Actinic keratoses (AKs) are precancerous skin lesions that require treatment.¹ There is little dispute among dermatologists about this. When it comes to treating AKs, there are many options to consider, such as topically applied creams and gels, cryosurgery, or photodynamic therapy (PDT). The selection of any of these options will depend on the specific presentation of the AKs and the patient’s individual needs.

For minimally to moderately thick AKs of the face or scalp, Levulan® Kerastick® (aminolevulinic acid HCl) (ALA) for Topical Solution, 20% plus blue light illumination using the BLU-U® Blue Light Photodynamic Therapy Illuminator (“BLU-U”) is a mainstay in my practice. This photodynamic therapy option (ALA-PDT) has easily integrated into my practice, and for years it has consistently given my patients a valuable option for the management of their AKs.

The efficacy of ALA-PDT using Levulan Keratick and BLU-U for the management of minimally to moderately thick actinic keratoses is well established.²³ One key attribute of this photodynamic therapy is that the BLU-U light source allows me to treat multiple different lesions on the face and/or the scalp in one treatment session. It also provides a balance of efficacy and good cosmesis of treated lesions, and unlike cryosurgery, ALA-PDT with Levulan Keratick plus BLU-U is not associated with the potential for scarring.⁴ And most of all, as an in-office treatment, Levulan Keratick plus BLU-U gives me control over therapy application. Ahead, I’ll discuss these factors in additional detail and explain why this photodynamic therapy fits well within my busy practice.

**IN-OFFICE TREATMENT CONTROLS**

Left untreated, an individual AK will progress to squamous cell carcinoma (SCC) at a rate of 0.025% to 16% per year.⁵ Researchers have suggested that nearly three-quarters of SCCs are associated with AKs,⁶ which helps explain why an international consensus agreement advocates for treatment of AK with a primary goal to reduce the risk of conversion to SCC.¹ Historically, topical treatment of AKs has been associated with poor adherence.⁷ Factors influencing patient adherence are the duration of treatment, discomfort associated with the treatment, and local skin reactions (LSRs)—including patients’ desire to hide the appearance of LSRs publically.¹

Unlike in-home therapies, Levulan Kerastick must be administered by a Qualified Health Care Professional in a professional setting (e.g., dermatology office). This in-office control eliminates any concern over whether the patient is receiving the prescribed treatment and at my recommended amount. In-office control means my patient cannot skip an application or inadvertently misapply the topical therapy.

In addition, after application of Levulan Keratick, patients need only avoid exposure of the photosensitive treatment site(s) for 40 hours. In other words, a patient must avoid exposure to sunlight or bright indoor light until they return to the health care professional’s office (14-18 hours later) for BLU-U administration, and then continue to do so for another 22 to 26 additional hours. Failing to comply with this light restriction could result in a stinging and/or burning sensation and may cause erythema or edema of the lesions.

Sunscreens will not protect against photosensitivity reactions caused by visible light after therapy. I should note, however, that once therapy is complete and the patient has recovered in full, I always recommend patients take adequate steps to protect their skin from further damage using sunscreen long-term.

With Levulan Keratick plus BLU-U, there is no long-term treatment protocol or therapy regimen after the in-office...
BLU-U administration. All patients are scheduled for follow-up after PDT, and I believe that post-treatment assessment is important. But if a patient ever is lost to follow-up, I know she completed one full course of therapy.

**ACCOMMODATING PATIENT CONCERNS ABOUT LSRS**

The LSRs associated with topical treatment regimens, including ALA-PDT, may not be the most accommodating treatment method for patients. Indeed, LSRs for topical therapies include erythema and localized swelling, crusting, and oozing—all of which can be very challenging for active patients.

I like the predictability of LSRs resulting from ALA-PDT with Levulan Keratick plus BLU-U. With Levulan Keratick plus BLU-U, the most common LSRs are scaling/crusting, hypo/hyper-pigmentation, itching, stinging, and/or burning, erythema and edema. During the BLU-U treatment, patients feel tingling, stinging, pricking, or burning of the treated areas, although the sensation of stinging and burning appears to plateau around 6 minutes. These feelings generally improve at the end of BLU-U treatment and should end within 24 hours. Following BLU-U treatment, the AKs and, to some degree, the surrounding skin, will redden. Swelling may also occur. These LSRs are temporary and generally improve by the end of the first week, and should be completely resolved by four weeks after treatment.

**DOWNTIME**

AKs can develop at any age, though the incidence understandably increases with age. No matter the age, all patients undergoing ALA-PDT with Levulan Keratick plus BLU-U must avoid exposure of the photosensitive treatment sites for 40 hours post drug application. After this 40 hours, however, patients are generally able to resume their normal activities. Some patients may take up to four weeks of social downtime to wait for the LSRs (e.g., erythema, edema, and peeling) to resolve. Others do not. Retirees who are active in their later years and don’t want to give up leisure and informal social activities, for instance, may not take the full four weeks for all LSRs to resolve. Working patients could schedule their ALA-PDT with Levulan Keratick plus BLU-U on a Thursday or Friday, allowing for partial recovery over the weekend and thus minimizing total time missed from work due to the 40-hour photosensitivity window.

**DEVICE-BASED CARE CENTERS**

My busy southern California office is a leading center for medical device-based care. I strive to offer proven treatments with lasers and light devices that optimize outcomes and represent the leading edge of patient care. That is why I continue to stand by ALA-PDT with Levulan Keratick plus BLU-U as a device-based therapy that fits my practice model.

