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LEVULAN®  
KERASTICK®  
for Topical Solution, 30%

BLU-U®  
Blue Light Photodynamic Therapy  
Aluminum Master Kit

Treatment  
Landscape

About LEVULAN®  
KERASTICK® + BLU-U®

Proven  
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## PROVEN RESULTS

In clinical studies of the face and scalp,  
LEVULAN® KERASTICK® + BLU-U®—high clearance, low downtime.

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.<sup>2</sup>

Help your patients achieve up to 100% clearance of actinic keratosis (AK) lesions, which may prevent them from developing squamous cell carcinoma (SCC) or basal cell carcinoma (BCC).<sup>2,10†</sup>

Click through the gallery to view before-and-after photos of real patients.



In multiple clinical studies, LEVULAN KERASTICK + BLU-U demonstrated significant efficacy with a strong safety profile for patients with minimally to moderately thick AKs of the face, scalp, and upper extremities.\*

## Face & Scalp

**72%** of patients had 100% clearance of AK lesions of the face or scalp at Week 12.<sup>2††</sup>

LEVULAN KERASTICK may cause serious side effects, including temporary memory problems, sensitivity to light, and skin irritation.

In the combined Phase III studies, the most common adverse events (≥5%) included scaling/crusting, itching, hypo/hyperpigmentation, erosion, skin disorder NOS, wheal/flare, and vesiculation.<sup>2</sup>

\*Results from a Phase IV open-label multicenter study of patients with AKs on the face or scalp. 28% of the 748 lesions were treated twice. Lesions were designated as cleared if the lesion had completely cleared and adherent scaling plaques were no longer evident on the surface of the treated skin when palpated. Of the 72 subjects with 100% of treated lesions cleared at Month 3, 53% had a recurrence by Month 12. 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.<sup>2</sup>

†78% (108/138) of face patients and 50% (21/42) of scalp patients were clear at 12 weeks after 1 or 2 treatments.<sup>2</sup>

††Results from two identically designed, Phase III studies. These were multicenter, blinded, active treatment-controlled, randomized, uneven parallel group, two-arm studies. A total of 243 patients were randomized at a 3-to-1 LEVULAN KERASTICK PDT-to-vehicle ratio. Patients returned for follow-up visits 24 hours after BLU-U light treatment and at Weeks 1, 4, and 8. Those patients who were not complete responders at Week 8 had retreatment of the persistent target lesions at Week 8. All patients returned at 12 weeks after the initial treatment.<sup>2</sup>

## Upper Extremities

**31% of patients had 100% clearance of AK lesions on the upper extremities.<sup>2§</sup>**

### 12 WEEKS AFTER TREATMENT

42% of upper-extremity patients who were clear at 12 weeks did not have a recurrent lesion in the 12-month follow-up period.<sup>2</sup>

§In a multicenter randomized, parallel-group, evaluator-blind, vehicle-controlled trial of 269 patients, subjects were randomized to a 1:1 ratio to receive either LEVULAN KERASTICK topical solution or vehicle for the treatment of actinic keratoses of the upper extremities (dorsal hand/forearm area between the elbow and the base of the fingers). 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.<sup>2</sup>

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.<sup>2</sup>

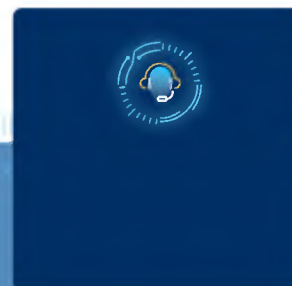
Transient amnesic episodes have been reported during postmarketing use of LEVULAN KERASTICK in combination with BLU-U Blue Light Photodynamic Therapy Illuminator. Inform patients and their caregivers that LEVULAN KERASTICK in combination with PDT may cause transient amnesic episodes. Advise them to contact their healthcare provider if they develop amnesia after treatment.<sup>2</sup>



## Safety Profile

**LEVULAN KERASTICK + BLU-U is proven to destroy AK cells without scarring or permanent bleaching of the skin.<sup>2,4,13</sup>**

- No scarring was reported in clinical trials<sup>2,4,13</sup>
- In clinical trials, at least 50% of patients experienced severe stinging and burning; however, less than 3% discontinued therapy due to stinging and/or burning<sup>2</sup>
- 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<sup>2</sup>



## 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, sulfonamides, 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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