What to expect BEFORE AND AFTER LEVULAN® KERASTICK® (AMINOLEVULINIC ACID HCL) FOR TOPICAL SOLUTION, 20% AND BLU-U® BLUE LIGHT PHOTODYNAMIC THERAPY

LEVULAN® KERASTICK®
(aminolevulinic acid HCl)
for Topical Solution, 20%
+ BLU-U®
Blue Light Photodynamic Therapy
Illuminator Model 4170

Patients following 1 treatment with LEVULAN KERASTICK plus BLU-U

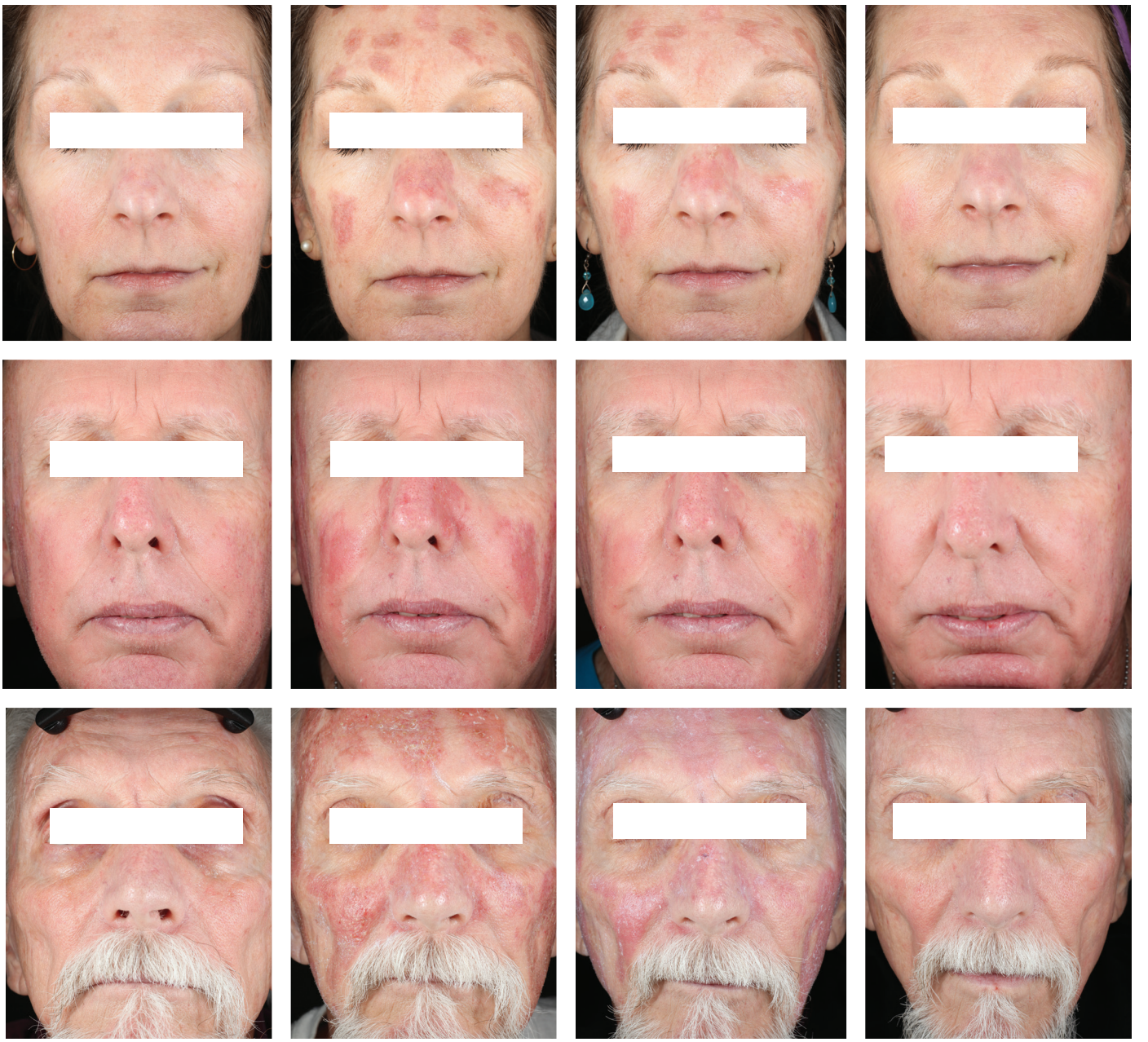

Photo prior to LEVULAN KERASTICK application

Approximately 48 hours post PDT application

Week 1

Week 4

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, scalp, or actinic keratosis of the upper extremities.

Important Safety Information

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

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.

Please see additional Important Safety Information on the back side of this sheet

LEVULAN® KERASTICK® + BLU-U®

(aminolevulinic acid HCl) for Topical Solution, 20%

Blue Light Photodynamic Therapy Illuminator Model 4170

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, scalp, or actinic keratosis of the upper extremities.

Before TREATMENT

- Be sure to tell your physician if you are taking any oral medications or using any topical prescription or nonprescription products on the area to be treated.
- Bring adequate sun-protective items with you to your appointments such as a wide-brimmed hat, long sleeve shirt and/or gloves.

During TREATMENT

TREATMENT STEP 1: Application of LEVULAN KERASTICK Topical Solution

- LEVULAN KERASTICK will be uniformly applied to your AK lesions.
- If the upper extremities were treated, your Qualified Healthcare Professional (QHP) will occlude with low-density polyethylene plastic wrap and hold in place with elastic net dressing.
- Your QHP will then direct you to wait the recommended time in order to allow the solution to penetrate the targeted cells. Then you will return for the second part of your treatment which includes illuminating your treated lesions with the BLU-U blue light.
- You should not wash the treatment area between treatment steps.
- Avoid prolonged exposure of the treated area to bright indoor and outdoor lighting including sunlight for 40 hours after the application of LEVULAN KERASTICK. Sunscreens do not protect against sensitivity to visible light. Protective clothing is most effective for this. Examples include exam room examination lights, operating room lamps, tanning bed lights, and household lights at close range. Sunscreens will not protect against photosensitivity reactions caused by visible light during this time.

