PATIENT INFORMATION

LEVULAN® KERASTICK® (LEV-you-lan KER-rah-stick) **(aminolevulinic acid HCl) for topical solution, 20%**

Important: LEVULAN KERASTICK is for use 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 (topical) 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. See the end of this leaflet for a complete list of 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 causing side effects.

How will I receive LEVULAN KERASTICK treatment?

- LEVULAN KERASTICK treatment is received in 2 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. Call your healthcare provider if you cannot return for blue light treatment during the prescribed time after LEVULAN KERASTICK topical solution has been applied. If you cannot return for blue light treatment, 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 be sensitive to light (photosensitive).

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 (photosensitivity).** See, "What should I avoid during LEVULAN KERASTICK treatment?"
- **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.

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: Sun Pharmaceutical Industries, Inc. Billerica, MA 01821

For more information call 1-877-533-3872 or 1-978-657-7500
www.levulanhcp.com

This Patient Information has been approved by the U.S. Food and Drug Administration.
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