

Photodynamic (Levulan) Therapy (PDT) / Blue Light Treatment Informed Consent Form

PDT for face / scalp AKs or other _____ ordered by Dr. S or Dr. H or _____

Levulan (Aminolevulinic acid 20%) is a naturally occurring photosensitizing compound, which has been approved by the Federal Drug Administration (FDA) to treat pre-cancerous skin lesions called actinic keratoses (AKs). Levulan is applied to the skin and subsequently "activated" by a specific wavelength of light. This process of activating Levulan is termed Photodynamic Therapy. The purpose of activating the Levulan is to reduce precancerous skin lesions. The treatment may improve the appearance of the skin and other signs of photoaging, decrease acne, decrease oiliness of the skin, reduce sebaceous hyperplasia (enlarged oil glands) and improve texture/smoothness by minimizing pore size. Improvements of these skin conditions (other than actinic keratosis) are considered an "off-label" use of Levulan. Blue light, by itself is also used to treat acne.

I understand that Levulan will be applied to my skin areas to be treated. After an incubation time determined by my doctor (usually 60-90 minutes; in the waiting room), the area will be treated with a specific wavelength of light to activate the Levulan. (Levulan will be washed or wiped off before treatment and protective eyewear will be placed over my closed eyes throughout the ~ 16 minute treatment session.)

I understand that I should avoid direct sunlight for forty (40) hours following the treatment due to photosensitivity. I understand that any, even indirect sun exposure during this time can increase possible side effects including: swelling, burning, redness and pain. Scarring has not been reported to date (per Levulan company DUSA). I must wear a SPF 30 or > sunscreen on the treated areas and wide brim hat when returning home from this treatment. I must stay home and avoid ANY light from windows for forty (40) hours and I must diligently use sun protection for 7 days following this treatment.

Likely side effects of Levulan treatment may include: discomfort / itching, burning, swelling, redness, and possible peeling, especially in any areas of sun damaged skin and pre-cancers on the skin, as well as lightening or darkening of skin tone and/or spots. Blisters or pustules may less commonly occur. This peeling may last many days, and the redness for one week if I have an exuberant response to the treatment. Some reactions may take 2-3 weeks to clear. The greater the number of pre-cancers on my skin the more exuberant the reaction will be and time required to recover.

I consent to photographs taken of my face before each treatment session which may be used by my physician for marketing. PDT treatment recommendations, based on many studies and thousands of patients treated, are: 1-2 treatments for AK's (actinic keratoses) and 2-4 treatments for acne. Periodic re-treatments are usual for AKs. Blue light, by itself (without Levulan), for acne requires 1-2 treatments per week for 10 to 20 treatments or more. Blue light alone has no significant risk factors, aftercare nor contraindications other than photosensitivity to blue light itself. Insurance companies may reimburse for AK's of the face & scalp every 60 to 90 days, but not any "off-label" uses, e.g. acne. I understand that medicine is not an exact science, and that there can be no guarantees of my results. I am aware that while some individuals have fabulous results, it is possible that these treatments will not work for me. I understand that alternative and / or complementary treatments / management include cryosurgery, excisional surgery, peels, topical medicines and observation.

I have read the above information and understand it.

My physician and/or his / her staff have answered my questions satisfactorily.

I accept the risks and possible complications of the procedure.

I do not have any contraindications to PDT, including being pregnant; or having porphyria or any known allergies to porphyrins or components of Levulan, or any other reason to be photosensitive or allergic to 400 to 450 nm wavelength (blue) light.

By signing this consent form I agree to have one or more Photodynamic Levulan or Blue Light treatments.

Patient Name (Print)

Patient Signature

Date

Tx Provider (Sig)

Witness (if different than Provider) Signature

Date

PDT Patient Instructions:

Before PDT Treatment:

