EYLEA® (aflibercept) Injection For Intravitreal Injection

FACT SHEET ABOUT EYLEA® (aflibercept) INJECTION

WHAT IS EYLEA?

EYLEA, an inhibitor of vascular endothelial growth factor (VEGF), was discovered and developed by Regeneron Pharmaceuticals, Inc.

The U.S. Food and Drug Administration (FDA) has approved EYLEA for the treatment of neovascular (wet) age-related macular degeneration (AMD), macular edema following retinal vein occlusion (RVO), diabetic macular edema (DME), and diabetic retinopathy in patients with DME. Since launch in 2011, more than 2 million doses of EYLEA have been administered.

EYLEA is contraindicated in patients with ocular or periocular infections, active intraocular inflammation or known hypersensitivity to aflibercept or to any of the excipients in EYLEA.

WHAT IS VASCULAR ENDOTHELIAL GROWTH FACTOR (VEGF) AND ITS ROLE IN EYE DISEASE?

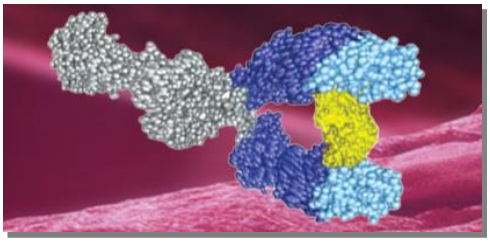
VEGF is a naturally occurring family of growth factors in the blood vessels that trigger the formation of new blood vessels, a process known as angiogenesis.

However, in certain diseases, such as wet AMD, macular edema following RVO, DME, and diabetic retinopathy with DME, the release or excessive production of VEGF is associated with:[1-3]

- increased vascular permeability (the capacity of a blood vessel wall to allow fluid and small molecules in and out of the vessel)
- swelling from fluid accumulation in cells or tissues
- the growth of fragile and abnormally formed blood vessels in the eye
- reduced vision

HOW DOES EYLEA WORK?

EYLEA is designed to block the growth of new blood vessels and decrease the ability of fluid to pass through blood vessels (vascular permeability) in the eye by blocking VEGF-A and placental growth factor (PLGF), two growth factors involved in angiogenesis. EYLEA helps prevent VEGF-A and PLGF from interacting with their native VEGF receptors, as shown in preclinical studies.



EYLEA binds to VEGF-A and PLGF like two hands on a football

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HOW IS EYLEA® (aflibercept) INJECTION ADMINISTERED?

EYLEA is injected into the eye (intravitreal injection). EYLEA is available as a single, 2-mg strength intravitreal injection for all approved indications.

EYLEA must only be administered by a qualified physician, such as a retina specialist.

WHAT PHASE 3 CLINICAL STUDIES WERE CONDUCTED WITH EYLEA?

INDICATION	**PIVOTAL STUDIES**[4-9]
Wet AMD	VIEW 1 VIEW 2
DME & diabetic retinopathy with DME	VISTA-DME VIVID-DME
Macular edema following RVO	COPERNICUS (macular edema following CRVO) GALILEO (macular edema following CRVO) VIBRANT (macular edema following BRVO)

IMPORTANT PRESCRIBING INFORMATION FOR EYLEA® (aflibercept) INJECTION

EYLEA® (aflibercept) Injection is a prescription medicine approved for the treatment of patients with:

Wet age-related macular degeneration (AMD): The recommended dose for EYLEA is 2 mg administered by injection in the eye every 2 months (8 weeks) following 3 initial monthly (4 weeks) injections. EYLEA may be dosed once per month, but additional benefit was not seen with this dosing plan.

Macular edema following retinal vein occlusion (RVO): The recommended dose for EYLEA is 2 mg administered by injection in the eye monthly (every 4 weeks).

Diabetic macular edema (DME) and diabetic retinopathy (DR) in patients with DME: The recommended dose for EYLEA is 2 mg administered by injection in the eye every 2 months (8 weeks) following 5 initial monthly (4 weeks) injections. EYLEA may be dosed once per month, but additional benefit was not seen with this dosing plan.

IMPORTANT SAFETY INFORMATION FOR EYLEA® (aflibercept) INJECTION

EYLEA® (aflibercept) Injection is a prescription medication 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. As with all medications, EYLEA can cause side effects.

Injection into the eye can result in an infection in the eye and retinal detachment. Inflammation in the eye has been reported with the use of EYLEA.

In some patients, injections with EYLEA may trigger 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 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 are rare but can occur including infection inside the eye and retinal detachment.

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

It is important that you contact your doctor right away if you think you might be experiencing any side effects.

EYLEA is for prescription use only. 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.

REFERENCES

1. Jager RD, Meiler WF, Miller JW. Age-related macular degeneration. *N Engl J Med* 2008;358:2606-2617.
2. Ciulla T, Amador A, Zinman B. Diabetic retinopathy and diabetic macular edema: pathophysiology, screening, and novel therapies. *Diabetes Care* 2003;26(9):2653-2664.
3. Karia N. Retinal vein occlusion: pathophysiology and treatment options. *Clinical Ophthalmology* 2010; 4:809–816.
4. Heier JS, Brown DM, Chong V, et al. Intravitreal aflibercept (VEGF Trap-Eye) in wet age-related macular degeneration. *Ophthalmology* 2012;119:2537-2548.
5. Korobelnik, JF, Do, DV, Schmidt-Erfurth, U. et al. Intravitreal aflibercept for diabetic macular edema. *Ophthalmology* 2014;121(11):2247-54.
6. Boyer D, Heier J, Brown DM, et al. Vascular endothelial growth factor Trap-EYE for macular edema secondary to central retinal vein occlusion: Six month results of the phase 3 COPERNICUS study. *Ophthalmology* 2012;119(5):1024-1032.
7. Holz FG, Roider J, Ogura Y, et al. VEGF Trap-Eye for macular oedema secondary to central retinal vein occlusion: 6-month results of the phase III GALILEO study. *Br J Ophthalmol* 2013; 97:278–284.
8. EYLEA® (aflibercept) Injection full U.S. Prescribing Information. Regeneron Pharmaceuticals, Inc. March, 2015
9. Campochiaro PA, Clark WL, Boyer DS. Intravitreal aflibercept for macular edema following branch retinal vein occlusion: The 24-week results of the VIBRANT study. *Ophthalmology* 2015; 122(3): 538-44.