VABYSMO™
faricimab-svoa injection 6 mg

FACT SHEET

Media Inquiries:
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About Vabysmo

Vabysmo (faricimab-svoa) is FDA-approved for the treatment of people with wet age-related macular degeneration (AMD), diabetic macular edema (DME) and macular edema following retinal vein occlusion (RVO). It targets two distinct 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
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), diabetic macular edema (DME) and macular edema following retinal vein occlusion (RVO).

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]

~1.5 MILLION PEOPLE IN THE U.S. HAVE LATE-STAGE AMD, WHICH INCLUDES WET AMD[5]

~200,000 NEW CASES OF WET AMD ARE DIAGNOSED EACH YEAR IN THE U.S.[6]

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.[7,8]

~750,000 AMERICANS HAVE DME[9]

DME IS ALSO A **LEADING CAUSE** OF VISION LOSS AMONG THE WORKING-AGE POPULATION OF MOST DEVELOPED COUNTRIES[8]

About Retinal Vein Occlusion (RVO)

Retinal vein occlusion is a retinal disease that occurs when normal blood flow through a retinal vein becomes blocked. This can cause fluid to become trapped within and under the retina, leading to swelling and bleeding in the macula. Without treatment, this condition typically leads to rapid and severe vision loss or blindness. There are two main types of RVO:

- Central RVO (CRVO) occurs when the eye's main, or central, retinal vein becomes blocked.[10]
- Branch RVO (BRVO) occurs when one of the smaller veins emptying into the eye's main retinal vein becomes blocked.[11]

1 MILLION+ PEOPLE IN THE U.S. ARE AFFECTED BY RVO[12]

RVO IS THE **2ND MOST COMMON** CAUSE OF VISION LOSS DUE TO RETINAL VASCULAR DISEASES[12]

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.

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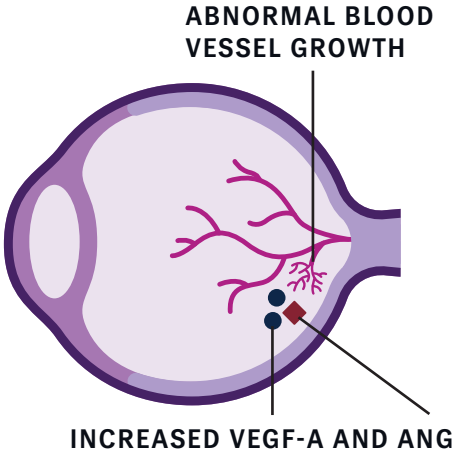
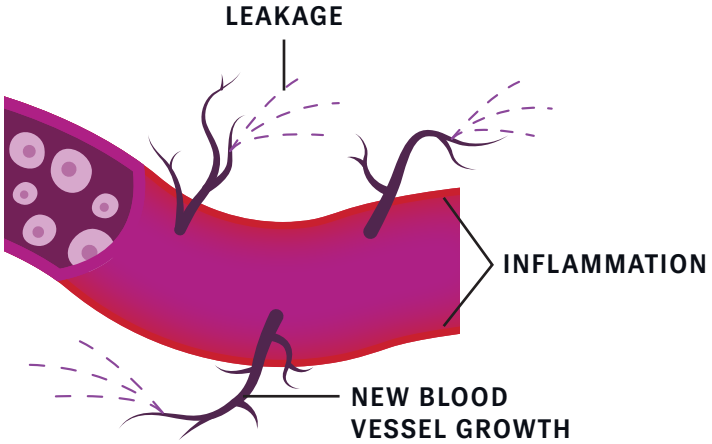
Please see additional Important Safety Information in the full Vabysmo Prescribing Information.

How Vabysmo Works

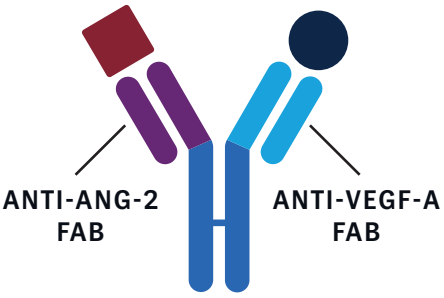
Vabysmo may decrease inflammation and swelling in the retina to help preserve a patient's vision.





In retinal conditions like wet AMD, DME and RVO, 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.[2,8,13]

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.[14] Ang-2 levels may be increased in some patients with wet AMD, DME and RVO.[14,15,16]



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.[2,8] 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.[17]

Important Safety Information (continued)

- 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 from baseline to week 100, 64 out of 1,262 patients treated with Vabysmo reported such an event. In clinical studies for RVO during 6 months, 7 out of 641 patients treated with Vabysmo reported such an event.
- Retinal vasculitis and/or retinal vascular occlusion, typically in the presence of intraocular inflammation, have been reported with the use of Vabysmo. Healthcare providers should discontinue treatment with Vabysmo in patients who develop these events. Patients should be instructed to report any change in vision without delay.

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

Vabysmo Efficacy[1]

The FDA approval of Vabysmo for wet AMD and DME 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 were 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 were 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).

