



VABYSMOTM
faricimab-svoa injection 6 mg

FACT SHEET

Media Inquiries:
(650) 467-6800

About Vabysmo

Vabysmo (faricimab-svoa) is FDA-approved for the treatment of people with wet age-related macular degeneration (AMD) and diabetic macular edema (DME). It targets and inhibits two disease pathways linked to a number of vision-threatening retinal conditions by neutralizing angiopoietin-2 (Ang-2) and vascular endothelial growth factor-A (VEGF-A).¹

**FIRST BISPECIFIC ANTIBODY
APPROVED FOR THE EYE**

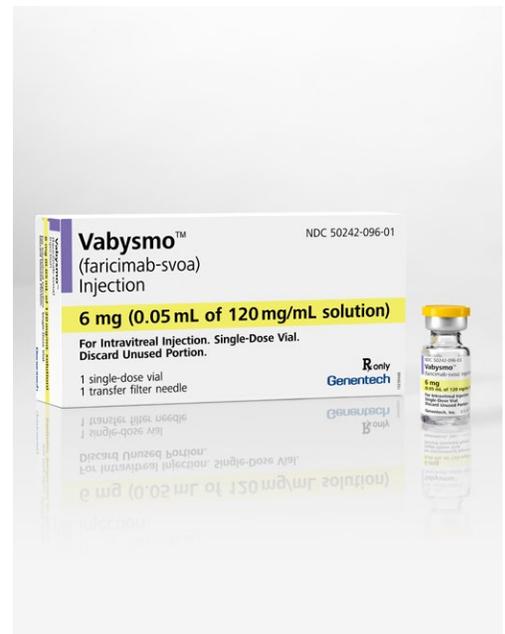
THAT TARGETS AND INHIBITS TWO DISEASE PATHWAYS LINKED TO VISION LOSS

FIRST & ONLY

FDA-APPROVED INJECTABLE EYE MEDICINE FOR WET AMD AND DME THAT
IMPROVES AND MAINTAINS VISION WITH TREATMENTS FROM

ONE TO FOUR MONTHS APART

IN THE FIRST YEAR*



*following four initial monthly doses, based on evaluation of the patient's anatomy and vision outcomes

Important Safety Information

Vabysmo U.S. Indications

Vabysmo (faricimab-svoa) is a prescription medicine given by injection into the eye, used to treat adults with neovascular (wet) age-related macular degeneration (AMD) and diabetic macular edema (DME).

Important Safety Information

Contraindications

Vabysmo is contraindicated in patients who have an infection in or around their eye, have active swelling around their eye that may include pain and redness, or are allergic to Vabysmo or any of the ingredients in Vabysmo.

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Please see additional Important Safety Information in the full Vabysmo Prescribing Information.

About Wet AMD

Age-related macular degeneration (AMD) is a condition that affects the macula, the part of the eye that provides sharp, central vision needed for activities like reading.² Wet, or neovascular, AMD is an advanced form of the disease that can cause rapid and severe vision loss when left untreated.³ Wet AMD is a leading cause of blindness for people aged 60 and over in the United States.⁴

~1.1 MILLION

PEOPLE IN THE U.S. HAVE WET AMD⁴

~200,000

NEW CASES OF WET AMD ARE DIAGNOSED EACH YEAR IN THE U.S.⁵

About Diabetic Macular Edema

Diabetic macular edema (DME) is a serious eye condition that affects people with diabetes (type 1 or type 2). DME results from the damaged blood vessels leaking fluid and causing swelling, which blurs vision and can lead to severe vision loss and even blindness when left untreated.^{6,7}

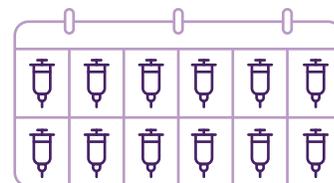
~750,000

AMERICANS HAVE DME⁸

DME IS ALSO A **LEADING CAUSE** OF VISION LOSS
AMONG THE WORKING-AGE POPULATION OF MOST DEVELOPED COUNTRIES⁹

Unmet Need

People with wet AMD and DME might need anti-vascular endothelial growth factor (VEGF) eye injections every one to two months to prevent vision loss and maintain their sight.^{10,11}



Important Safety Information (continued)

