Clearer, Healthier Skin is Possible with LEVULAN® KERASTICK® + BLU-U® Blue Light Photodynamic Therapy (PDT)

LEVULAN®
KERASTICK®
(aminolevulinic acid HCI)
for topical solution, 20%

Blue Light Photodynamic Therapy
Illuminator Model 4170

TIPS TO PREPARE FOR YOUR TREATMENT

Actinic keratoses (AKs) are spots on your skin that form due to years of sun exposure. These spots can become more noticeable over time. If you have AKs now, it's likely that new ones will develop, so it's important to have a dermatologist monitor and treat them regularly to help reduce your risk of skin cancer.

Regular treatments with LEVULAN KERASTICK + BLU-U blue light may be an effective way to manage your AKs without the need for daily topical treatments and without the risk of scarring.

Before your in-office treatment with LEVULAN KERASTICK + BLU-U blue light, please let your doctor know if you're taking any oral medications or using any prescription or over-the-counter products on your skin.

Your treatment will be administered in 2 steps:

- Application of LEVULAN KERASTICK
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- **Light illumination with the BLU-U blue light**

Your dermatologist will begin by gently washing your skin and applying the LEVULAN KERASTICK 20% solution to your AKs. To work effectively, the solution needs to remain on your skin for 14-18 hours if treating your face or scalp, and 3 hours if treating your arms and hands. You should avoid washing off the solution during this time.

After the application, your skin will be photosensitive (sensitive to light). Because of this, it's important to keep your skin covered and avoid direct sunlight and bright indoor light during this period. If you have any questions or concerns, don't hesitate to ask your dermatologist.

Next, you'll return to the office for your BLU-U Blue Light PDT treatment. For this session, you'll sit in front of the blue light for 16 minutes and 40 seconds. The specially designed BLU-U blue light is low intensity, so it won't overheat your skin. Its purpose is to provide just the right amount of light and energy to activate the solution and eliminate your AKs.

During your blue light session, you may experience some tingling, stinging, prickling, or a slight burning sensation on the treated areas. Don't worry—these sensations typically decrease or level off about 6 minutes into the treatment. Your dermatologist may also provide a fan for your comfort.

Following treatment, it's important that you stay out of sunlight or visible indoor light for 40 hours. Bring appropriate clothing to cover your skin to your treatment session. This will help ensure protection when you leave.



For Treatment on the Face/head: Bring a wide-brimmed hat or a head covering that's a light-opaque material to help protect from the sun.



For Treatment on the Arms/hands: Bring clothing that protects you from the sun, like a long-sleeved shirt and/or gloves.

It's important to note that sunscreens won't protect against photosensitivity reactions caused by sunlight or visible light.

After the light session, your treatment with LEVULAN KERASTICK + BLU-U will be complete, and the healing process will begin. As your skin heals, you'll start to see new, healthier skin emerging.

You may experience some common side effects after the treatment, such as stinging, burning, redness, swelling, scaling, crusting, itching, oozing, and dryness in the areas where LEVULAN KERASTICK was applied. These effects are temporary. You can expect the redness and swelling to improve after about 4 weeks if treated on your face or scalp, and around 8 weeks if treated on your arms or hands.

When scheduling your BLU-U Blue Light PDT treatment, please consider the possible side effects. It's best to avoid scheduling close to important events, vacations, or outdoor activities, as you may need time to heal.



IMPORTANT PATIENT SAFETY INFORMATION

LEVULAN KERASTICK (aminolevulinic acid HCl) is for use only as an in-office treatment. LEVULAN KERASTICK treatment is given by a healthcare provider only and is not for use at home.

What is LEVULAN KERASTICK?

LEVULAN KERASTICK is a prescription medicine applied in your doctor's office and used on the skin in combination with blue light treatment (BLU-U Blue Light Photodynamic Therapy or PDT) for the treatment of minimally to moderately thick actinic keratoses (AKs) of the face, scalp, or arms.

It is not known if LEVULAN KERASTICK is safe and effective in children under 18 years of age.

Who should not receive LEVULAN KERASTICK treatment?

Do not receive LEVULAN KERASTICK treatment if you:

- are allergic to aminolevulinic acid HCl or to any of the ingredients in LEVULAN KERASTICK.
- have porphyria or are allergic to porphyrins
- · have a skin sensitivity to blue light.

Before receiving LEVULAN KERASTICK treatment, tell your healthcare provider about all of your medical conditions, including if you:

- have blood clotting problems
- are pregnant or plan to become pregnant. It is not known if LEVULAN KERASTICK will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known
 if LEVULAN KERASTICK passes into your breast milk.
 Talk to your healthcare provider about the best way to
 feed your baby during LEVULAN KERASTICK treatment.
- Tell your healthcare provider about all of the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. LEVULAN KERASTICK and other medicines may affect each other.

How will I receive LEVULAN KERASTICK treatment?

- LEVULAN KERASTICK treatment is received in two parts:
 - » Your healthcare provider will apply LEVULAN KERASTICK topical solution to your skin lesions. You should not wash the treated areas before you return to your healthcare provider for blue light treatment.
 - » After the prescribed amount of time you will return to your healthcare provider for blue light treatment. If you cannot return for blue light treatment on schedule, avoid sunlight and bright indoor light for at least 40 hours after LEVULAN KERASTICK topical solution has been applied.
- During blue light treatment, you will likely feel tingling, stinging, prickling, or burning of the treated areas.

What should I avoid during LEVULAN KERASTICK treatment?

After LEVULAN KERASTICK topical solution is applied to your skin you should avoid sunlight or bright indoor light (such as examination lights, operating room lights, tanning beds, or lights that are close to you) for 40 hours. During this time, the treated areas of your skin will become sensitive to light.

Exposure to light during this time may cause you to feel a burning or stinging sensation and may cause your treated lesions to become red or swollen. You should wear appropriate protective apparel such as a wide-brimmed hat, long sleeve shirt, and gloves to protect your treated skin from sunlight and other bright light.

Sunscreen will not protect the treated areas of your skin against sensitivity to light.

What are the possible side effects of LEVULAN KERASTICK?

LEVULAN KERASTICK may cause serious side effects, including:

- Temporary memory problems: Temporary memory problems have happened during treatment with LEVULAN KERASTICK in combination with BLU-U Blue Light Photodynamic Therapy Illuminator. You or your family members or caregiver should call your healthcare provider right away if you develop any problems with memory, confusion, or disorientation during treatment.
- Sensitivity to light
- **Skin irritation.** LEVULAN KERASTICK topical solution contains alcohol and may cause skin irritation if covered or bandaged for longer than 3 hours.

The common side effects of LEVULAN KERASTICK include:

Local skin reactions including redness, swelling, stinging and burning, scaling, crusting, oozing, pustules, welts, scabbing, itching, erosion, changes in skin color, bleeding, tenderness, changes in the sense of touch, and dryness.

These are not all the possible side effects of LEVULAN KERASTICK.

Call your doctor for medical advice about side effects.

You may report side effects to FDA at <u>1-800-FDA-1088</u> or <u>www.fda.gov/medwatch</u>.

Please see full Prescribing Information linked here.



