate that the system control electronics and the neon light are functioning normally, and that the **BLU-U®** is ready for use.

If **System Status Indicator** light fails to flash three (3) times immediately after the initiation of timed light treatment, the **BLU-U®** *should not be used* until the problem has been identified or a qualified service technician has serviced the unit. (*See the* **Troubleshooting Table**)

If a patient has been dosed with the Levulan® Kerastick® for Topical Solution, 20%, for the treatment of actinic keratoses of the face, scalp or upper extremities, see the Levulan® Kerastick® for Topical Solution, 20% Package Physician Insert for further instructions on early termination or cancellation of light treatment.

If the **System Status Indicator** lights at any other time, refer to **Table 1** on the following page.

System Status Indicator Error Conditions:

Table 1

CONDITION	ACTION
Rapid Flashing Continuous rapid flashing of the **System Status Indicator** immediately after initiation of the timed light treatment indicates a problem with the electronic control system. If this happens, the **BLU-U®** will not be operational and will not light.	Discontinue the treatment. Turn the **Key Switch** and the **Main Power Switch** to the "**0**" (off) position, and call for service. *If the patient has been dosed with the Levulan® Kerastick® for Topical Solution, 20%, see the Levulan® Kerastick® for Topical Solution, 20% Package Physician Insert for further instructions on early termination or cancellation of light treatment.*
Slow Flashing Continuous slow flashing of the **System Status Indicator** (3 flashes every 4 seconds) after initiation of the timed light treatment indicates that either: • The **BLU-U®** output power is too high, or • A problem exists with the **BLU-U®** electronic control system.	Discontinue the treatment. Turn the **Key Switch** and the **Main Power Switch** to the "**0**" (off) position, and call for service. *If the patient has been dosed with the Levulan® Kerastick® for Topical Solution, 20%, see the Levulan® Kerastick® for Topical Solution, 20% Package Physician Insert for further instructions on early termination or cancellation of light treatment.*
Steady On The **System Status Indicator** lights steadily during the treatment (for at least 10 seconds at a time) This indicator code, which may occur after initiation of the timed light treatment, indicates that: • The **BLU-U®** output power is too low, or • The end of tube lifetime has been reached.	• Complete the treatments of any patients who have already been dosed with the Levulan® Kerastick®, and • Call for service.
Exposure Time Indicator	This four-digit red LED located on the Timer unit displays the remaining exposure time in minutes and seconds. Prior to pushing the Start button to begin light exposure, the display indicates the amount of exposure time set. When you press the Start button, the *Exposure Time Indicator* display counts down the amount of exposure time remaining. The tubes turn off automatically when the display reaches "00:00".

Head Position Lock:

To lock the head position rotate handle clockwise. To unlock head rotate handle counter-clockwise see Figure 1.

Figure 1

Instructions for Use with the Levulan® Kerastick® for the Treatment of Actinic Keratoses:

Note - If a patient's light treatment is interrupted, terminated prematurely, or cannot be administered, see the Levulan® Kerastick® for Topical Solution, 20% Package Physician Insert for important further instructions.

Initial Set-Up:

1. Inspect the unit power fuse holder to ensure the correct line voltage has been selected.
2. Be sure **NOT** to have the unit placed/positioned flush against a wall that will block access to the AC inlet module.
3. Plug the female end of the supplied electrical cord into the mating jack on the floor stand base and plug the other end into a standard 120/220 - 240 VAC outlet.
4. Press the **Main Power Switch** to the "**I**" (on) position.

Set-Up:

1. Using the key, turn the **Key Switch** to the "**I**" (on) position. Verify that the red **Timer** display is active.
2. Position the eye protection on the patient prior to treatment. Place the eye protection over the patient's eyes and ensure the eye protection is secure against the patient's face. Verify that the eye protection does not cover or shadow any area intended for treatment.
3. Place the patient in an upright, sitting position. **The procedure for positioning the BLU-U® depends on the location of the lesions to be treated and is found in the following 2 sections**. The patient's head may be supported during treatment. Ensure that the method of head support does not cover or shadow any area intended for treatment.