Warnings and Precautions

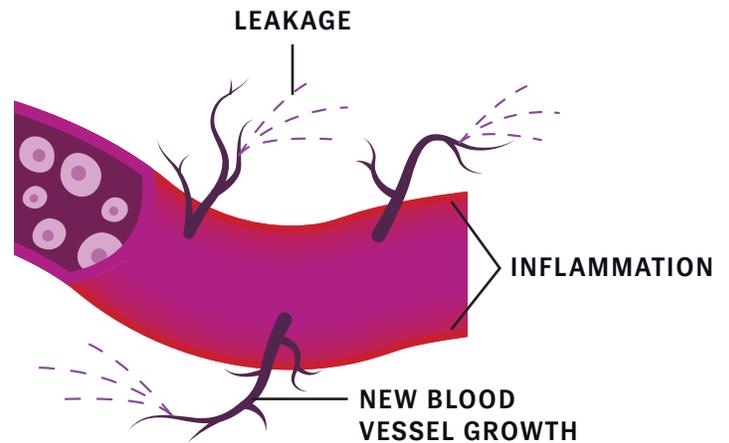
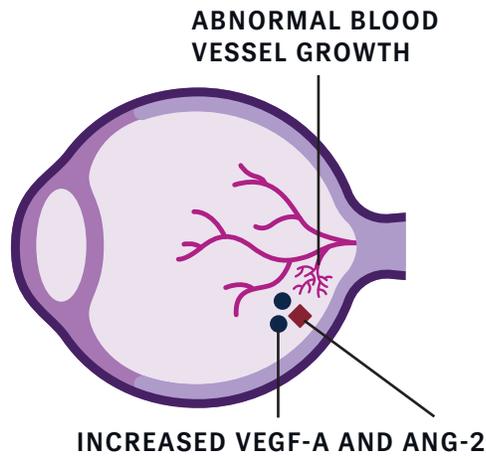
- Injections like the one for Vabysmo can cause an eye infection (endophthalmitis) or separation of layers of the retina (retinal detachment). Patients should seek medical care if they experience increasing eye pain, vision loss, sensitivity to light, or redness in the white of the eye.
- Vabysmo may cause a temporary increase in pressure in the eye (intraocular pressure), which occurs 60 minutes after the injection.
- Although not common, Vabysmo patients have had serious, sometimes fatal, problems related to blood clots, such as heart attacks or strokes (thromboembolic events). In clinical studies for wet AMD during the first year, 7 out of 664 patients treated with Vabysmo reported such an event. In DME studies during the first year, 25 out of 1,262 patients treated with Vabysmo reported such an event.

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Please see additional Important Safety Information in the full Vabysmo Prescribing Information.

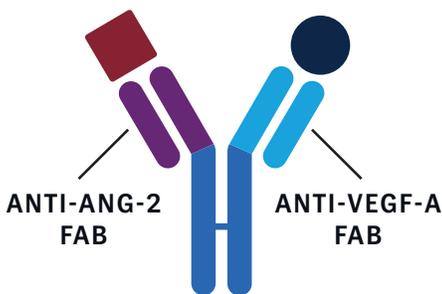
How Vabysmo Works

Vabysmo may decrease inflammation and swelling in the retina to help preserve a patient's vision.



In retinal conditions like wet AMD and DME, an overproduction of a protein called vascular endothelial growth factor (VEGF-A) causes abnormal blood vessels to grow and leak into the macula, the part of the eye responsible for sharp, central vision.^{2,7}

In these conditions, overproduction of a second protein called Angiopoietin-2 (Ang-2) results in vascular instability, leading to leakage, inflammation and stimulation of new blood vessel growth.¹² Ang-2 levels may be increased in some patients with wet AMD and DME.¹²



Vabysmo is designed to block pathways involving Ang-2 and VEGF-A.¹ Ang-2 and VEGF-A are thought to contribute to vision loss by destabilizing blood vessels, which may cause new leaky blood vessels to form and increase inflammation.^{2,7} While additional research continues, inhibition of both pathways has been shown in preclinical studies to have potentially complementary benefits, stabilizing vessels and thereby reducing vessel leakage and inflammation.¹³

Important Safety Information (continued)

Adverse Reactions

The most common adverse reaction ($\geq 5\%$) reported in patients receiving Vabysmo was blood on the white of the eye (conjunctival hemorrhage, 7%). These are not all the possible side effects of Vabysmo.

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Please see additional Important Safety Information in the full Vabysmo Prescribing Information.

Vabysmo Efficacy¹

The FDA approval of Vabysmo was based on positive results from four global Phase III clinical trials. The studies consistently showed that Vabysmo given at intervals of up to four months offered non-inferior vision gains versus aflibercept given every two months.

TENAYA and LUCERNE are two identical, randomized, multicenter, double-masked, global Phase III studies, evaluating the efficacy and safety of Vabysmo compared to aflibercept in 1,329 people living with wet AMD (671 in TENAYA and 658 in LUCERNE).

YOSEMITE and RHINE are two identical, randomized, multicenter, double-masked, global Phase III studies that evaluated the efficacy and safety of Vabysmo compared to aflibercept in 1,891 people living with DME (940 in YOSEMITE and 951 in RHINE).

