HOW LEVULAN® KERASTICK® + BLU-U® WORKS

LEVULAN KERASTICK powerfully strikes AKs.

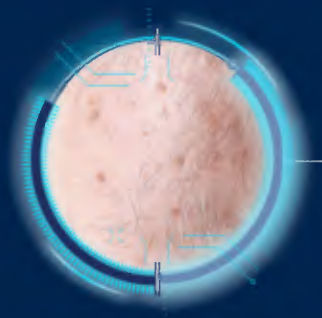
LEVULAN KERASTICK 20% aminolevulinic acid HCl (ALA) has the power to efficiently penetrate to the root of the actinic keratosis (AK) lesions and successfully incite cell death when activated by BLU-U.[2-4]

BLU-U is focused precisely on AKs.

BLU-U delivers light with the precise wavelength, energy, and penetration to activate the photosensitizer protoporphyrin IX (PpIX) after LEVULAN KERASTICK has been applied to AK lesions and allowed to incubate.[2]

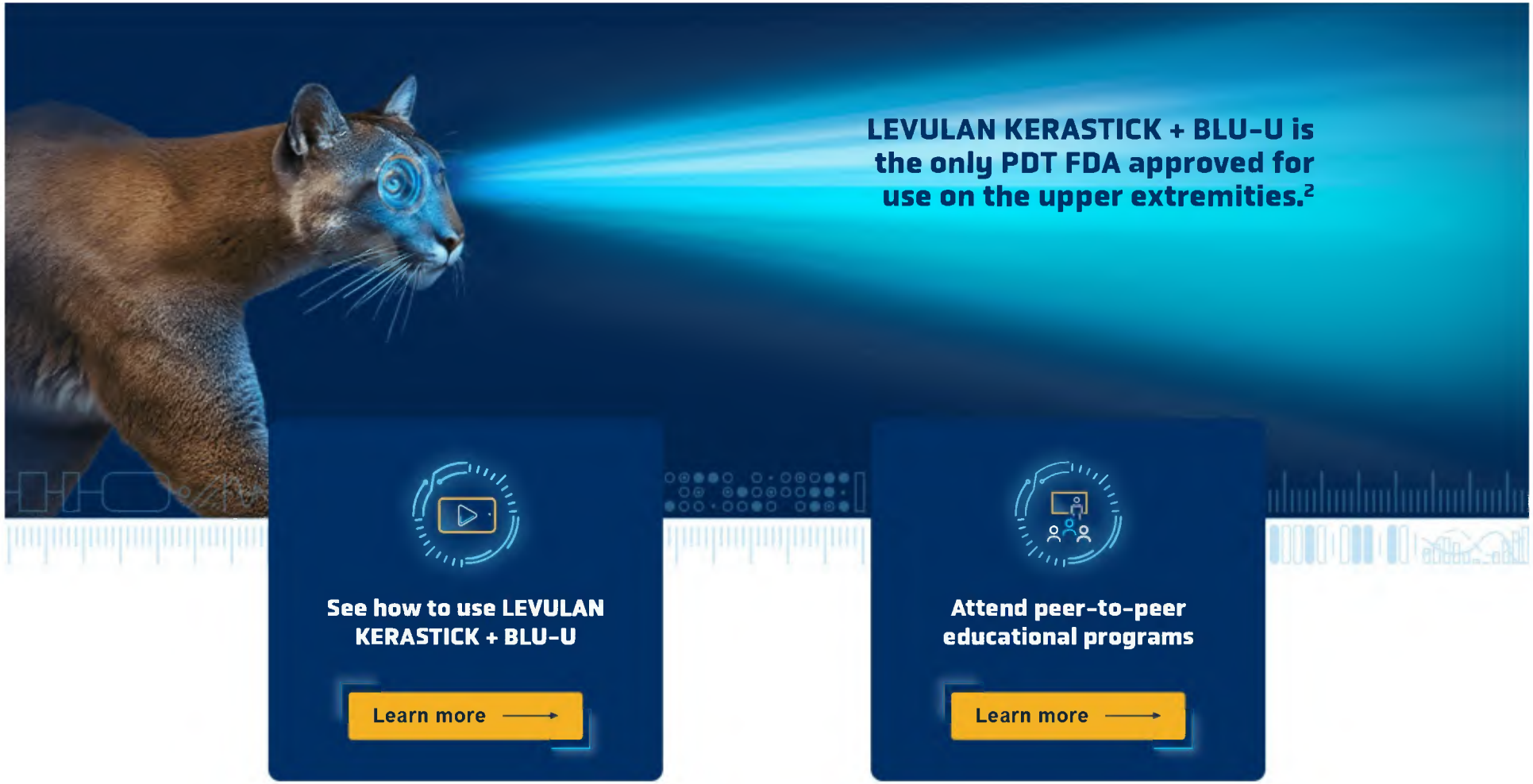
Do not apply to the eyes or to mucous membranes. The most common local adverse reactions (incidence ≥ 10%) were erythema, edema, stinging/burning, scaling/crusting, itching, erosion, hypo/hyperpigmentation, oozing/vesiculation/crusting, scaling and dryness.[2]