Procedure for Treating Lesions on the Face:

1. Loosen the knobs on either side of the light unit and rotate it to the vertical position (the "U" shaped bulbs stacked vertically). Retighten the knobs to lock the light unit in place. To lock the height of the light-head, tighten the "head position lock" handle (which is located in back) by rotating the handle in a clockwise direction.
2. Position the **BLU-U®** around the patient's head so the entire surface area to be treated lies between 2" and 4" from the **BLU-U®** surface:
   a.) The patient's nose should be ***no closer*** than 2" from the surface
   and
   b.) The patient's forehead and cheeks should be ***no further*** than 4" from the surface
   and
   c.) The sides of the patient's face and the patient's ears should be ***no closer*** than 2" from the **BLU-U®** surface

Note:
The patient's hair should not cover or shadow the area to be treated. However, the patient's hair may be closer than 2" to the surface of the BLU-U® without any deleterious effects.

3. Set the **Timer** to the prescribed treatment time of 16 minutes 40 seconds by depressing the *Time Select* buttons. Continue to depress these buttons until the correct time is displayed.
4. Ensure that all personnel are wearing appropriate eye protection and then depress the *Start/Stop* button on the **BLU-U® Timer**. The **System Status Indicator** will flash three (3) times and go off. *If it does not flash three times, try the remedies in the **Troubleshooting Table (Table 2)**. If the **System Status Indicator** still does not flash three times, do not use the **BLU-U®** even if the **Timer** works and the tubes light; system output may be incorrect under these circumstances. [See the Levulan® Kerastick® for Topical Solution, 20% Package Physician Insert for further instructions on cancellation of light treatment.]*
5. Verify that all seven tubes are lit. If one or more does not light, discontinue the light treatment and **call for service**. See the Levulan® Kerastick® for Topical Solution, 20% Package Physician Insert for further details on early termination or cancellation of light treatment.
6. Periodically check the **System Status Indicator**. If the **System Status Indicator** lights during treatment, see "System Status Indicator Error Conditions" (Table 1) in the Controls section.
7. Take care that the patient does not move during the time the **BLU-U®** is on as this may result in under exposure of the lesion(s).
8. At the end of the treatment period, the **Timer** will automatically turn off the **BLU-U®**.

Following Patient Treatment:

1. Remove the patient from the **BLU-U®** and remove the patient's eye protection.
2. Turn the **Key Switch** on the **BLU-U®** to the "**0**" position
3. Remove the key from the **BLU-U®** and store it in a secure location where unauthorized personnel cannot use it.

Procedure for Treating Lesions on the Scalp:

1. Loosen the knobs on either side of the light unit and rotate it to the horizontal position (the "U" shaped bulbs stacked horizontally). Retighten the knobs to lock the light unit in place.
2. Position the **BLU-U®** around the patient's head so the entire surface area to be treated lies between 2" and 4" from the **BLU-U®** surface:
   a.) The patient's scalp should be ***no closer*** than 2" from the surface
   and
   b.) The patient's scalp should be ***no further*** than 4" from the surface
   and
   c.) The sides of the patient's face and the patient's ears should be ***no closer*** than 2" from the **BLU-U®** surface

Note:
The patient's hair should not cover or shadow the area to be treated. However, the patient's hair may be closer than 2" to the surface of the BLU-U® without any deleterious effects.

3. Set the **Timer** to the prescribed treatment time of 16 minutes 40 seconds by depressing the *Time Select* buttons. Continue to depress these buttons until the correct time is displayed. To lock the height of the light-head, tighten the "head position lock" handle (which is located in back) by rotating the handle in a clockwise direction.
4. Ensure that all personnel are wearing appropriate eye protection and then depress the *Start/Stop* button on the **BLU-U® Timer.** The **System Status Indicator** will flash three (3) times and goes off. *If it does not flash three times, try the remedies in the* ***Troubleshooting Table*** *(Table 2). If the* ***System Status Indicator*** *still does not flash three times, do not use the* ***BLU-U®*** *even if the* ***Timer*** *works and the tubes light; system output may be incorrect under these circumstances. [See the Levulan® Kerastick® for Topical Solution, 20% Package Physician Insert for further instructions on cancellation of light treatment.]*
5. Verify that all seven tubes are lit. If one or more does not light, discontinue the light treatment and call customer service. See the Levulan® Kerastick® for Topical Solution, 20% Package Physician Insert for further details on early termination or cancellation of light treatment.
6. Periodically check the **System Status Indicator**. If the **System Status Indicator** lights during treatment, see "System Status Indicator Error Conditions" (Table 1) in the Controls section.
7. Take care that the patient does not move during the time the **BLU-U®** is on as this may result in under exposure of the lesion(s).
8. At the end of the treatment period, the **Timer** will automatically turn off the **BLU-U®**.

