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EYLEA® (aflibercept) Injection

WET AGE-RELATED MACULAR DEGENERATION (WET AMD)

KEEP LIVING LIFE THROUGH YOUR EYES

TAKE CONTROL OF YOUR SIGHT WITH EYLEA

If Wet AMD has impacted your eyes—and how you see life—fight back with EYLEA.

INDICATIONS
EYLEA® (aflibercept) Injection 2 mg (0.05 mL) is a prescription medicine approved for the treatment of patients with Wet Age-related Macular Degeneration (AMD), Macular Edema following Retinal Vein Occlusion (RVO), Diabetic Macular Edema (DME), and Diabetic Retinopathy (DR).

IMPORTANT SAFETY INFORMATION
EYLEA® (aflibercept) Injection is a prescription medicine administered by injection into the eye. You should not use EYLEA if you have an infection in or around the eye, eye pain or redness, or known allergies to any of the ingredients in EYLEA, including aflibercept.

Injections into the eye with EYLEA can result in an infection in the eye and retinal detachment (separation of retina from back of the eye) can occur. Inflammation in the eye has been reported with the use of EYLEA.

In some patients, injections with EYLEA may cause a temporary increase in eye pressure within 1 hour of the injection. Sustained increases in eye pressure have been reported with repeated injections, and your doctor may monitor this after each injection.

There is a potential but rare risk of serious and sometimes fatal side effects, related to blood clots, leading to heart attack or stroke in patients receiving EYLEA.

The most common side effects reported in patients receiving EYLEA were increased redness in the eye, eye pain, cataract, vitreous (gel-like substance) detachment, vitreous floaters, moving spots in the field of vision, and increased pressure in the eye.

You may experience temporary visual changes after an EYLEA injection and associated eye exams; do not drive or use machinery until your vision recovers sufficiently.

Contact your doctor right away if you think you might be experiencing any side effects, including eye pain or redness, light sensitivity, or blurring of vision, after an injection.

For additional safety information, please talk to your doctor and see the full Prescribing Information for EYLEA.

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 the Consumer Brief Summary on the adjacent page.

*IQVIA Medical claims: Number of injections administered Q1 - Q4 2020. Data on File.

ASK A RETINA SPECIALIST ABOUT EYLEA

VISIT EYLEA.COM
Consumer Brief Summary
This summary contains risk and safety information for patients about EYLEA. It does not include all the information about EYLEA and does not take the place of talking to your eye doctor about your medical condition or treatment.

What is EYLEA?
EYLEA is a prescription medicine that works by blocking vascular endothelial growth factor (VEGF). VEGF can cause fluid to leak into the macula (the light-sensitive tissue at the back of the eye responsible for sharp central vision). Blocking VEGF helps reduce fluid from leaking into the macula.

What is EYLEA used for?
EYLEA is indicated for the treatment of patients with:
- Neovascular (Wet) Age-Related Macular Degeneration (AMD)
- Macular Edema Following Retinal Vein Occlusion (RVO)
- Diabetic Macular Edema (DME)
- Diabetic Retinopathy (DR)

How is EYLEA given?
EYLEA is an injection administered by your eye doctor into the eye. Depending on your condition, EYLEA injections are given on different schedules. Consult with your eye doctor to confirm which EYLEA schedule is appropriate for you.

Who should not use EYLEA?
Do not use EYLEA if you have an infection in or around the eye, eye pain or redness, inflammation in the eye, or are allergic to aflibercept and/or any other ingredients in EYLEA.

