

TREAT

What Happened Yesterday,
TODAY



**LEVULAN[®]
KERASTICK[®]**

(aminolevulinic acid HCl)
for topical solution, 20%



BLU-U[®]

Blue Light Photodynamic Therapy
Illuminator Model 4170

LEVULAN[®] KERASTICK[®] (aminolevulinic acid HCl) is a prescription medicine used on the skin with blue light treatment (BLU-U[®] Blue Light Photodynamic Therapy or PDT) for the treatment of minimally to moderately thick actinic keratoses (AK's) of the face, scalp or upper arms. It 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.

IMPORTANT SAFETY INFORMATION

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

Please read the full Prescribing Information and additional Important Safety Information provided throughout this brochure.

What are Actinic Keratoses

Actinic keratoses (AKs) are rough-textured, dry, scaly, crusty patches on the skin that are caused by long term exposure to ultraviolet light (UV), such as sunlight. If untreated, AKs may develop into skin cancer.

- AKs are often called “sun spots”
- There may be a single AK or multiple AKs
- They can be as small as a pinhead or larger than a quarter
- They can range in color from skin toned to reddish brown



**58 Million Americans
have at least one AK**



**AKs are precancerous,
and 1 in 10 may
become cancerous.**



**Both men and women
can get crusty, scaly AK
sunspots on their skin.**

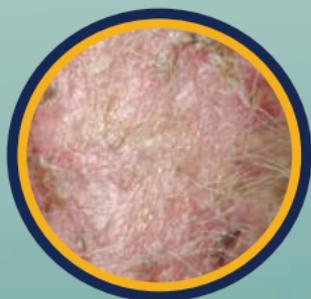
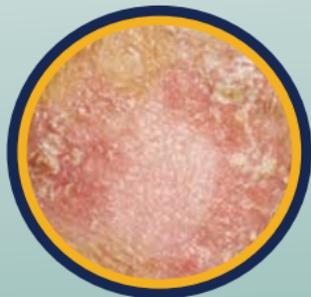
Who gets Actinic Keratoses

58 million Americans have AK sunspots. Even if you didn't sunbathe much, years of just doing simple tasks outside like playing sports, walking the dog or driving in your vehicle can add up to a significant amount of sun exposure.

What are some of the risk factors?

- A history of cumulative sun exposure
- Fair skin
- Blond or red hair, in particular if combined with blue, hazel, or green eyes
- A tendency to freckle or burn after sun exposure
- A weakened immune system

Photographs supplied courtesy of The Skin Cancer Foundation



Why treat Actinic Keratoses

Actinic keratoses are the most common precursor to skin cancer

AKs may be found anywhere on the body that has been exposed to UV radiation. **They are most commonly found on the face, scalp, ears and arms.**



AKs are considered to be the first step in the development of skin cancer. They have the potential to progress to squamous cell carcinoma (SCC). While most AKs remain benign, a study has shown that the majority of SCC arises from AK lesions.¹

Since there is no way to know ahead of time which AKs will develop into SCC, it is very important for individuals with AKs to be under a dermatologist's care.

Frequent skin examinations are the key to early detection and prevention.

1. <https://www.ncbi.nlm.nih.gov/pubmed/23228303> Rigel DS, Gold LFS. The importance of early diagnosis and treatment of actinic keratosis. J Am Acad Dermatol. 2013;68(1 Suppl 1):S1.



