

Valeda® Light Delivery System Information for Patients



1. Who is suitable for the Valeda treatment?

Valeda is indicated for use in the treatment of Dry Age-Related Macular Degeneration (AMD). Those individuals receiving treatment should have an eye care professional's diagnosis of Dry AMD. The stage of Dry AMD may impact the benefits of the treatment.

Your eye care professional will discuss your diagnosis and treatment plan with you.

2. Who is NOT suitable for the Valeda treatment?

As a precaution, patients have not been tested and should not be treated with Valeda if they have any known reactions to light exposure, or if they have a history of light-activated central nervous system disorders (e.g., epilepsy, migraine). In addition, patients should not receive treatment within 30 days of using any photosensitizing medications (e.g., topicals, injectables) without first consulting with their eye care professional.

3. What's involved with the Valeda treatment? Do I need any special preparation?

If you wear glasses or contact lenses, you will be asked to remove them prior to receiving treatment. Your eyes will not be dilated for the Valeda treatment. You will be seated comfortably in front of the Valeda Light Delivery System. The person administering the treatment will guide you through each step of the treatment, which takes less than 5 minutes. Treatment for both eyes will take less than 10 minutes.

Clinical trials have shown benefits in visual function following treatment 3 times a week for 3-4 weeks. This is the recommended treatment protocol for patients with Dry AMD. In a recent clinical study, patients received no more than 3 treatments a week and no more than one treatment in a 24-hour period. If you miss a treatment, it is recommended to make up the session within the 3-4 week treatment series period.

4. What are the clinical benefits of the Valeda treatment?

Treatment with Valeda improves overall visual function, including improvement in vision when scored on the eyechart and improved detailed vision. Photographic imaging also shows improvement in scans of the eye when assessed for drusen (protein deposits that are observed in the diseased eye).

5. What are the potential side effects of the Valeda treatment?

Photobiomodulation (PBM) is a low-level light based therapy that helps cells improve their function. PBM has been used in many different diseases and disorders for decades with a positive safety profile. In clinical trials in Dry AMD patients, the use of light therapy has also been shown to be safe. Valeda is designed to be eye safe. There have been no treatment-related side effects noted in previous studies with the Valeda treatment.

6. What can I expect during and after the Valeda treatment?

Bright lights can produce an afterimage following treatments. This is also known as photostress, where the cells that "see" a specific color become fatigued. Photostress recovery may take a few minutes after treatment. This phenomenon may be seen immediately following the treatment, but you will recover in a couple of minutes. You will be able to take part in normal activities following the treatment.

7. What if I have cataracts?

Patients can receive the Valeda treatment if they have cataracts



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