

Medication Guide | Full Prescribing Information | For Healthcare Professionals >

LEVULAN[®] KERASTICK[®]
(aminolevulinic acid HCl)
for topical solution, 20%

+

BLU-U[®]
Blue Light Photodynamic Therapy
Illuminator Model 4170

HOME

ABOUT ACTINIC
KERATOSIS

+ WHY LEVULAN
KERASTICK + BLU-U

FIND A PROVIDER

ENROLL INTO BLU-U + YOU[™]

LOGIN

Treatment that turns
back the clock on AKs

STANDARD OF CARE
#1
BY PHOTODYNAMIC THERAPY

With up to 100% clearance and no risk of
scarring, LEVULAN[®] KERASTICK[®] + BLU-U[®]
blue light therapy helps clear skin damage
from the past to protect your future.

FIND A PROVIDER TODAY

Proven results for
millions of patients

As the first and only photodynamic therapy (PDT) approved to treat the face, scalp, arms, and hands, LEVULAN[®] KERASTICK[®] + BLU-U[®] blue light has been trusted and proven for more than 20 years.

100% clearance

Most patients get 100% clearance of AK sunspots with 1-2 in-office treatments

Long-lasting results

Most face or scalp AKs remain 100% clear 1 year after the first treatment

Focused on safety

The most common side effects are stinging, burning, redness, and itching where LEVULAN KERASTICK was applied

Covered by Medicare and most commercial insurance plans

Confirm coverage details with your provider and insurance company before your treatment

Get exclusive treatment offerings and resources

Whether it's before, during, or after treatment, our email program
is designed to support you throughout your journey with
LEVULAN KERASTICK + BLU-U blue light therapy.

ENROLL TODAY

BLU-U + YOU[™]

Seeing is believing

Check out these real results from real LEVULAN KERASTICK + BLU-U patients.

IPR2024-01312

Biofrontera Inc. et al v. Sun Pharmaceutical et al

Sun Pharmaceutical's Exhibit 2076

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Getting started with LEVULAN KERASTICK + BLU-U blue light therapy

Just 2 simple steps can help you achieve lasting results.

#1

Apply LEVULAN KERASTICK

Your dermatologist will apply LEVULAN KERASTICK 20% solution to your AKs.

- The solution needs time to properly absorb into your skin
- The waiting period is 3 hours for AKs on the arms or hands and 14-18 hours for AKs on the face or scalp

#2

Illuminate with BLU-U blue light

To activate the solution, you'll sit in front of the blue light for 16 minutes and 40 seconds.

- Your dermatologist will give you protective eyewear during this step
- You can resume your normal activities afterward
- Keep treated areas out of the sun and away from bright light for 40 hours

Know before you go

Before treatment, it's important to let your doctor know if you're taking any oral medications or using any prescription or nonprescription products on your face, head, arms, or hands. There are also a few steps you'll need to take after your treatment:



Avoid exposing treated areas to sun or any bright light for 40 hours.



Wear a hat or long-sleeved shirt to cover treated areas if you go outside.

or hands. The most common side effects after treatment are all temporary. They include stinging, burning, redness, swelling, scaling/crusting, itching, erosion, oozing, and dryness.



Caring for your skin after treatment:

Wash treated areas with a gentle cleanser and pat dry. Then use thicker, unscented moisturizers or petroleum jelly.

Common questions

— Are my sunspots AKs?

They could be. Only a licensed dermatologist can determine that, based on a thorough skin check. If you have a questionable spot on your skin or feel that you may be at risk for AK, schedule a visit with your dermatologist right away. [Find a dermatologist to see if LEVULAN KERASTICK + BLU-U blue light therapy is right for you.](#)

- + How long does treatment with LEVULAN KERASTICK + BLU-U take?
- + How do I know if my dermatologist offers LEVULAN KERASTICK + BLU-U?
- + What areas can be treated with LEVULAN KERASTICK + BLU-U?
- + Does BLU-U emit UVA or UVB light?
- + Does LEVULAN KERASTICK + BLU-U blue light therapy hurt?
- + What can I say to a spouse or friend who's putting off treatment?
- + Should LEVULAN KERASTICK and BLU-U be used together?
- + Is LEVULAN KERASTICK + BLU-U covered by insurance?



Find a LEVULAN KERASTICK +
BLU-U provider near you



Learn more about sunspots
and how to spot them



LEVULAN KERASTICK + BLU-U LOCATOR 

IMPORTANT SAFETY INFORMATION

PATIENT 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 [1-800-FDA-1088](tel:1800FDA1088) or www.fda.gov/medwatch

Please see full Prescribing Information [linked here](#).

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