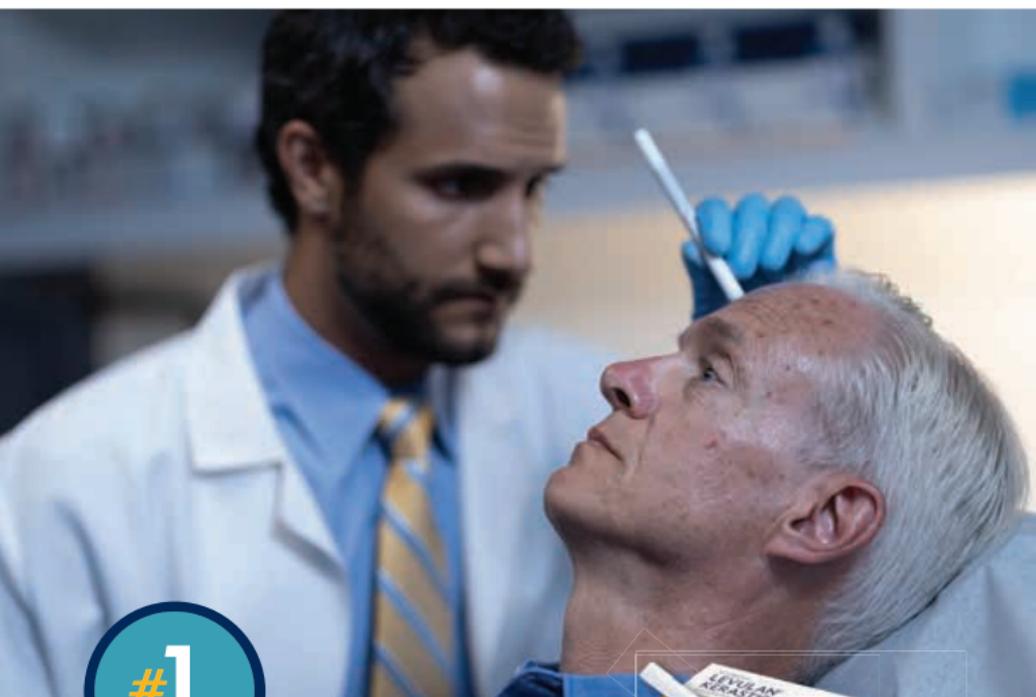
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**LEVULAN[®]
KERASTICK[®]** +
(aminolevulinic acid HCl)
for topical solution, 20%

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



#1



Apply

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 upper arms, forearms, and hands and 14-18 hours for AKs on the face or scalp.

IMPORTANT SAFETY INFORMATION

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.

LEVULAN KERASTICK + BLU-U is a 2-step in-office (medication + blue light) treatment designed to treat minimally to moderately thick actinic keratoses (AK) lesions on the face, scalp, or upper arms.



#2



Illuminate

To activate the LEVULAN KERASTICK 20% solution, you'll sit or stand next to the BLU-U blue light Illuminator for 16 minutes and 40 seconds. Your dermatologist will give you protective eye wear 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.

IMPORTANT SAFETY INFORMATION

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.

Please see additional Important Safety Information on pages 12-14

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.
- Expect any redness and swelling to subside after 4 weeks on your face or head or 8 weeks on your arms 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.

100% clearance

of your minimally to moderately thick actinic keratosis (AK) sunspots is possible with just 1 or 2 in-office treatments with LEVULAN KERASTICK + BLU-U



IMPORTANT SAFETY INFORMATION

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.



Ask your doctor if
LEVULAN KERASTICK 20% solution
+ BLU-U blue light is right for you.

A convenient in-office treatment covered by Medicare and most commercial insurance plans

- 2-step treatment procedure that can be completed within 24 hours
- Low downtime
- Administered by a qualified healthcare professional
- Typically no pharmacy visit is required
- No daily medication to apply
- Flexible treatment for a range of minimally to moderately thick AKs on the face, scalp, or upper arms
- Recovery begins when your treatment with the BLU-U blue light ends
- No scarring reported in clinical trials

IMPORTANT SAFETY INFORMATION

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.

Please see additional Important Safety Information on pages 12-14

Healing begins

when treatment ends...

