



susvimo™
ranibizumab injection 100 mg/mL
For Ocular Implant

FACT SHEET

Media Inquiries:
(650) 467-6800

About Susvimo

Susvimo (ranibizumab injection) 100 mg/mL for intravitreal use via ocular implant, previously called Port Delivery System with ranibizumab (PDS), is approved by the FDA for the treatment of people with wet age-related macular degeneration (AMD) who have responded to at least two anti-vascular endothelial growth factor (VEGF) injections. Susvimo continuously delivers a customized formulation of ranibizumab into the eye through a refillable implant. If necessary, supplemental ranibizumab treatment can be given to the affected eye while the Susvimo implant is in place.¹

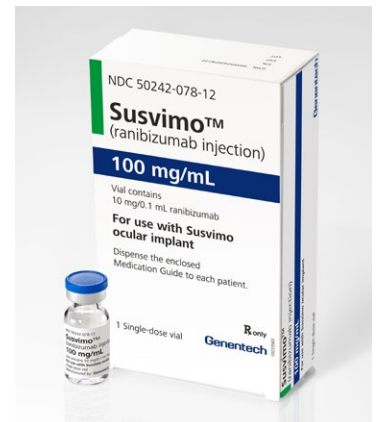
FIRST & ONLY

WET AMD TREATMENT THAT OFFERS AS FEW AS TWO TREATMENTS PER YEAR

FIRST

REFILLABLE EYE IMPLANT FOR THE TREATMENT OF WET AMD

FIRST WET AMD TREATMENT IN 15 YEARS THAT GIVES PATIENTS AN ALTERNATIVE TO STANDARD-OF-CARE EYE INJECTIONS NEEDED AS OFTEN AS ONCE A MONTH



Important Safety Information

Susvimo Indication

Susvimo (ranibizumab injection) 100 mg/mL for intravitreal use via ocular implant is indicated for the treatment of patients with neovascular (wet) age-related macular degeneration (AMD) who have previously responded to at least two intravitreal injections of a vascular endothelial growth factor inhibitor medication.

Susvimo Important Safety Information

WARNING: ENDOPTHALMITIS

The Susvimo implant has been associated with a three-fold higher rate of endophthalmitis than monthly intravitreal injections of ranibizumab. In clinical trials, 2.0% of patients receiving an implant experienced at least one episode of endophthalmitis.

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Please see Important Safety Information, including Serious Side Effects, as well as the SUSVIMO full Prescribing Information and Medication Guide.

About Wet AMD

Age-related macular degeneration (AMD) is a disease that impacts the macula, part of the eye that provides sharp, central vision.² Wet AMD is an advanced form of the disease that can cause rapid and severe vision loss.² Wet AMD is a leading cause of blindness for people aged 60 and over.³

~1.1 MILLION

PEOPLE IN THE U.S. HAVE WET AMD^{2,3}

~200,000

NEW CASES OF WET AMD ARE
DIAGNOSED EACH YEAR IN THE U.S.⁴

~90%

OF THOSE WITH WET AMD WILL
ADVANCE TO LEGAL BLINDNESS IF
LEFT UNTREATED^{2,3}

SYMPTOMS OF WET AMD INCLUDE:⁵



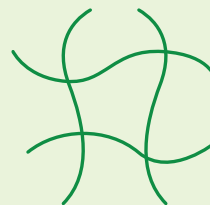
**SUDDEN BLURRED
VISION**



**BLIND SPOTS IN
CENTRAL VISION**



**DIFFICULTY
DISTINGUISHING COLORS**



**LINES APPEAR
WAVY**

Important Safety Information (continued)

Warnings and Precautions:

The Susvimo implant and the procedures associated with inserting, filling, refilling, and (if medically necessary) removing the implant can cause other serious side effects, including:

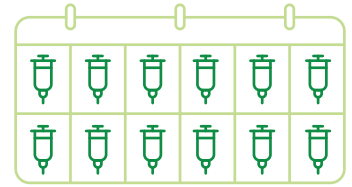
- **An eye infection (endophthalmitis).** Endophthalmitis is an infection of the eyeball that can cause permanent damage to your eye, including blindness. Endophthalmitis requires urgent (same-day) medical or surgical treatment.
- **A missing layer on top of the white part of the eye (conjunctival erosion).** Conjunctival erosion is an area that becomes missing (defect) in the layer (conjunctiva) that covers the white part of the eye, which may result in exposure of the implant. Conjunctival erosion may require surgical treatment.
- **An opening of the layer that covers the white part of the eye (conjunctival retraction).** Conjunctival retraction is an opening or gaping in the layer (conjunctiva) that covers the white part of the eye, which may cause the implant to be exposed. Conjunctival retraction may require surgical treatment.

