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## Levulan PDT

**Two Step Levulan® PDT Offers and Effective Treatment Options** Levulan Photodynamic Therapy (Levulan PDT) is an advanced 2-step treatment for Grade 1 or 2 Actinic Keratoses (AKs that have not yet become enlarged and thick) of the face or scalp. This treatment consists of Levulan Kerastick Topical Solution, 20% and the BLU-U Blue Light Photodynamic Therapy Illuminator, and is unique because it uses a light activated drug therapy to destroy AKs.

**Efficacy Proven in Medical Studies** Many of the patients participating in the studies experienced 75-100% clearance of Grade 1 or 2 AKs eight weeks after treatment with Levulan Kerastick Topical Solution and BLU-U. The Levulan Kerastick for Topical Solution plus blue light illumination using BLU-U Blue Light Photodynamic Therapy Illuminator is indicated for the treatment of minimally to moderately thick actinic keratoses (Grade 1 or 2) of the face or scalp. There are other medications that may increase your sensitivity to light. 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.

**Many Patients Rated the Cosmetic Response as Good to Excellent** Based on the combined results of two medical studies, 94% of patients treated with Levulan PDT and BLU-U rated the cosmetic response as good to excellent. Additionally, no scarring was reported during the medical studies. The most common side effects experienced by patients in these medical studies included scaling/crushing, hypo/hyper-pigmentation, itching, stinging, and/or burning, redness and swelling. Sever stringer and/or burning at one or more lesions being treated was reported by at least 50% of patients at some time during treatment.

How does Levulan PDT work?

When Levulan Kerastrick Topical Solution is applied to Grade 1 or 2 AKs, the solution is absorbed by the AK cells where it is converted to a chemical that makes the cells extremely sensitive to light. When the AK cells are exposed to BLU-U, this light causes reactions, which destroy the AK cells. Levulan® PDT: The 2-step Treatment Procedure

### Step 1: Application of the Levulan Kerastick® Topical Solution

The first step in Levulan PDT treatment is the application of the Levulan Kerastick Topical Solution, 20% to the individual AKs on your face or scalp by your dermatologist or other care professional. This solution is an acid that occurs naturally in your body. It makes the AKs more sensitive to light. This application prepared the AKs for step 2 in the Levulan PDT treatment. Once the Levulan Kerastick Topical Solution is applied to the AKs, your doctor will direct you to wait the recommended time in order to allow the solution to penetrate the target cells we mentioned earlier.

### Step 2: BLU-U® Treatment

After your incubation period, you will receive a blue light treatment, which is the second and final step in the treatment. The BLU-U treatment time is 16 minutes and 40 seconds. What to Expect During and After Levulan® PDT Treatment

The BLU-U blue light is of low intensity and will not heat the skin. However, during the light treatment, which lasts approximately 17 minutes, you may experience sensations of tingling, stinging, prickling, or burning of the treated AKs. These feelings of discomfort should improve at the end of the BLU-U treatment and should subside between 1 minute and 24 hours after the BLU-U is turned off. Following treatment, the AKs and to some degree the surrounding skin may redden, and swelling and scaling may also occur. However, these effects are temporary and should completely resolve by 4 weeks after treatment. Less than 3% of patients discontinued light treatment due to stinging and/or burning. What To Do After Levulan PDT Treatment

Avoid exposure of your Levulan treated face or scalp to sunlight or bright indoor light prior to and for at least 48 hours after blue light treatment. Sunscreens will not protect against photosensitivity reactions caused by visible light. Important Safety 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 (Grad 1 or 2) 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. Levulan Kerastick should not be 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.

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## 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 48 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.