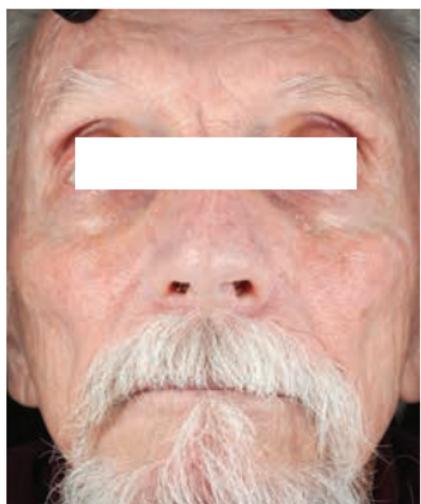
Patients following 1 treatment with LEVULAN KERASTICK + BLU-U.



Before application of
LEVULAN KERASTICK



Week 4 post LEVULAN
KERASTICK + BLU-U treatment



Before application of
LEVULAN KERASTICK



Week 4 post LEVULAN
KERASTICK + BLU-U treatment

IMPORTANT SAFETY INFORMATION

LEVULAN KERASTICK may cause serious side effects, including sensitivity to light and skin irritation.

LEVULAN KERASTICK topical solution contains alcohol and may cause skin irritation if covered or bandaged for longer than 3 hours.

Please see additional Important Safety Information on pages 12-14

Patients following 2 treatments with LEVULAN KERASTICK + BLU-U.

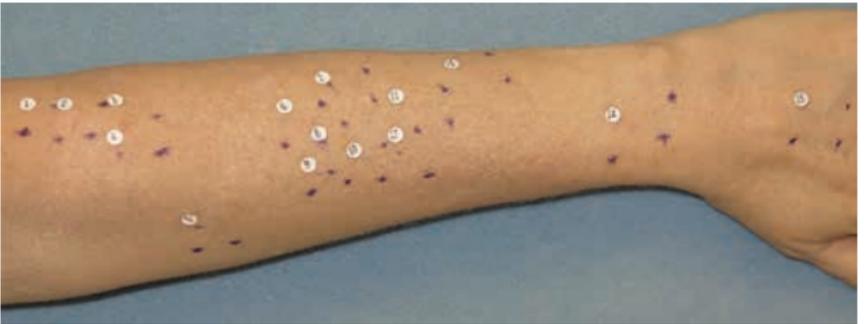
Before treatment the perimeter of each AK lesion was marked with 3 dots and then labeled with a numbered label. At follow-up visits, lesions that were cleared were not marked or numbered.



Before application of LEVULAN KERASTICK



Week 12 post LEVULAN KERASTICK + BLU-U treatment



Before application of LEVULAN KERASTICK



Week 12 post LEVULAN KERASTICK + BLU-U treatment

Proven results

for millions of patients

As the first and only PDT approved to treat the face and scalp as well as the upper arms, forearms, and hands, LEVULAN KERASTICK 20% solution + BLU-U blue light has been trusted and proven for over 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, with no reported scars

✓ Treat even more AKs

This treatment covers larger areas of your body than other PDTs, so you can have multiple AK sunspots treated at once

✓ 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



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 used on the skin with blue light treatment (BLU-U Blue Light Photodynamic Therapy or PDT) for the treatment of minimally to moderately thick actinic keratoses (AK's) of the face, scalp, or upper 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.

Please see additional Important Safety Information on pages 13-14

IMPORTANT SAFETY INFORMATION CONTINUED...

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 or www.fda.gov/medwatch

General Information about LEVULAN KERASTICK

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. You can ask your pharmacist and healthcare provider for information about LEVULAN KERASTICK that is written for health professionals.

What are the Ingredients in LEVULAN KERASTICK?

Active ingredient: aminolevulinic acid HCl, inactive ingredients: alcohol USP (ethanol content = 48% v/v), water, laureth-4, isopropyl alcohol, polyethylene glycol

Manufactured by:

DUSA Pharmaceuticals, Inc.[®],
a Sun Pharma company
29 Dunham Road
Billerica, MA 01821

For more information visit www.MyLevulan.com

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for more information
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solution + **BLU-U**
blue light therapy.

www.MyLevulan.com



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APPOINTMENT 1: _____

APPOINTMENT 2: _____

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a SUN PHARMA company


SUN
PHARMA

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