CONSENT: Photodynamic Therapy (PDT) prepayment consent

Aminolevulinic acid is a naturally occurring photosensitizing compound, and has been approved by the FDA to treat pre-cancerous skin lesions called actinic keratosis. This acid is applied to the skin and subsequently “activated” by a specific wavelength of light. This process of activating the aminolevulinic acid is termed Photodynamic Therapy. The purpose of activating the Aminolevulinic acid is to reduce pre-cancerous skin lesions. Aminolevulinic acid will be applied to my skin. After an incubation time determined by my doctor, the area will be treated with a specific wavelength of light to activate the Aminolevulinic acid.

I understand that I should avoid direct sunlight for 48 hours following the treatment due to photosensitivity. _______ pt initial

I understand that any, even indirect sun exposure during this time can increase possible side effects including; swelling, burning, redness and pain. I should wear sunscreen, a hat and a scarf on my face returning home from this treatment. I must stay home and avoid ANY light from windows for 48 hours and I must diligently use sun protection for 7 days following this treatment. _______ pt initial

Possible side effects of Aminolevulinic acid treatment include discomfort, 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 spots. The peeling may last many days, and the redness for 1-2 weeks if I have an exuberant response to the treatment. The greater the number of precancers on my skin the more exuberant these reactions will be. _______ pt initial

I understand that I may require several treatment sessions spaced 3-4 weeks apart to achieve optimal results. The recommendations, based on many studies and thousands of patients treated, are 1-2 treatments for AK's (actinic keratosis) and 2-4 treatments for acne. _______pt initial

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 treatments include topical medicines, oral medications, cryosurgery, excision, and surgery. _______ pt initial

Financial Consent: Full payment due at time of service. (Medicare excluded) Due to the cost of the drug and uncertainty in the actual benefits paid prior to treatment by your insurance provider we require all individuals who are treated to prepay when they arrive for their visit. Your estimated out of pocket costs based on typical insurance reimbursement for 2019/2020 is $490.00 per area and would be due when you arrive for your treatment. ________pt initial

I have read the above information and understand it. The doctor and his/her staff have answered my questions satisfactorily. I accept the risks and complications of the procedure. By signing this consent form I agree to have one or more Aminolevulinic acid treatments. __________

Patient's signature ______________________________ Date ____________
Printed name _______________________________ Witness ______________________________

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PRE-TREATMENT INSTRUCTIONS
Photodynamic Therapy (PDT)

What is Photodynamic Therapy?
This treatment will remove sun damaged pre-cancerous spots called actinic keratosis (AK's). It may also minimize pores, reduce oil glands, treat can. Lastly, the skin will become softer and smoother with the reduction of sun damaged cells.

What can I expect post-treatment?
Depending on the length of Aminolevulinic acid incubation and the amount of sun damage you have, you can expect to have a sunburn-like reaction that may last up to 5-7 days. Swelling, peeling, crusting and discomfort may occur. Some patients may have an exuberant response to PDT and experience much more severe sunburn-like effect. However, no matter how severe the response there is absolutely NO possibility of scarring or permanent damage since this procedure only affects the superficial layer of the skin.

There is a nominal fee for your one month follow-up.
1. On the day of treatment please come to the office with CLEAN SKIN and the treatment area free of any makeup, creams, perfumes and lotions.
2. Bring some type of physical block for the ride home, sunglasses, a brimmed hat or scarf. If you're having your hands or arms treated you will need gloves or long sleeves. The risks of side effects (swelling, redness, peeling, crusting and discomfort) increase dramatically with ANY sun exposure, including, INDIRECT exposure in the 48 hours following treatment. Plan to cover up when leaving the office.
3. Plan to be here for a few hours. Following your treatment you will be required to go directly home with the treated area covered. You may consider having someone drive you and/or pick you up to allow you to apply cold compresses if you have a long ride home.
4. If you have a history of herpes outbreaks in the areas being treated, let us know. We recommend that you take Lysine 500mg daily for one week before the treatment and increase to 2 capsules 3x/day for 5 days if you have a flare up. We can also prescribe medications to prevent severe herpes outbreaks during your treatment.
5. Dr. George recommends these products following your procedure.
   - A mild facial cleanser – CeraVe gentle cleaner
   - A good thick moisturizer – CeraVe moisturizing lotion
   - Dr. George highly recommends a high quality sunblock SPF 30 or higher (zinc and/or titanium dioxide >10%) such as ISDIN actinic care sunscreen or Elta Pure sunscreen. These are available in our office.
   - You may also use the items below which are available at your local drugstore;
     - Cold gel packs and refrigerated gel like Aloe Vera gel 100%
     - You may need a pain reliever such as ibuprofen or acetaminophen
     - Vaseline or antibiotic ointment (polysporin). Hydrocortisone if needed.

