A patient's guide to treatment with VISUDYNE® (verteporfin for injection)

Indication

VISUDYNE® (verteporfin for injection) is used along with laser light treatment to stop leaking from blood vessels in the eye due to the following serious eye conditions: age-related macular degeneration (a condition affecting the retina of the eye which can impair vision), pathologic myopia (extreme nearsightedness) or ocular histoplasmosis (a certain type of fungus infection in the eye).

Please see Important Safety Information on Page 3 and accompanying full Prescribing Information here.

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Visudyne® verteporfin for injection

Contents

This brochure answers important questions about age-related macular degeneration (AMD) and provides important information on VISUDYNE® treatment—from how it works to what you should do before and after therapy. Some of the medical terminology used in this brochure may be unfamiliar. To help you to understand these medical terms, words that appear in boldface are defined in a glossary on page 11.

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Important Safety Information

- VISUDYNE® (verteporfin for injection) should not be used if you have a condition known as porphyria (blood enzyme deficiency), or if you are allergic to it or any of its components.
- If there is leakage of medication into the tissue around the injection site, it may cause damage. If this happens, protect the area from direct light until swelling and discoloration have faded.
- Avoid exposure of skin and eyes to direct sunlight or bright indoor light for 5 days after treatment with VISUDYNE. Wear protective clothes and dark sunglasses if going outdoors during this time. A UV sunscreen will not offer enough protection for your skin. Wear a wristband to remind you to do this. However, do not stay in totally dark areas. You should expose your skin to regular indoor and/or indirect light because doing so will help inactivate the drug in your skin.
- In clinical studies, the most common side effects were injection site reactions (such as pain, redness, irritation, rashes and swelling) or changes in vision (including blurred vision and flashes of light). Tell your doctor about any side effects that you may have.
- If you develop or have changes or a decrease in vision after treatment, do not drive or use machines as long as these symptoms continue.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.FDA.gov/medwatch or call 1-800-FDA-1088.

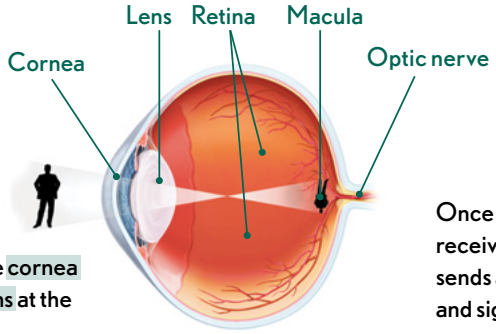
Please see accompanying full Prescribing Information for VISUDYNE® here.

What is age-related macular degeneration?

Age-related macular degeneration (AMD) is a progressive eye disease that damages the **macula**. This part of the eye is responsible for central vision, which is needed to perform straight-ahead activities, such as reading, driving, or watching TV. A person diagnosed with AMD has either dry AMD or wet AMD.

AMD is not uncommon. In fact, AMD is a leading cause of severe vision loss in people over the age of 50. Many people may already have AMD without realizing it. Although wet AMD is far less common than the dry type, it is responsible for about 80% to 90% of severe vision loss related to AMD. That's why it's important to visit your eye doctor on a regular basis. It's the best defense to preserve your vision.

The parts of the eye and what they do



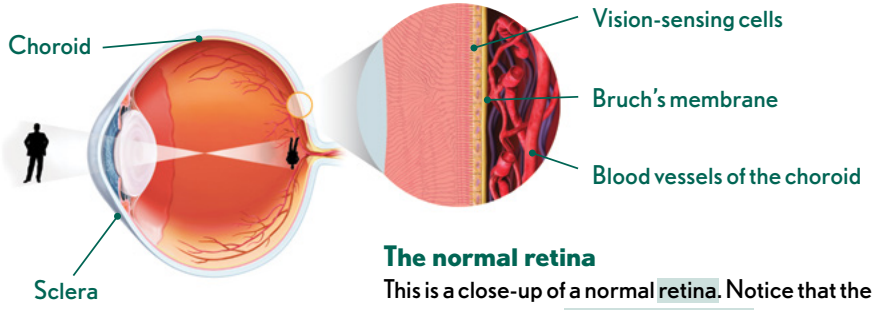
Light passes through the cornea and then through the lens at the front of the eye.