TREATMENT STEP 2: BLU-U Treatment

- Before your BLU-U treatment, gently rinse and pat dry the treated area.
- Your treatment with the BLU-U will take approximately 17 minutes.
- Protective eyewear should be worn during your BLU-U treatment.
- You may experience stinging or burning during your BLU-U treatment, but this should subside between 1 minute and 24 hours after the BLU-U is turned off. During studies, the sensation of stinging and/or burning appeared to reach a plateau at 6 minutes into the light treatment.*

After TREATMENT

You may experience these most common side effects:

- Burning/stinging, which could be severe, may last up to 24 hours after your BLU-U treatment.
- Swelling and redness, scaling/crusting may last up to 4 weeks after your BLU-U treatment of the face or scalp. Swelling resolved by 4 weeks and redness resolved by 8 weeks for upper extremities.
- You may apply moisturizers as needed.

* In clinical studies, 9% of subjects undergoing treatment of upper extremities and 50% of subjects undergoing face and scalp studies reported severe stinging during treatment. The majority of patients reported that all lesions treated exhibited at least slight stinging and/or burning.

Important Safety Information

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 mucus 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 amnestic episodes have been reported during postmarketing use of LEVULAN KERASTICK in combination with BLU-U Blue Light Photodynamic Therapy Illuminator. Inform patients and their caregivers that LEVULAN KERASTICK in combination with PDT may cause transient amnestic episodes. Advise them to contact the healthcare provider if the patient develops amnesia after treatment.

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 qualifi ed 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.

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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 specifi ed in the BLU-U Blue Light Photodynamic Therapy Illuminator Operating Instructions.

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.

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 see full Prescribing Information linked here.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

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