Following patient treatment:

1. Remove the patient from the **BLU-U®** and remove the patient's eye protection.
2. Turn the **Key Switch** on the **BLU-U®** to the "**0**" position.
3. Remove the key from the **BLU-U®** and store it in a secure location where unauthorized personnel cannot use it.

Procedure for Treating Lesions on the Upper Extremities:

1. Loosen the knobs on either side of the light unit and rotate it to the horizontal position (the "U" shaped bulbs stacked horizontally). Retighten the knobs to lock the light unit in place.
2. Position the **BLU-U®** around the patient's upper extremities so the entire surface area to be treated lies between 2" and 4" from the **BLU-U®** surface:

   a. The patient's upper extremities should be ***no closer*** than 2" from the surface

   and

   d.) The patient's upper extremities should be ***no further*** than 4" from the surface

3. Set the **Timer** to the prescribed treatment time of 16 minutes 40 seconds by depressing the *Time Select* buttons. Continue to depress these buttons until the correct time is displayed. To lock the height of the light-head, tighten the "head position lock" handle (which is located in back) by rotating the handle in a clockwise direction.
4. Ensure that all personnel are wearing appropriate eye protection and then depress the *Start/Stop* button on the **BLU-U® Timer.** The **System Status Indicator** will flash three (3) times and goes off. *If it does not flash three times, try the remedies in the **Troubleshooting Table** (Table 2). If the **System Status Indicator** still does not flash three times, do not use the **BLU-U®** even if the **Timer** works and the tubes light; system output may be incorrect under these circumstances. [See the Levulan® Kerastick® for Topical Solution, 20% Package Physician Insert for further instructions on cancellation of light treatment.]*
5. Verify that all seven tubes are lit. If one or more does not light, discontinue the light treatment and call customer service. See the Levulan® Kerastick® for Topical Solution, 20% Package Physician Insert for further details on early termination or cancellation of light treatment.
6. Periodically check the **System Status Indicator**. If the **System Status Indicator** lights during treatment, see "System Status Indicator Error Conditions" (Table 1) in the Controls section.
7. Take care that the patient does not move during the time the **BLU-U®** is on as this may result in under exposure of the lesion(s).
8. At the end of the treatment period, the **Timer** will automatically turn off the **BLU-U®**.

Following patient treatment:

1. Remove the patient from the **BLU-U®** and remove the patient's eye protection.
2. Turn the **Key Switch** on the **BLU-U®** to the "**0**" position.
3. Remove the key from the **BLU-U®** and store it in a secure location where unauthorized personnel cannot use it.

Instructions for Use for the Light Only Treatment of Acne:

Initial Set-Up:

1. Inspect the unit power fuse holder to ensure the correct line voltage has been selected.
2. Be sure **NOT** to have the unit placed/positioned flush against a wall that will block access to the AC inlet module.
3. Plug the female end of the supplied electrical cord into the mating jack on the floor stand base and plug the other end into a standard 120/220 - 240 VAC outlet.

4. Press the **Main Power Switch** to the "**I**" (on) position.

Set-Up:

1. Using the key, turn the **Key Switch** to the "**I**" (on) position. Verify that the red **Timer** display is active.
2. Position the eye protection on the patient prior to treatment. Place the eye protection over the patient's eyes and ensure the eye protection is secure against the patient's face. Verify that the eye protection does not cover or shadow any area intended for treatment.
3. Place the patient in an upright, sitting position. The patient's head may be supported during treatment. Ensure that the method of head support does not cover or shadow any area intended for treatment.

Procedure for treating Acne:

1. Loosen the knobs on either side of the light unit and rotate it to the vertical position (the "U" shaped bulbs stacked vertically). Retighten the knobs to lock the light unit in place. To lock the height of the light-head, tighten the "head position lock" handle (which is located in back) by rotating the handle in a clockwise direction.
2. For treatment of the face, position the **BLU-U®** around the patient's head so the entire surface area to be treated lies between 2" and 4" from the **BLU-U®** surface:
   a.) The patient's nose should be ***no closer*** than 2" from the surface
   and
   b.) The patient's forehead and cheeks should be ***no further*** than 4" from the surface
   and
   c.) The sides of the patient's face and the patient's ears should be ***no closer*** than 2" from the **BLU-U®** surface.

Note:
The patient's hair should not cover or shadow the area to be treated. However, the patient's hair may be closer than 2" to the surface of the BLU-U® without any deleterious effects.