The light then travels to the back part of the eye, called the retina.

The light strikes the macula at the center of the retina, where vision is sharpest.

Once the retina and macula have received the light, the optic nerve sends a visual message to the brain, and sight is created.

What happens inside the eye?



The normal retina

This is a close-up of a normal retina. Notice that the yellow layer called Bruch's membrane separates blood vessels of the choroid from the rest of the retina.

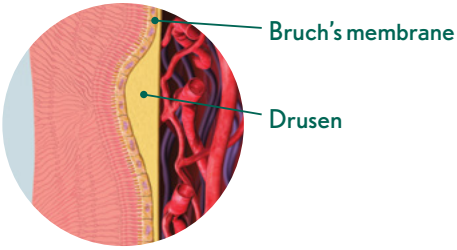
The eye is surrounded by a protective layer of fibrous tissue called the **sclera**. Deep in the back of the eye, tiny blood vessels supply blood to the **retina** and **macula**. The **macula** is located at the center of the **retina**. These blood vessels can be found in the **choroid**, a layer of the eye that lies between the **retina** and the **sclera**.

In wet AMD, when vision loss occurs, **drusen** (fatty deposits under the **macula**) and abnormal vessel growth are responsible. Abnormal vessel growth is also called choroidal neovascularization (CNV). Neo = new; vascularization = vessel growth.

What happens inside an eye with AMD?

Dry AMD

Fatty deposits called **drusen** accumulate in **Bruch's membrane**, which may negatively impact vision as they increase in size. VISUDYNE® is not approved to treat dry AMD.

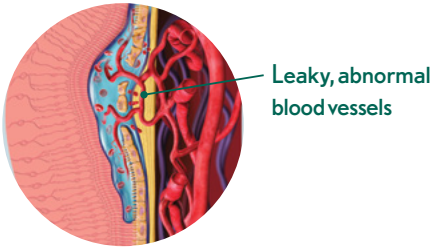


Wet AMD

Abnormal blood vessels push up into **Bruch's membrane**, leaking fluid and/or blood under the **macula** and causing serious vision loss.

A person with wet AMD may experience:

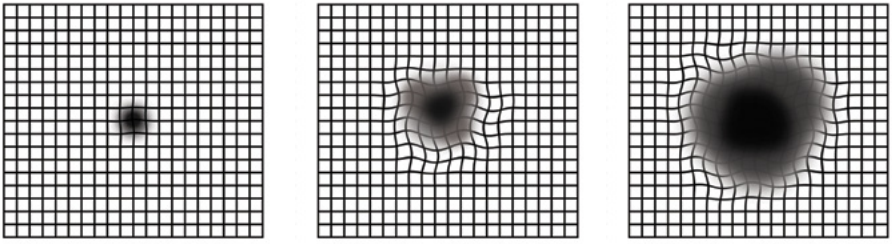
- Lines that appear wavy
- Blurring of faces
- Difficulty seeing colors
- Gaps in vision (i.e., dark or empty spaces that may block the center of vision)



How vision may change over time

When abnormal vessels leak fluid and/or blood under the **macula**, vision loss occurs because of damage and disruption to the retinal tissue. This damage often rapidly advances over time, affecting more of your vision. That is why it is so important for you to commit to a treatment plan with your eye care professional and stick to your regularly scheduled visits.

How changes might distort the appearance of an Amsler grid.*
An Amsler grid is a tool that lets you check changes in your vision.



What those changes may look like in everyday life.*

*The above are artists' representations and may not depict all patient situations.

