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LEVULAN®
KERASTICK® + BLU-U®
(aminolevulinic acid HCl) + Blue Light Photodynamic Therapy
Illuminator Model #170
for Topical Solution, 20%

Treatment
Landscape

About LEVULAN®
KERASTICK® + BLU-U®

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THE TREATMENT LANDSCAPE

Treat AKs early and powerfully.

**APPROXIMATELY
1 IN 10 AK LESIONS
WILL TURN INTO
SKIN CANCER.⁹**

AKs are the most common epithelial precancerous lesions. While AK lesions are often thought of as surface lesions, they can reach a depth of 1.86 mm below the surface, which is within the epidermis.¹⁰⁻¹²

If the cells that extend below the surface are not removed during treatment, they can progress into squamous cell carcinoma (SCC) or basal cell carcinoma (BCC).^{9,10}

Do not apply to the eyes or to mucous membranes. The most common local adverse reactions (incidence $\geq 10\%$) were erythema, edema, stinging/burning, scaling/crusting, itching, erosion, hypo/hyperpigmentation, oozing/vesiculation/crusting, scaling and dryness.²



Why use LEVULAN® KERASTICK® + BLU-U®?

Photodynamic therapy (PDT) utilizes light in conjunction with a photosensitizing agent (protoporphyrin [PpIX]) to produce singlet oxygen within the epidermis that results in subsequent cell death.^{4,13}

Not all light sources are designed the same because:

- Red light penetrates much deeper into the skin, surpassing the depth of AK lesions, causing unnecessary exposure to deeper tissue^{4,11}
- BLU-U covers an active working area of 214 square inches—14 times larger than the red light of other PDT treatments^{6,7}
- The patented U-shaped design of BLU-U allows for uniform light coverage of the treatment area in a single illumination session⁶

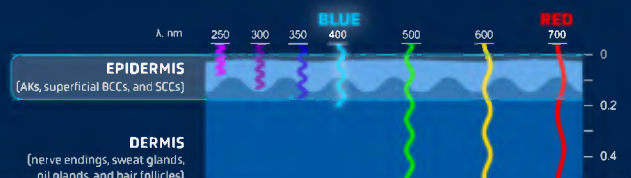
LEVULAN KERASTICK + BLU-U can offer you and your patients:

- The ability to treat multiple AK lesions over a larger area and precisely penetrate down to the root of AK^{4,14}
- Minimal risk of scarring—there were no accounts of scars reported in clinical trials^{2,4,13}
- An in-office treatment option—no required extra effort at home²



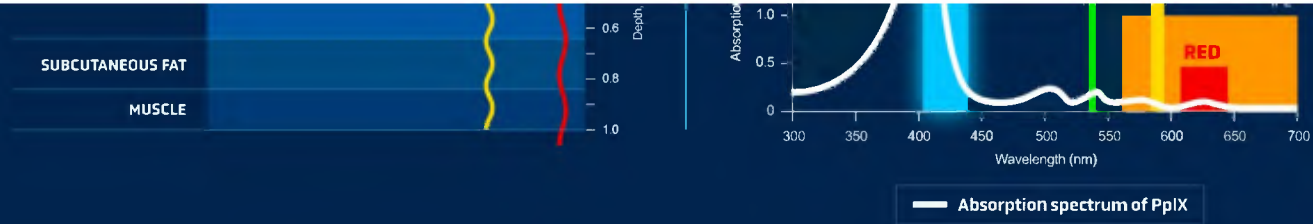
The depth and wavelength of BLU-U were designed to precisely attack AKs, while avoiding unnecessary exposure to deeper tissue^{2,4,6}

The BLU-U depth of penetration corresponds with the location of AKs (2 mm vs ≥ 1.86 mm) in the epidermis^{4,6,11,12,15}



The BLU-U wavelength is matched to protoporphyrin IX's peak absorption (417 nm $\pm$ 5 vs 410 nm)^{4,6,8,12}





*KTP=Potassium titanyl phosphate laser. PDL=Pulsed dye laser. IPL=Intense pulsed light.

BLU-U blue light is **6-10X more efficient** than other light sources in treating AKs because the wavelength is matched to the PPIX peak absorption.^{4,6,8,12}



Important Safety Information

LEVULAN® KERASTICK® (aminolevulinic acid HCl) for topical solution, 20%, plus blue light illumination using the BLU-U® Blue Light Photodynamic Therapy Illuminator is indicated for the treatment of minimally to moderately thick actinic keratoses of the face or scalp, or actinic keratosis of the upper extremities.

Contraindicated in patients with cutaneous photosensitivity at wavelengths of 400–450 nm, porphyria, or known allergies to porphyrins, and in patients with known sensitivity to any of the components of the LEVULAN KERASTICK topical solution.

Application of LEVULAN KERASTICK topical solution should involve lesions on the face or scalp, or upper extremities. Multiple lesions can be treated within a treatment region, but multiple treatment regions should not be treated simultaneously.

Do not apply to the eyes or to mucous membranes. Irritation may be experienced if LEVULAN KERASTICK topical solution is applied to eyes or mucous membranes. Treatment of upper extremities is approved after an incubation time of 3 hours under occlusion. Excessive irritation may be experienced if this product is applied under occlusion longer than 3 hours.

Transient amnesic 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 amnesic episodes. Advise them to contact the healthcare provider if the patient develops amnesia after treatment.

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. To avoid unintended photosensitivity, LEVULAN KERASTICK topical solution should be applied by a qualified health professional to no more than 5 mm of perilesional skin surrounding each target actinic keratosis lesion.

Advise patients to wear a wide-brimmed hat or similar head covering of light-opaque material or a long-sleeved shirt and/or 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. Sunscreens will not protect against photosensitivity reactions caused by visible light. The patient should be advised to reduce light exposure if the sensations of stinging and/or burning are experienced.

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

It is 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 the LEVULAN KERASTICK topical solution.

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.

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

In clinical trials, severe stinging and/or burning was reported by at least 50% of face and scalp patients and 9% of upper extremity patients at some time during treatment. However, 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.

Please refer to the [full Prescribing Information](#) for complete discussion of the risks associated with LEVULAN KERASTICK (aminolevulinic acid HCl) for topical solution, 20%.

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