The FDA approval of Vabysmo for macular edema following RVO was based on positive results from two global Phase III clinical trials. BALATON and COMINO demonstrated that treatment with Vabysmo provided early and sustained improvement in vision, meeting the primary endpoint of non-inferior visual acuity gains at 24 weeks compared to aflibercept. BALATON and COMINO were two randomized, multicentre, double-masked, global phase III studies that evaluated the efficacy and safety of Vabysmo compared to aflibercept.[18,19]

The studies were similar in design but were conducted in different patient populations.[18,19] The BALATON study was conducted in 553 people with BRVO,[18] while the COMINO study was conducted in 729 people with CRVO or hemiretinal vein occlusion (HRVO).[19]

Vabysmo Safety[1]

In all six studies, Vabysmo was generally well-tolerated with a favorable benefit-risk profile. In TENAYA and LUCERNE, the most common adverse reactions (≥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 (≥3% of patients) included conjunctival hemorrhage, vitreous floaters and increase of intraocular pressure.

In BALATON and COMINO the most common adverse reaction (3% of patients) was conjunctival hemorrhage.

Important Safety Information (continued)

Adverse Reactions

The most common adverse reactions (≥5%) reported in patients receiving Vabysmo were cataract (15%) and blood on the white of the eye (conjunctival hemorrhage, 8%). These are not all the possible side effects of Vabysmo.

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.

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

Vabysmo Dosing[1]

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. People with macular edema following RVO receive monthly treatments.

Important Safety Information (continued)

- 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.

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** or visit **www.Vabysmo.com**.

1. Vabysmo (faricimab-svoa) Prescribing Information. Genentech, Inc. 2023.
2. BrightFocus Foundation. Macular Degeneration: Essential Facts. Available at: https://www.brightfocus.org/macular/news/macular-essential-facts. Accessed November 7, 2023.
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 7, 2023.
4. BrightFocus Foundation. Age-Related Macular Degeneration: Facts & Figures. Available at: https://www.brightfocus.org/macular/article/age-related-macular-facts-figures. Accessed November 7, 2023.
5. JAMA Ophthalmology. Original Investigation: Prevalence of Age-Related Macular Degeneration in the US in 2019. Available at: https://jamanetwork.com/journals/jamaophthalmology/article-abstract/2797921. Accessed November 7, 2023.
6. 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 November 7, 2023. ldi.upenn.edu/sites/default/files/pdf/Issue%20Brief%2017_8.pdf.
7. National Eye Institute. Diabetic Retinopathy. Available at: https://www.nei.nih.gov/learn-about-eye-health/eye-conditions-and-diseases/diabetic-retinopathy. Accessed November 7, 2023.
8. 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.
9. National Eye Institute. Macular Edema. Available at: https://www.nei.nih.gov/learn-about-eye-health/eye-conditions-and-diseases/macular-edema. Accessed November 7, 2023.
10. American Academy of Ophthalmology. Central Retinal Vein Occlusion. Available at https://www.aao.org/eye-health/diseases/what-is-central-retinal-vein-occlusion. Accessed November 7, 2023.
11. American Academy of Ophthalmology. Branch Retinal Vein Occlusion. Available at https://www.aao.org/eye-health/diseases/what-is-branch-retinal-vein-occlusion. Accessed November 7, 2023.
12. Genentech data on file (Based on population-based studies/the Beaver Dam Eye Study 2000 and 2008 and the United States Census)
13. Stewart MW. The expanding role of vascular endothelial growth factor inhibitors in ophthalmology. *Mayo Clin Proc*. 2012 Jan;87(1):77-88. doi:10.1016/j.mayocp.2011.10.001. PMID: 22212972; PMCID: PMC3498409.
14. Khan M, et al. Targeting Angiopoietin in retinal vascular diseases: A literature review and summary of clinical trials involving faricimab. *Cells*. 2020;9:1869.
15. Regula JT, et al. Targeting key angiogenic pathways with a bispecific CrossMab optimized for neovascular eye diseases. *EMBO Molecular Medicine*. 2016;8:1265–88.
16. Joussen et al. Angiopoietin/Tie2 signalling and its role in retinal and choroidal vascular diseases: a review of preclinical data. *Eye*. 2021;35:1305-1316.
17. Heier JS, et al. The Angiopoietin/Tie pathway in retinal vascular diseases: a review. *Retina-J Ret Vit Dis*. 2021;41:1-19.
18. Clinical Trials.gov. A study to evaluate the efficacy and safety of faricimab in participants with macular edema secondary to branch retinal vein occlusion (BALATON) [Internet; cited October 2022]. Available from: https://clinicaltrials.gov/ct2/show/NCT04740905.
19. Clinical Trials.gov. A study to evaluate the efficacy and safety of faricimab in participants with macular edema secondary to central retinal or hemiretinal vein occlusion (COMINO) [Internet; cited October 2022]. Available from: https://clinicaltrials.gov/ct2/show/NCT04740931.