With up to 100% clearance in 1-2 treatments, LEVULAN KERASTICK + BLU-U has been the most trusted and reliable photodynamic therapy (PDT) for more than two decades.[1,2]



LEVULAN KERASTICK + BLU-U was designed to target AKs where they exist in the epidermis without unnecessary exposure to deeper tissue.[2,4,6,11]

LEVULAN KERASTICK + BLU-U has been approved to treat minimally to moderately thick AKs of the face or scalp since 1999, and as of 2018, AKs on the upper extremities.[2,5] It is a dual-mechanism PDT that utilizes the power of 20% ALA, a porphyrin precursor present in LEVULAN KERASTICK, and the precision of the BLU-U blue-light source, which is used to activate the topical solution.[2]


LEVULAN KERASTICK + BLU-U is the only PDT FDA approved for use on the upper extremities.[2]
See how to use LEVULAN KERASTICK + BLU-U
Learn more
Attend peer-to-peer educational programs
Learn more

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 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 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 ≥ 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%.

References:

1. Symphony Health. Actinic Keratosis Total Patient Share. June 2018.
2. LEVULAN KERASTICK. Package insert. Sun Pharma; 2020.
3. Nestor MS, Gold MH, Kauvar ANB, et al. The use of photodynamic therapy in dermatology: results of a consensus conference. *J Drugs Dermatol*. 2006;5(2):140-154.
4. MacCormack MA. Photodynamic therapy. *Adv Dermatol*. 2006;22:219-258.
5. US Department of Health and Human Services. FDA approval letter. March 2018.
6. Model 4170 System Specifications. BLU-U® Optical Specifications Document. Wilmington, MA: DUSA Pharmaceuticals, 2006.
7. AMELUZ®. Package insert. Biofrontera Pharma GmbH; 2016.
8. Data on file. Sun Pharmaceutical Industries, Inc. Princeton, NJ.
9. Fuchs A, Marmur E. The kinetics of skin cancer: progression of actinic keratosis to squamous cell carcinoma. *Dermatol Surg*. 2007;33(9):1009-1101.
10. Criscione VD, Weinstock MA, Naylor MF, Luque C, Eide MJ, Bingham SF; Department of Veterans Affairs Topical Tretinoin Chemoprevention Trial Group. Actinic keratoses: natural history and risk of malignant transformation in the Veterans Affairs Topical Tretinoin Chemoprevention Trial. *Cancer*. 2009;115(11):2523-2530.
11. Pyne JH, Myint E, Barr EM, Clark SP, Hou R. Basal cell carcinoma: variation in invasion depth by subtype, sex, and anatomic site in 4,565 cases. *Dermatol Pract Concept*. 2018;8(4):314-319.
12. Lee CN, Hsu R, Chen H, Wong TW. Daylight photodynamic therapy: an update. *Molecules*. 2020;25(21):5195.
13. Patel G, Armstrong AW, Eisen DB. Efficacy of photodynamic therapy vs other interventions in randomized clinical trials for the treatment of actinic keratoses: a systematic review and meta-analysis. *JAMA Dermatol*. 2014;150(12):1281-1288.
14. Taub AF. Photodynamic therapy in dermatology: history and horizons. *J Drugs Dermatol*. 2004;3(1 Suppl):S8-S25.
15. Kochevar I, Taylor C. Photophysics, photochemistry, and photobiology. In: Freedberg IM, Eisen AZ, Wolff K, Austen KF, Goldsmith LA, Katz S, eds. *Fitzpatrick's Dermatology in General Medicine*. 6th ed. McGraw-Hill Professional; 2003:1417-1426.
16. Shergill B, Zokaie S, Carr AJ. Non-adherence to topical treatments for actinic keratosis. *Patient Prefer Adherence*. 2014;8:35-41.

DUSA a SUN PHARMA company | SUN PHARMA