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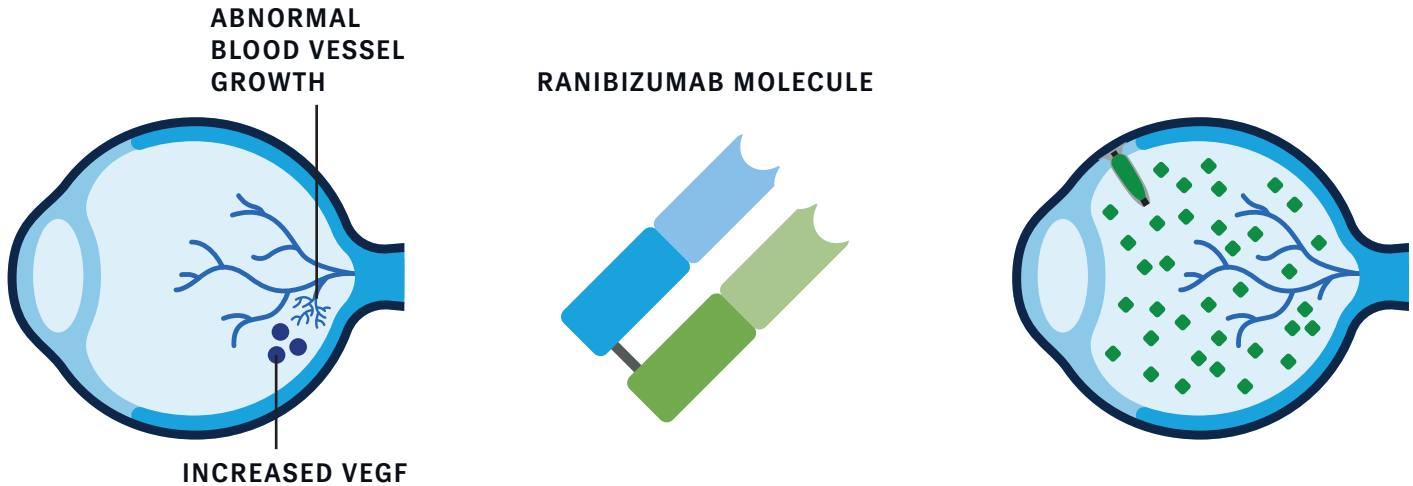
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Unmet Need

People with wet AMD need anti-vascular endothelial growth factor (VEGF) eye injections **as often as once a month** to prevent vision loss and maintain their sight.



How Susvimo Works¹



Wet AMD may have several causes, one of which is linked to an overproduction of a protein called vascular endothelial growth factor (VEGF) that causes abnormal blood vessels to grow and leak into the macula.²

Susvimo continuously delivers a customized formulation of ranibizumab. Ranibizumab is an anti-VEGF medicine designed to bind to and inhibit VEGF.¹

Susvimo is a refillable implant surgically inserted into the eye during a one-time, outpatient procedure and refilled about every six months to maintain therapeutic levels of medicine.¹

Important Safety Information (continued)

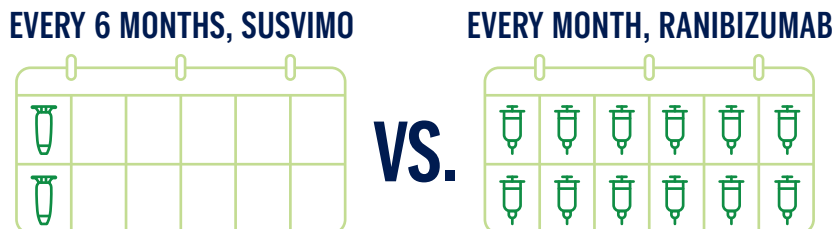
- **Tear and separation of layers of the retina (rhegmatogenous retinal detachment).** Rhegmatogenous retinal detachment is a tear and separation of one of the layers of the retina in the back of the eye that senses light. Rhegmatogenous retinal detachment requires surgical treatment.
- **Implant movement (implant dislocation):** This movement may require surgical treatment to correct.
- **Bleeding (vitreous hemorrhage):** Vitreous hemorrhage is bleeding within the gel-like substance (vitreous) inside of your eye. This may require an additional eye surgery.
- **Bump on top of the white layer of the eye (conjunctival bleb):** Conjunctival bleb is a small bulge in the layer (conjunctiva) that covers the white part of the eye where the implant is inserted. This may be due to leakage of fluid from the inside of the eye. This may require medical or surgical treatment.
- **Temporary decrease in vision after the Susvimo procedure.**