6. Be prepared for 'downtime'. You will be extremely photosensitive and will need to remain out of direct AND indirect sunlight even when you're indoors. Plan to stay inside for 48 hours. Cover your windows or cover yourself. Prepare for indoor activities. Do any shopping in advance. Avoid fluorescent lighting.
7. For the treatment of sun damage and/or AK's, generally 1-2 treatments are necessary.
For the treatment of acne, generally 2-4 are necessary.

The treatment may improve the appearance of the skin and other signs of photoaging, decrease acne, reduces sebaceous hyperplasia, decrease oiliness of the skin, and improve texture/smoothness by minimizing pore size. Improvements of these skin conditions (other than actinic keratosis) are considered an “off-label” use of Aminolevulinic acid.
POST TREATMENT INSTRUCTIONS
Photodynamic Therapy (PDT)
What can I expect Post-Treatment?

A sunburn-like effect is normal for 2-3 days and can last for up to 5-7 days. This can mean anything from being light pink to a swollen, red and itchy sunburn with scaling or scabbing. Peeling or flaking may begin on day 3 or 4, make sure you do not pick! Crusting may occur where there was sun damage and/or actinic keratosis. Not everybody visibly peels. Swelling, peeling, crusting and discomfort may also occur. Some patients may have an exuberant response to PDT and experience a much more severe sunburn-like effect. However, no matter how severe the response there is absolutely NO possibility of scarring or any permanent damage as long as you follow our directions.

There is a nominal fee for the one month follow up appointment.

1. Stay out of direct AND indirect sunlight for 48 hours. Use a good SPF 30 sunblock daily. You should plan to stay indoors for 2 days and avoid sunlight through uncovered windows.
2. Keep the treated area clean so there is no risk of infection. Dr. George recommends washing with CeraVe gentle cleanser twice a day and using a high quality moisturizer such as CeraVe moisturizing lotion. These are available in our office for your convenience!
3. If use of a pain reliever is necessary, ibuprofen or acetaminophen are fine.
4. Keep cooling gel in refrigerator, 100% Aloe Vera gel (with solarcaine) or the plant.
5. Use ice or cold packs, frozen peas or corn if necessary, to keep down the swelling.
6. Avoid any acne regime or topical irritants such as Retin-A, glycolics or salicylic acid until your skin is no longer peeling, flaking or red.
7. If blisters form use an antibiotic ointment (Bacitracin, Polysporin) twice a day.
8. If the treated area is stinging: Soak the area with 1 tablespoon white vinegar in 1 cup of cold water for 20 minutes 4-6 times a day. You may apply ice packs over the soak for additional comfort.
9. It is very important to apply a quality SPF 30 sunblock to the face daily after this treatment. Chemical free sunblocks like zinc or titanium dioxide are ideal: Dr. George recommends ISDIN actinic care sunscreen or Elta Pure sunscreen.
10. You may begin applying makeup as soon as you feel comfortable and once any crusting has peeled. Do not pick scabs.

Please call the office if you have any questions or concerns during your recovery period, or email Wendy at wbullard@wilmingtondermatologycenter.com. You can also email in the evening and over the weekend with any questions.

910-256-4350 ext 111 Wendy