What is the most important information I should know about EYLEA?
- EYLEA must only be administered by a qualified eye doctor. Injection into the eye with EYLEA can result in an infection in the eye and retinal detachment (separation of retina from back of the eye) can occur. Inflammation in the eye has been reported with the use of EYLEA. If your eye becomes red, sensitive to light, painful, or develops a change in vision, seek immediate care from an eye doctor.
- In some patients, injections with EYLEA may cause a temporary increase in eye pressure within 1 hour of the injection. Sustained increases in eye pressure have been reported with repeated injections, and your eye doctor may monitor this after each injection.
- There is a potential but rare risk of serious and sometimes fatal side effects related to blood clots, leading to heart attack or stroke in patients receiving EYLEA.
- Serious side effects related to the injection procedure with EYLEA are rare but can occur including infection inside the eye and retinal detachment.
- You may experience temporary visual changes after an EYLEA injection and associated eye exams; do not drive or use machinery until your vision recovers sufficiently.
- Because EYLEA is composed of large molecules, your body may react to it; therefore, there is a potential for an immune response (allergy-like) in patients treated with EYLEA.

What are possible side effects of EYLEA?
EYLEA can cause serious side effects, including
- See important safety information listed under “What is the most important information I should know about EYLEA?”

The most common side effects include
- Increased redness in the eye
- Eye pain
- Cataract
- Vitreous (gel-like substance) detachment
- Vitreous floaters
- Moving spots in the field of vision
- Increased pressure in the eye

There are other possible side effects of EYLEA. For more information, ask your eye doctor.

It is important that you contact your doctor right away if you think you might be experiencing any side effects, including eye pain or redness, light sensitivity, or blurring of vision, after an injection.

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.

What should I tell my eye doctor before receiving EYLEA?
- Tell your eye doctor if you have any medical conditions.
- Tell your eye doctor if you are pregnant or are planning to become pregnant. It is not known if EYLEA may harm your unborn baby.
- Tell your eye doctor if you are breastfeeding. It is not known if EYLEA may harm your baby. You and your eye doctor should decide whether you should be treated with EYLEA or breastfeed, but you should not do both.

How is EYLEA supplied?
EYLEA is supplied in a clear, colorless to pale yellow solution. It is provided in a pre-filled glass syringe or glass vial containing the amount of product required for a single injection into the eye, which is 0.05 mL (or 2 mg of the medicine product).

Where can I learn more about EYLEA?
For a more comprehensive review of EYLEA safety and risk information, talk to your health care provider and see the full Prescribing Information at EYLEA.com.

REGENERON

Manufactured by:
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based on the August 2019 EYLEA® (aflibercept) injection full Prescribing information.
STATS & FACTS

By Sonya Collins
Reviewed by Brunilda Nazario, MD, WebMD Chief Physician Editor, Medical Affairs

Estimated number of people in the U.S. who have AMD—either wet or dry.

Up to 11 million

Amount of risk for developing AMD after age 75.

30%

Expected increase in U.S. cases of AMD—either wet or dry—by 2050.

2x

Amount of AMD-related legal blindness cases caused by the “wet” form.

90%

Amount of risk for developing AMD between ages 50 and 59.

2%
A CULPRIT IN SIGHT
Anti-VEGF medications block the VEGF protein that promotes macular degeneration. But not everyone with wet AMD responds to the drugs. To find out why this may be, researchers compared the eye fluids of responders and nonresponders and discovered several inflammatory proteins. In nonresponders, the proteins were overactive. In responders, the proteins were less active. They also uncovered a few anti-inflammatory proteins. These were more active in responders’ eyes and less active in nonresponders’ eyes. This discovery could help doctors predict who will benefit from treatment. It could also lead to new drugs to help get those proteins under control.

SOURCE: Frontiers in Medicine - Ophthalmology

FIGHTER GENES
One day, doctors could deliver new genes to your eyes that will treat wet AMD. Researchers are testing treatments that involve injecting special helper genes into the eyes. These genes are programmed to make disease-fighting proteins that fight against VEGF—the protein that plays the biggest role in promoting macular degeneration. They are still in clinical trials, but if they work, a one-time treatment with gene therapy could be all your eyes need to stave off AMD for years.

SOURCE: Journal of Clinical Medicine

10%
Amount of AMD cases that are the “wet” form.