1. Please tell us if you have any contraindications to PDT or Blue Light Therapy:
including pregnancy, porphyria, allergies or hypersensitivity to porphyrins or Levulan / PDT, or 400-450 nm blue light.
2. Discontinue use of any topical retinoids or related derivatives, such as Differin, Epiduo, tretinoin (Retin-A) and Tazorac for several days to a week before PDT. (You may restart these medications when healed.)
3. Please tell us if you have a history of fever blisters, cold sores or herpes in the skin areas to be treated.
If you do, we may provide you with a written prescription for an oral anti-herpes medication to take on the morning of PDT.
4. Wash the area/s to be treated, on the morning of treatment. Avoid lotion, makeup and sun exposure as well.
For one to two weeks prior treatment, protect the areas to be treated from the sun (with SPF 30 or > sunscreen).
Men should shave their face the day of the procedure and avoid shaving for the next 3-5 days after PDT.
(If you have any active skin infection on the day of treatment, we may re-schedule your treatment for when you are better.)
5. On treatment day, remember to bring a wide-brimmed hat and/or adequate SPF 30 or UVA and UVB sunscreen.

During PDT Treatment:

1. Do not wash off Levulan while waiting to be treated.
2. Keep your eyes closed under the protective eyewear that you will wear during the treatment.
3. Expect some mild burning, stinging or pain during the treatment that usually quickly dissipates within a few minutes or when done, but may possibly last for up to a few days after or slowly diminish over several days.
If you experience significant discomfort during the treatment, please let us know as we can stop and restart the treatment.
Or the treatment may be stopped early if you desire and the PDT treatment will be complete.

After PDT Treatment:

1. AVOID exposure of the treated areas to sunlight and other forms of bright light for at least 40 hours, including exam room and operating room lights, tanning bed lights, and household lights at close range.
Sunscreens may not completely protect against photosensitivity reactions caused by visible light in the first 40 hours.
Windows do not protect against UVA light – so, avoid indirect light through windows, as well in the first 40 hours.
2. After 40 hours, avoid direct sunlight or use sunscreen with SPF 30 or > (and wear a hat) until completely healed.
Also, avoid using artificial tanning products until completely healed (up to 3-4 weeks.)
3. Skin Care – Wash your hands before touching your face. Cleanse with a mild, gentle cleanser (e.g. Aquanil) twice daily or use a dilute vinegar (1 teaspoon of white vinegar in 2 cups cool water) 5 minute washcloth soak 2-4 times daily beginning the day following treatment to promote the healing of any crusts if present. Rinse off and apply moisturizer.
Avoid picking, peeling, vigorous scrubbing or electronic skin cleansing brushes (e.g. Clarisonic) for the first 3-5 days.
Allow any peeling skin / crusts to slough naturally or with gentle cleansing (usually, within 3-5 days);
After 5 days, you may gently exfoliate with Clarisonic or other skin cleansing brush or gentle scrubs, if you desire.
Use a moisturizing cream (e.g. Vanicream) or Aquafor / Hydrofor as needed if your skin feels dry or tight.
Avoid make-up until any crusting, if present, is healed. Avoid hot tubs / pools and spas for one week after treatment.
However, you may shower daily starting the next day.
4. AKs and surrounding sun damaged skin may redden. Swelling, dryness, scaling, crusting and itching may occur.
Age spots / freckles may darken after treatment, then crust and flake off within several days to weeks.
Acne may worsen temporarily, including redness / irritation and swelling, for up to 7-10 days after PDT.
Topical antibiotic ointment (Bacitracin or Polysporin or similar) twice daily should be used on open skin or blisters until healed.
In addition, hydrocortisone 1% ointment twice daily for several days may be useful to small, focal areas of inflammation.
These effects are not uncommon, temporary and usually resolve within several weeks or less.
Usually, healing is complete by 7-10 days. Unresolved skin lesions by 4-8 weeks may require additional treatment.
Best results may require several treatments. PDT may be repeated at up to 4-6 week intervals or more.
5. Comfort Measures – OTC ibuprofen or acetaminophen (Tylenol) may be taken as needed per package insert instructions.
OTC antihistamines such as Claritin, Zyrtec or Benadryl may be taken for itching as needed per package instructions.
Cold or ice packs may be applied post-treatment 10 to 15 minutes per hour as needed for comfort and any swelling.
Elevate your head on two pillows at night to reduce any swelling if present or needed.
Under eye swelling is the most common area of swelling.
Notify us of any signs or symptoms of infection (fever, increasing pain), cold sore outbreaks, excessive swelling, or other.

If you have any questions, please do not hesitate to ask or contact our office, Strimling Dermatology Laser & Vein Institute at (702) 243-6400