To this day, ALA-PDT with Levulan Keratick plus BLU-U remains a very good option for many patients who present with minimally to moderately thick actinic keratoses of the face or scalp. I know patients will generally see optimal results from one to two treatments. Patients simply come to my office as directed, avoid sunlight or bright indoor light for 40 hours, and endure a predictable LSR period of up to four weeks. These patients do not need to remember to apply a treatment according to a set schedule and do not need to track treatment off- and on-times. No matter what manner it is dispensed to the patient (in-office or through a pharmacy), I control the product application and the therapy administration.

“As an in-office treatment, Levulan Keratick plus BLU-U gives me control over therapy application.”

Please see Important Safety Information on adjacent page.

**DISCLOSURES**

Dore J. Gilbert, MD, is a consultant to DUSA Pharmaceuticals, Inc., A Sun Pharma Company, and is a member of the Speakers Bureau for DUSA.

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LEVULAN KERASTICK 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.

Application of LEVULAN KERASTICK should involve either scalp or face lesions, but not both simultaneously. LEVULAN KERASTICK should not be applied to the periorbital area or allowed to contact ocular or mucosal surfaces. Excessive irritation may be experienced if this product is applied under occlusion.

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 for Topical Solution.

LEVULAN KERASTICK has not been tested on patients with inherited or acquired coagulation defects. It is possible that concomitant use of other known photosensitizing agents might increase the photosensitivity reaction of actinic keratoses treated with the LEVULAN KERASTICK.

LEVULAN KERASTICK 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.

Patients should avoid exposure of the photosensitive treatment sites to sunlight or bright indoor light for at least 40 hours after LEVULAN KERASTICK application. Exposure may result in a stinging and/or burning sensation and may cause erythema or edema of the lesions. Patients should protect treated lesions from the sun by wearing a wide-brimmed hat or similar head covering of light-opaque material. Sunscreens will not protect against photosensitivity reactions caused by visible light.

Transient local symptoms of stinging and/or burning, itching, erythema, and edema were observed in all clinical studies. Severe stinging and/or burning at one or more lesions being treated was reported by at least 50% of patients at some time during treatment. However, less than 3% of patients discontinued light treatment due to stinging and/or burning.

During light treatment, both patients and medical personnel should be provided with blue blocking protective eyewear, as specified in the BLU-U operating instructions to minimize ocular exposure.

Please see attached full Prescribing Information.
Topical Solution Photodynamic Therapy for actinic keratoses has been tested on patients with inherited or acquired actinic keratoses of the face or scalp. Sunscreens will not protect against photosensitivity reactions caused by the LEVULAN KERASTICK Topical Solution overdose has not been reported. In the unlikely event that the drug is ingested, monitoring and supportive care are recommended. The patient should be advised to avoid accidental exposure to intense light sources for at least 40 hours after ingestion. The consequences of exceeding the recommended topical dosage are unknown.

**ADVERSE REACTIONS**

In Phase 3 studies, no non-cutaneous adverse events were found to be consistently associated with LEVULAN KERASTICK Topical Solution application followed by blue light exposure.

**Photodynamic Therapy Response;** The constellation of transient local symptoms of stinging and/or burning, itching, erythema and edema as a result of LEVULAN KERASTICK Topical Solution plus 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.

In two Phase 3 trials, the sensation of stinging and/or burning appeared to reach a plateau at 6 minutes into the treatment. Severe stinging and/or burning at one or more lesions being treated was reported by at least 50% of the patients at some time during treatment. The majority of patients reported that all lesions treated exhibited at least slight stinging and/or burning. Less than 3% of patients discontinued light treatment due to stinging and/or burning.

In the Phase 3 trials, the most common changes in lesion appearance after LEVULAN KERASTICK for Topical Solution Photodynamic Therapy were erythema and edema. In 99% of active treatment patients, some or all lesions were erythematosus shortly after treatment, while in 79% of vehicle treatment patients, some or all lesions were erythematosus. In 35% of active treatment patients, some or all lesions were edematous, while no vehicle-treatment patients had edematous lesions. Both erythema and edema resolved or baseline or improved by 4 weeks after therapy. LEVULAN KERASTICK Topical Solution application to photosensitized perilesional skin resulted in photosensitization of photosensitized skin and in a photodynamic response (see Warnings and Precautions).

**Other Localized Cutaneous Adverse Experiences:** Table 1 depicts the incidence and severity of cutaneous adverse events in Phase 3 studies, stratified by anatomic site treated.

**Adverse Experiences Reported by Body System:** In the Phase 3 studies, 7 patients experienced a serious adverse event. All were deemed remote or not related to treatment. No clinically significant patterns of clinical laboratory changes were observed for standard serum chemical or hematologic parameters in any of the controlled clinical trials.

**OVERDOSAGE**

LEVULAN KERASTICK Topical Solution overdose has not been reported. In the unlikely event that the drug is ingested, monitoring and supportive care are recommended. The patient should be advised to avoid accidental exposure to intense light sources for at least 40 hours after ingestion. The consequences of exceeding the recommended topical dosage are unknown.

**BLU-U Blue 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.

**Information for Patients:**

- **LEVULAN KERASTICK Photodynamic Therapy for Actinic Keratoses.**
  - The first step in LEVULAN KERASTICK Photodynamic Therapy (PDT) for actinic keratoses is application of the LEVULAN KERASTICK Topical Solution to actinic keratoses located on the patient's face or scalp.