3. Set the **Timer** for the desired treatment time by depressing the *Time Select* buttons. Continue to depress these buttons until the correct time is displayed. The recommended exposure time is 16 minutes and 40 seconds per treatment (10 joules/cm²). Light treatments should be performed two to three times per week until the desired clinical results have been achieved with a maximum recommended total cumulative light exposure of 320 joules/cm².
4. Ensure that all personnel are wearing appropriate eye protection and then depress the *Start/Stop* button on the **BLU-U® Timer**. The **System Status Indicator** will flash three (3) times and go off. *If it does not flash three times, try the remedies in the **Troubleshooting Table (Table 2)**. If the **System Status Indicator** still does not flash three times, do not use the **BLU-U®** even if the **Timer** works and the tubes light; system output may be incorrect under these circumstances.*
5. Verify that all seven tubes are lit. If one or more does not light, discontinue the light treatment and **call for service**.
6. Periodically check the **System Status Indicator**. If the **System Status Indicator** lights during treatment, see "System Status Indicator Error Conditions" (Table 1) in the Controls section.
7. Take care to minimize patient movement during the time the **BLU-U®** is in use.

8. At the end of the treatment period, the **Timer** will automatically turn off the **BLU-U®**.

Following Patient Treatment:

1. Remove the patient from the **BLU-U®** and remove the patient's eye protection.
2. Turn the **Key Switch** on the **BLU-U®** to the "**0**" position
3. Remove the key from the **BLU-U®** and store it in a secure location where unauthorized personnel cannot use it.

Troubleshooting/Service and Repair:

CAUTION: Components of the system should not be opened, except by a Qualified Service Person. Tampering by Unqualified Persons can the person and/or damage the unit.

The following chart has been included to assist in determining a solution for a problem or error.

Troubleshooting Table:

Table 2

SYMPTOM	POSSIBLE CAUSE	WHAT TO DO
No power / Fans not running / No **Timer** display upon turning **Key Switch** to the "**I**" (on) position.	**BLU-U®** is not plugged in.	Verify that the proper line voltage has been selected on the fuse holder. Verify that the **BLU-U®** is plugged into a standard 120/220 - 240 VAC wall outlet.
	No power is present at the wall outlet.	Verify that power is present at the outlet.
	Main Power Switch is not set to "**I**" (on).	Verify that the **Main Power Switch** is in the "**I**" (on) position.
	Key Switch is not fully turned to "**I**" (on).	Verify that the **Key Switch** is in the "**I**" (on) position by rotating it clockwise 1/4 turn until a "click" is felt. If the fans now run, but the **Timer** still does not light or lights intermittently, there is an internal electrical fault. In this case use of the **BLU-U®** will not be possible. Call for service.

SYMPTOM	POSSIBLE CAUSE	WHAT TO DO
	One or more fuses in the Fused Power Entry Module have blown.	Check the fuses in the Fused Power Entry Module, located next to the socket for the electrical cord on the base of the floor stand. • Turn the **Key Switch** and **Main Power Switch** to the "**0**" (off) position. • Unplug the unit. • With a small screwdriver, slide out the fuse holder. • Check the status of the two fuses by using the fuse key. If either or both fuses are blown (as indicated by a break in the thin wire connecting the two metal ends of the fuse), replace with two (2) 10A fuses provided in the Fuse Kit Assembly (D1015). • Reinsert the fuse holder with the desired voltage reading right side up. • Plug the unit into a standard 120/220 - 240 VAC wall outlet. • Turn the **Main Power Switch** and **Key Switch** to the "**I**" (on) position.
		•
		If normal operation does not resume or the fuse continues to blow, there is an internal electrical fault. In this case use of the **BLU-U®** will not be possible. Call for service.
	Internal electrical fault.	Use of the **BLU-U®** will not be possible. Call for service.
System Status Indicator does not flash three (3) times when the *Start/Stop* button on the **Timer** is pressed	Neon light or control circuitry is not functioning properly.	Discontinue use of the **BLU-U®**. Call for service.
System Status Indicator rapidly flashing *Tubes not lit*	Control circuitry is not functioning properly.	Use of the **BLU-U®** will not be possible. Call for service.
System Status Indicator slowly flashing *Tubes lit*	Power output is above specified range.	Discontinue use of the **BLU-U®**. Call for service.
	Control circuitry is not functioning properly.	Discontinue use of the **BLU-U®**. Call for service.
System Status Indicator on steady or intermittently *Tubes lit*	Power output is below specified range.	Complete treatment of patients. Call for service.