SOURCE: BrightFocus Foundation
A handful of goji berries could be good for your eyes. In a small study, a group of middle-aged and older adults ate an ounce of these red berries 5 days a week. Another group took a daily supplement that’s supposed to improve eye health. After 90 days, folks in the berry group had higher levels of retina-protecting pigments called lutein and zeaxanthin in their eyes. The supplement group did not. While the tart berries won’t cure or treat AMD, it won’t hurt most people to try them as a way to boost eye health. (If you take blood thinners, ask your doctor before you snack on gojis.)

SOURCE: Nutrients

Estimated global cost of visual impairment from AMD.

SOURCE: BrightFocus Foundation

$343 BILLION

Estimated global cost of visual impairment from AMD.

SOURCE: BrightFocus Foundation
In the late ’90s, I was at my annual checkup with my optometrist when I learned some of the cells in my macula were beginning to deteriorate. It was unexpected news because I wasn’t having any vision problems. Other than needing glasses to read, nothing seemed off with my sight. But I knew my genetic risk was high: Every member of my family on my father’s side who lived past 60 had developed macular degeneration.

I started taking eye vitamins. Things continued to appear normal to me, but the doctors could see that the cells in my macula were becoming more and more involved. I was diagnosed with diabetes around
that time, and so they also stressed the importance of keeping my blood sugar levels low as another way to protect my eyes from getting worse.

It wasn’t until a few years later that I suddenly realized while driving one day that I had no depth perception. I had finally lost the central vision in my right eye. I began getting injections in that eye—a stopgap measure to prevent all the cells from dying and to keep fluid from developing behind the retina.

Despite how they sound, eye injections aren’t that bad. They deaden the nerves in your eye with lidocaine, so you don’t feel it. The worst part is really just the thought of a needle going in your eye. Dealing with symptoms can be harder. Once my second eye lost central vision, I couldn’t read, I couldn’t watch TV very well, and worst of all, I couldn’t see faces, which meant I couldn’t recognize people I knew.

Last year at the age of 82, I was diagnosed as legally blind. The macular cells had finally given up. I figured since I couldn’t see anymore, I’d quit taking vitamins. But once I did, my peripheral vision started going away. Colors started fading. So I started taking them again. And now I can see colors. They’re not vivid, but I can see what’s red and green and blue.

Even though I lived for years with the disease, I’m still trying to come to grips with my loss of central vision. But I’m not completely blind. I have peripheral vision. I can cook, wash clothes, clean the house, and help my wife. This is a very slow progressive disease, and treatments have helped reduce the fluid buildup behind the retina so I can do these things.

**JIM’S TIPS**

**Take eye vitamins.**
As soon as you’re diagnosed, start treatment, even if you don’t have symptoms.

**See a retina specialist.**
It’s important to go every 6 months.

**Find resources.**
Organizations for vision impairment can help you with visual aids and connect you to others going through the same thing.
When you have wet age-related macular degeneration (AMD), your doctor will schedule you for regular appointments to monitor your vision and see how well treatment is working.

“Once you’ve started treatment, it’s very important to follow up [with your doctor],” says Alex Yuan, an ophthalmologist at the Cleveland Clinic in Ohio. “We need to follow up to see if treatment is actually working and whether the retina is responding in a positive way.”

WHAT TO EXPECT
Medicines most often used to treat wet AMD are injected into your affected eye at the doctor’s office. You’ll need to go in at regular intervals, often every 4 to 6 weeks. At each follow-up visit, your doctor will check your vision. They’ll look for fluid under your retina to see if it’s time for another treatment.

Your doctor may bring you back on a fixed schedule, say every 4 weeks. If they see fluid is leaking into your retina, you’ll get another treatment. If the previous treatment is still working and there’s no fluid, they’ll hold off.