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Susvimo Efficacy¹

The FDA approval of Susvimo was based on the positive results from the Phase III Archway clinical trial. The Archway trial evaluated the efficacy and safety of Susvimo administered via the Susvimo eye implant, refilled every six months at fixed intervals, compared to monthly intravitreal injections of ranibizumab 0.5 mg. The study evaluated 415 people living with wet AMD who had previously responded to prior treatment with anti-VEGF therapy.



THE ARCHWAY TRIAL SHOWED:¹

SUSVIMO PATIENTS ACHIEVED VISION GAINS
EQUIVALENT TO MONTHLY
RANIBIZUMAB INJECTIONS

ONLY 1.6%

OF SUSVIMO PATIENTS NEEDED SUPPLEMENTAL TREATMENT
BEFORE THEIR FIRST REFILL

>98%

OF SUSVIMO PATIENTS COULD GO SIX MONTHS
BEFORE THEIR FIRST REFILL

5X FEWER

SUSVIMO TREATMENTS THAN MONTHLY RANIBIZUMAB
AT ONE YEAR*⁶

**For Archway trial patients who did not receive supplemental treatment in the first six months*

Susvimo Safety¹

In the Archway study, Susvimo was generally well-tolerated, with a favorable benefit-risk profile. However, the Susvimo implant has been associated with a three-fold higher rate of endophthalmitis than monthly intravitreal injections of ranibizumab. Many of these events were associated with conjunctival retractions or erosions. Appropriate conjunctiva management and early detection with surgical repair of conjunctival retractions or erosions may reduce the risk of endophthalmitis. In clinical trials, 2.0% of patients receiving a ranibizumab implant experienced at least one episode of endophthalmitis. The most common adverse events (AEs) were conjunctival hemorrhage, conjunctival hyperemia, iritis and eye pain. The safety profile of Susvimo in the clinical trial setting is well understood and will continue to be monitored closely.

Important Safety Information (continued)

Who should not receive Susvimo?

- Patients who have an infection in or around their eye, have active inflammation in their eye, or have had an allergic reaction to ranibizumab or any of its ingredients in Susvimo in the past.

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Please see Important Safety Information, including Serious Side Effects, as well as the SUSVIMO full Prescribing Information and Medication Guide.

Important Safety Information (continued)

Information for patients who are of childbearing potential

- If patients are pregnant, think that they might be pregnant, or plan to become pregnant. It is not known if Susvimo will harm an unborn baby. Patients should use birth control (contraception) during treatment with Susvimo and for 12 months after the last refill of Susvimo.
- If patients are breastfeeding or plan to breastfeed. Susvimo is not recommended during breastfeeding. It is not known if Susvimo passes into breast milk.

Adverse Reactions

The most common adverse reactions were blood on the white of the eye (72%), redness in the white of the eye (26%), sensitivity to light (23%), and eye pain (10%). These are not all the possible side effects of Susvimo.

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

Please see additional Important Safety Information in the full Susvimo [Prescribing Information](#), including **BOXED WARNING**.

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1. Susvimo (ranibizumab injection) Prescribing Information. Genentech, Inc. 2021.
 2. BrightFocus Foundation. Macular Degeneration: Essential Facts. Available at: <http://www.brightfocus.org/macular/news/macular-essential-facts>. Accessed August 2021.
 3. BrightFocus Foundation. Age-Related Macular Degeneration: Facts & Figures. Available at: <https://www.brightfocus.org/macular/article/age-related-macular-facts-figures>. Accessed August 2021.
 4. Stewart, M. (2012) The Expanding Role of Vascular Endothelial Growth Factor Inhibitors in Ophthalmology. Mayo Clinic Proceedings 87(1):77-88.
 5. 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 January 13, 2021.
 6. Campochiaro P, et al. Primary analysis results of the phase 3 Archway trial of the port delivery system with ranibizumab for patients with neovascular AMD. American Society of Retina Specialists Annual Meeting; 2020 July 24–26.

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