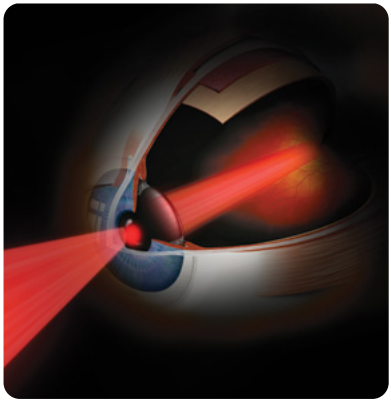
Why VISUDYNE® therapy may be right for you

VISUDYNE® therapy is approved to stop leaking from blood vessels in eyes that is caused by AMD (a condition affecting the retina of the eye which can impair vision). The sooner you begin therapy, the better your chances of retaining more of your vision.

Wet AMD is a serious eye disease that, if left untreated, can quickly cause severe vision loss. VISUDYNE® is a drug therapy that can slow the progression of wet AMD and may help you maintain your vision. Talk to your doctor about whether VISUDYNE® is right for you. Be sure to follow all of your doctor's instructions, as well as all recommended safety precautions.

How VISUDYNE® therapy works

VISUDYNE®, also known as verteporfin for injection, is a light-activated, or photodynamic, drug that is injected into the bloodstream and travels to the abnormal vessels. It is then activated by a low-energy laser, which produces a reaction that damages and closes abnormal vessels.



Multiple courses of therapy are often necessary because the abnormal blood vessels may not be fully closed off and leakage may recur. Despite the need for multiple treatments, stoppage of leakage and stability of visual function are achieved in many patients. VISUDYNE® therapy may be repeated at 3-month intervals if necessary.

VISUDYNE® is administered through an infusion into the patient's arm. The drug then circulates throughout the body; the abnormal vessels in the patient's eye attract and absorb the drug.

A low-energy laser is directed into the back of the eye at the abnormal vessels, activating the drug. The activated drug closes these abnormal vessels, most of which are thereby destroyed or sealed in such a way that they no longer leak.

Before you have VISUDYNE® therapy

Be sure to follow all of your doctor's instructions.
VISUDYNE® therapy causes your skin and eyes to become temporarily sensitive to light.
Bring these items with you on the day of your VISUDYNE® treatment appointment:

- **Dark sunglasses**
- A wide-brimmed hat
- Gloves
- Long pants
- A tight-weave, light-colored, long-sleeved shirt
- Socks and shoes

You should also make arrangements for someone to drive you home after your treatment.

During your treatment

1. You will receive an intravenous infusion of VISUDYNE®, usually in your arm, which should take about 10 minutes.
2. At the end of the infusion, your doctor will numb your eye with eye drops.
3. Fifteen minutes after the infusion begins, the doctor will place a special contact lens on your eye. A laser is then directed through the contact lens onto the affected area of the **retina** and applied for 83 seconds.
4. The laser activates the drug within the abnormal blood vessels to close the blood vessels and stop the leakage.

After you have VISUDYNE® therapy

Your skin will be sensitive to bright light and direct sunlight for 5 days after you have VISUDYNE® therapy. After 5 days, you may resume normal outdoor activities without any special precautions.

DO:

- Wear a wristband to remind yourself of your sensitivity
- Expose your skin to normal (fluorescent or incandescent) indoor light (this helps to inactivate the drug that may be present in your skin)
- Wait until sundown for outdoor activities if possible
- Be sure to wear protective clothing and sunglasses if you do go out during daylight hours in the first 5 days following therapy

DON'T:

- Stay in the dark indoors (normal indoor light helps to remove the drug from your skin)
- Visit your dentist or have surgery (lighting used in dentists' offices or surgical operating rooms can be dangerous as the drug may remain in your skin for several days)
- Go to tanning salons
- Use a pulse oxygen monitor

AVOID:

- Surgical procedures unless instructed by your doctor
- Unprotected skin and eye exposure to direct sunlight, skylights, undraped windows, and bright indoor light such as halogen lighting for the first 5 days after your treatment (wear protective clothing and sunglasses if you cannot avoid these situations; UV sunscreens are not effective in protecting against photosensitivity reactions)
- Driving or operating machinery if you develop visual disturbances such as blurred vision and other visual abnormalities

Be sure to follow all of your doctor's instructions.

