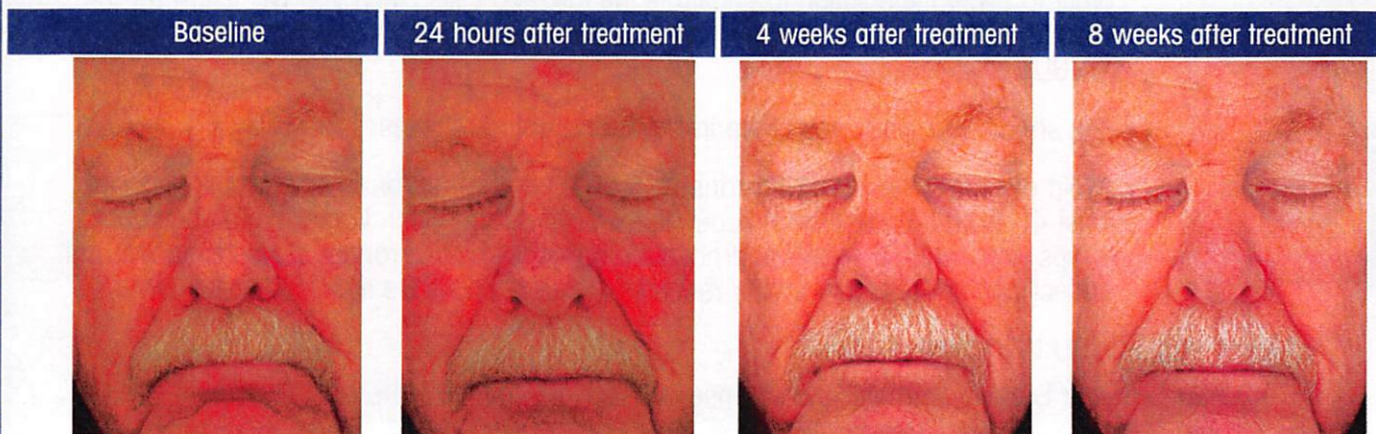


Levulan® PDT treatment: Before and After

Patient 1



Patient 2



Important Risk Information

What is Levulan® Kerastick® used for?

The Levulan Kerastick for Topical Solution 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.

Who should NOT take Levulan?

Levulan Kerastick should not be taken by patients who have cutaneous photosensitivity at wavelengths at 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. There have been no formal studies of the interaction of Levulan Kerastick for Topical Solution with any other drugs and no drug-specific interactions were noted during any of the controlled clinical trials. It is possible that concomitant use of other known photosensitizing agents might increase the photosensitivity reaction of actinic keratoses treated with the Levulan Kerastick. It is important to tell your physician if you are taking any oral medications or using any topical prescription or non-prescription products on your face or scalp. Tell your doctor if you are pregnant or nursing.

What are the possible side effects?

The most common side effects include scaling/crusting, hypo/hyper-pigmentation, itching, stinging, and/or burning, erythema and edema. Severe stinging and/or burning at one or more lesions being treated was reported by at least 50% of patients at some time during the treatment.

What precautions should be taken?

Patients should avoid exposure of the photosensitive treatment sites to sunlight or bright indoor light prior to and at least 40 hours after blue light treatment. Exposure may 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.

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.

Now's the time to...
Manage your Damage

www.levulan.com

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MKT-1486AW Rev C

Levulan® Kerastick®
(aminolevulinic acid HCl)
for Topical Solution, 20%

Levulan® PDT Patient Treatment Preparation



Before treatment starts

- Be sure to tell your physician if you are taking any oral medications or using any topical prescription or non-prescription products on your face or scalp.
- Bring adequate sun-protective items with you to your appointments such as a wide-brimmed hat and umbrella.

The Levulan PDT treatment*

- Treatment step 1: Application of Levulan® Kerastick® Topical Solution
- Levulan will be uniformly applied to your AK lesions.



- Your qualified healthcare professional will 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 your face in between treatment steps.
- Avoid exposing the treated lesions to sunlight and other forms of bright light for at least 40 hours. 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.*

After treatment

- You may experience side effects following your Levulan PDT treatment.
 - The most common side effects are:
 - Burning/stinging, which could be severe, may last up to 24 hours after your BLU-U treatment
 - Redness and swelling which may last up to 4 weeks after your BLU-U treatment
 - Scaling/crusting which may last up to 4 weeks after your BLU-U treatment
 - You may apply moisturizers as needed.

General precaution for sun exposure

- On a daily basis, always remember to use sunscreen and wear sun protective clothing to shield your skin from the sun's damaging rays.

*In clinical studies, severe stinging was experienced by 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.