SYMPTOM	POSSIBLE CAUSE	WHAT TO DO
Tubes not all lit	Tube(s) cracked or broken.	Discontinue use of the **BLU-U®**. Call for service.
	Control circuitry is not functioning properly.	Discontinue use of the **BLU-U®**. Call for service.
Timer Display Illuminated, tubes and fans not operating.	Improper orientation of fuse holder in the Fused Power Entry Module.	Verify proper orientation of fuse holder in the Fused Power Entry Module, located next to the socket for the electrical cord on the base of the floor stand. • Turn the **Key Switch** and **Main Power Switch** to the "**0**" (off) position. • Unplug the unit. • With a small screwdriver, slide out the fuse holder. • Reinsert the fuse holder with the desired voltage reading right side up. • Plug the unit into a standard 120/220 - 240 VAC wall outlet. • Turn the **Main Power Switch** and **Key Switch** to the "**I**" (on) position. If normal operation does not resume call customer service to receive further instructions.
F001 Error Code Displayed on **Timer**	**Timer** error	With the **Key Switch** turned to "**I**" (on), press the *Start/Stop* button to clear the **Timer** display. If normal operation does not resume call customer service to receive further instructions.
F101 Error Code Displayed on **Timer**	**Timer** error	Call customer service to receive further instructions.
F002 Error Code Displayed on **Timer**	Improper orientation of fuse holder in the Fused Power Entry Module.	Verify proper orientation of fuse holder in the Fused Power Entry Module, located next to the socket for the electrical cord on the base of the floor stand. • Turn the **Key Switch** and **Main Power Switch** to the "**0**" (off) position. • Unplug the unit. • With a small screwdriver, slide out the fuse holder. • Reinsert the fuse holder with the desired voltage reading right side up. • Plug the unit into a standard 120/220 - 240 VAC wall outlet. • Turn the **Main Power Switch** and **Key Switch** to the "**I**" (on) position. If normal operation does not resume call customer service to receive further instructions.

SYMPTOM	POSSIBLE CAUSE	WHAT TO DO
F202 Error Code Displayed on **Timer**	**Timer** error	Call customer service to receive further instructions.
F303 Error Code Displayed on **Timer**	**Timer** error	Call customer service to receive further instructions.
Err Error Code Displayed On Tinmer	**Timer error**	Call customer service to receive further instructions.

Transport and Storage:

WARNING: When transporting or moving the device, take caution by making sure the device is in the transport position and utilize the handle to move the device.

1. The **BLU-U®** can be safely stored in a cool dry area. Care should be taken to avoid rough handling or jarring of the unit.
2. **Storage Conditions:**
   - -20°C to 60°C (-4°F to 140°F)
   - 0 to 95% RH, Non-Condensing
3. Place post in storage mode prior to transporting the **BLU-U®**, see Figure 2.

Step 1: Lift latch.

Step 2: Rotate post 90° clockwise, release latch.

Figure 2

Cleaning/Disinfecting:

	**WARNING:** Turn power off and disconnect the power cord before cleaning the machine. Failure to do so may result in severe electrical shock or death.
	**CAUTION:** Never immerse machine in liquids. Do not use abrasive materials to clean the machine. Do not allow water to enter this device. Do not clean the inside of this device. Doing so will cause damage to this machine.

1. The exterior surface of the **BLU-U®** may be wiped down with a mild disinfectant or isopropyl alcohol. Dry with a clean dry cloth.

2. The outside surface of the plastic shield may be wiped down with a mild disinfectant or isopropyl alcohol. Dry with a clean dry cloth.

3. If goggles are used for eye protection, their surface may be wiped down with a mild disinfectant or isopropyl alcohol after each use. Dry with a clean dry cloth.

Calibration and Preventive Maintenance:

1. The **BLU-U®** is calibrated during manufacuring and does not require calibration or preventive maintenance.

Disposal of Unit:

1. Follow all local, governmental and/or international laws and regulations when disposing of the **BLU-U®**.

Customer Service:

For service, repair, or calibration of this equipment call:

DUSA Pharmaceuticals, Inc. ®

Phone: 1-877-533-3872

or

978-657-7500

Warranty Coverage and Disclamers:

See the Terms and Conditions of your contract for specific information.

Manufactured For:
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OPERATING MANUAL
BLU-U® Blue Light Photodynamic Therapy Illuminator, Model 4170

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Revised: 03/2018