What to expect at follow-up

Within 3 months, you should have another eye examination.

- Pictures will be taken of your eyes to show if any leakage is present
- VISUDYNE® therapy usually consists of a series of sessions. If the pictures show that there is more leakage, additional therapy will be necessary

Retreatment with VISUDYNE® therapy

More than one treatment with VISUDYNE® may be necessary to fully address the issues of wet AMD. In clinical studies, the need for retreatment steadily declined over time. Please note that the efficacy and safety of VISUDYNE® in clinical studies have not been demonstrated beyond 2 years.

What can you do about vision you've already lost?

- Visit your eye care professional on a regular basis to explore all of your treatment options
- Ask your eye care professional about low vision services and devices that may help you make the most of your remaining vision. Ask for a referral to a specialist in low vision
- Many organizations offer information about low vision counseling, training, and other special services. Some of those are listed in this brochure

Glossary

Bruch's membrane: A thin layer of tissue that separates the pigmented layer of the retina from the choroid layer

Choroid: Layer of the eye that is made up of tiny blood vessels, which lies between the retina and the sclera. The dark-colored pigment in the choroid absorbs light and limits reflections within the eye that could affect vision

Cornea: The clear front window of the eye that allows light to enter the eyeball

Drusen: Tiny yellow or white fatty deposits in the retina

Lens: Transparent body located behind the cornea that focuses the incoming light rays onto the retina

Macula: A small spot of light-sensitive cells located at the center of the retina. The macula is specifically responsible for central vision

Optic nerve: The nerve that carries visual signals from the retina to the brain

Retina: Light-sensitive nerve layer that lines the back of the eye. The retina receives visual images from the lens and transmits them to the optic nerve

Sclera: The protective layer of fibrous tissue that surrounds the entire eyeball, except the cornea

Where can you find more information about AMD?

Foundation Fighting Blindness
7168 Columbia Gateway Drive, Suite 100
Columbia, MD 21046
Phone: 1-800-683-5555
Web address: www.fightingblindness.org

Macular Degeneration Support
3600 Blue Ridge Blvd
Grandview, MO 64030
Phone: 1-888-866-6148
1-816-761-7080
Web address: www.mdsupport.org

National Alliance for Eye and Vision Research
1801 Rockville Pike, Suite 400
Rockville, MD 20852
Phone: 1-240-221-2905
Web address: www.eyeresearch.org

Prevent Blindness America
225 West Wacker Drive, Suite 400
Chicago, IL 60606
Phone: 1-800-331-2020
Web address: www.preventblindness.org

Alliance for Aging Research
1700 K Street NW, Suite 740
Washington, DC 20006
Phone: 1-202-293-2856
Web address: www.agingresearch.org

Low vision services and programs

American Foundation for the Blind
1401 South Clark Street, Suite 730
Arlington, VA 22202
Phone: 1-212-502-7600
Web address: www.afb.org

Lighthouse Guild
The Sol and Lillian Goldman Building
250 West 64th Street
New York, NY 10023
Phone: 1-800-284-4422
1-212-821-9200
1-212-821-9713 (TTY)
Web address: www.lighthouse.org

References: 1. VISUDYNE Prescribing Information. Bausch & Lomb Incorporated. **2**. Kaiser PK; Treatment of Age-Related Macular Degeneration With Photodynamic Therapy (TAP) Study Group. Verteporfin therapy of subfoveal choroidal neovascularization in age-related macular degeneration: 5-year results of two randomized clinical trials with an open-label extension. TAP report no. 8. *Graefes Arch Clin Exp Ophthalmol.* 2006;244(9):1132-1142.

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www.VISUDYNE.com