“On that schedule, it’s critical to return,” Yuan says. “If you’re not treated one month, the following month [the AMD] might be active. You can imagine if you don’t get treated and then miss appointments, you could have active AMD and lose vision.”

AVOID THE ‘GUESSING GAME’
Alternatively, your doctor may treat you again at the next visit whether there’s fluid or not. Then they’ll extend the time until your next visit. The goal is to find the right treatment interval for your AMD.

“With that type of schedule, when a pa-
tient doesn’t return, we won’t know which interval works for that patient,” Yuan says. “When they come back, it’s a guessing game as to how frequently you need to be dosed.”

VISION CHECK
Yuan says checking your eyes and vision at each return visit is critical. Your doctor will use an eye chart to see how well you can see. Imaging will tell them if there’s fluid under the retina. “We want to look for less fluid than at the last visit, to determine if things are headed in the right direction,” he says.

TAKE IT EASY
Yuan says you should take it easy after any follow-up appointment that may involve treatment. Your doctor will numb your eye before delivering the medicine. If you try and use your eye too much while you can’t feel it, it’s likely to dry out and get irritated.

While treatment is generally well-tolerated, the best plan is to “go home and go to sleep,” Yuan says. If you can’t take time out to rest, he recommends using plenty of artificial tears. Most people can return to normal activities the following day.
MACULAR DEGENERATION AND AGING

WHAT TO EXPECT

By Rachel Reiff Ellis
Reviewed by Brunilda Nazario, MD, WebMD Chief Physician Editor, Medical Affairs

Like the name says, age plays a key role in bringing on age-related macular degeneration (AMD). It happens when aging causes damage to your macula—the part of the eye that controls sharp, straight-ahead vision.

The macula is part of your retina, and has some of the most metabolically active cells in your body. Over time, wear and tear can lead to the symptoms of the disease.

“As the retina is churning out all this energy and turning light into a signal that our brain can use, unfortunately there's going to be breakdown of those components,” says Peter Krall, MD, ophthalmologist at Scripps Clinic in Oceanside, CA.

WHY IT HAPPENS

Macular degeneration is the most common cause of vision loss of people ages 50 and older. Besides age, other factors can raise your risk
of it, such as:

• Family history
• Exposure to ultraviolet light
• High-fat diet
• Smoking
• High blood pressure

“In the aging eye, it’s the combination of increased exposure to stresses and compromised defense systems that is thought to lead to the development of AMD,” says Akrit So- dhi, MD, PhD, associate professor of oph- thalmology at the Johns Hopkins Wilm- er Eye Institute in Columbia, MD.

WHAT YOU CAN DO ABOUT IT
Over time you may have trouble with daily activities such as driving and reading, and may need certain tools to help you see. But Krall says catching it early is the key to holding off symptoms. “There are really effective medications that can reduce the fluid buildup in the
retina, and really extend the amount of time that you have your vision,” Krall says.

If you’re in the early stages of AMD, your doctor won’t treat it. Instead, you’ll go in regularly for eye exams to keep tabs on your condition.

The main treatment for wet AMD is a medication called anti-VEGF. You get it through injection into your (numbed) eye. VEGF stands for vascular endothelial growth factor, which helps new blood vessels grow. These new blood vessels cause most of the symptoms of wet AMD. By blocking their growth, you halt the progression of the disease.

Sometimes doctors use a laser treatment called photodynamic therapy (PDT) along with anti-VEGF injections.

Sodhi says these therapies seem to work well for wet AMD and continue to improve. “With early treatment, most patients with wet AMD maintain good vision,” he says. “Researchers around the world are currently developing new treatments for advanced AMD with the goal of improving upon current treatments for wet AMD and preserving or improving vision in patients with advanced dry AMD.”

### WATCH OUT

**Pay attention to these symptoms specific to macular degeneration:**

- Blurry, blank, or distorted spots (instead of general blur)
- Normal peripheral vision, but problems with front focus
- Missing details of faces or letters in words
- Straight lines appearing wavy