Vabysmo Safety¹

In all four studies, Vabysmo was generally well-tolerated with a favorable benefit-risk profile. In TENAYA and LUCERNE, the most common adverse reactions ($\geq 3\%$ of patients) included conjunctival hemorrhage, vitreous floaters, retinal pigment epithelial (RPE) tears, increase of intraocular pressure and eye pain. In YOSEMITE and RHINE, the most common adverse reactions ($\geq 3\%$ of patients) included conjunctival hemorrhage, vitreous floaters and increase of intraocular pressure.

Vabysmo Dosing¹

With Vabysmo, people with wet AMD initially receive four monthly treatments. Based on anatomical and vision outcomes, they may receive subsequent treatments every two, three or four months. People with DME are initially given four monthly treatments. Subsequently their treatment may be extended or reduced based on anatomical and vision outcomes, with a range of one to four months between doses. A second approved treatment regimen for DME involves six monthly loading doses, followed by treatment every two months. Some people with wet AMD and DME may be treated monthly if needed, although additional efficacy was not demonstrated in most patients given Vabysmo every month.

Important Safety Information (continued)

Pregnancy, Lactation, Females and Males of Reproductive Potential

- Based on how Vabysmo interacts with your body, there may be a potential risk to an unborn baby. Patients should use birth control before their first injection, during their treatment with Vabysmo, and for 3 months after their last dose of Vabysmo.
- It is not known if Vabysmo passes into breast milk. Patients should talk to their healthcare provider about the best way to feed their baby if they receive Vabysmo.

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Please see additional Important Safety Information in the full Vabysmo Prescribing Information.

Important Safety Information (continued)

Patients may report side effects to the FDA at (800) FDA-1088 or www.fda.gov/medwatch. Patients may also report side effects to Genentech at (888) 835-2555.

Please see additional Important Safety Information in the full Vabysmo [Prescribing Information](#).

1. Vabysmo (faricimab-svoa) Prescribing Information. Genentech, Inc. 2022.
2. BrightFocus Foundation. Macular Degeneration: Essential Facts. Available at: <https://www.brightfocus.org/macular/news/macular-essential-facts>. Accessed November 2021.
3. National Eye Institute. Age-Related Macular Degeneration. Available at: <https://www.nei.nih.gov/learn-about-eye-health/eye-conditions-and-diseases/age-related-macular-degeneration>. Accessed November 2021.
4. BrightFocus Foundation. Age-Related Macular Degeneration: Facts & Figures. Available at: <https://www.brightfocus.org/macular/article/age-related-macular-facts-figures>. Accessed August 2021.
5. Maguire MG. Comparing treatments for age-related macular degeneration: safety, effectiveness and cost. Issue Brief. 2012;17(8). Leonard Davis Institute of Health Economics. Accessed February 7, 2020. idi.upenn.edu/sites/default/files/pdf/Issue%20Brief%2017_8.pdf.
6. National Eye Institute. Diabetic Retinopathy. Available at: <https://www.nei.nih.gov/learn-about-eye-health/eye-conditions-and-diseases/diabetic-retinopathy>. Accessed November 22, 2012.
7. Lee, R., Wong, T.Y. & Sabanayagam, C. Epidemiology of diabetic retinopathy, diabetic macular edema and related vision loss. Eye and Vis 2, 17 (2015). <https://doi.org/10.1186/s40662-015-0026-2>.
8. National Eye Institute. Macular Edema. Available at: <https://www.nei.nih.gov/learn-about-eye-health/eye-conditions-and-diseases/macular-edema>. Accessed November 22, 2021.
9. Ciulla TA, Amador AG, Zinman B. Diabetic retinopathy and diabetic macular edema: pathophysiology, screening, and novel therapies. Diabetes Care. 2003 Sep;26(9):2653-64. doi: 10.2337/diacare.26.9.2653. PMID: 12941734.
10. National Eye Institute. Injections to Treat Diabetic Retinopathy and Diabetic Macular Edema. Available at: <https://www.nei.nih.gov/learn-about-eye-health/eye-conditions-and-diseases/diabetic-retinopathy/injections-treat-diabetic-retinopathy-and-diabetic-macular-edema>. Accessed November 2021.
11. Holz FG, et al. Multi-country real-life experience of anti-vascular endothelial growth factor therapy for wet age-related macular degeneration. The British Journal of Ophthalmology. 2015;99:220-6.
12. Khan M, et al. Targeting Angiotensin II in retinal vascular diseases: A literature review and summary of clinical trials involving faricimab. Cells. 2020;9:1869.
13. Heier JS, et al. The Angiotensin II/Tie pathway in retinal vascular diseases: a review. Retina-J Ret Vit Dis. 2021;41:1-19.

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