HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use SUSVIMO safely and effectively. See full prescribing information for SUSVIMO.

SUSVIMO™ (ranibizumab injection) for intravitreal use via SUSVIMO ocular implant
Initial U.S. Approval: 2006

WARNING: ENDOPHTHALMITIS
See full prescribing information for complete boxed warning.

The SUSVIMO implant has been associated with a 3-fold higher rate of endophthalmitis than monthly intravitreal injections of ranibizumab. In clinical trials, 2.0% of patients receiving an implant experienced an episode of endophthalmitis.

----------INDICATIONS AND USAGE----------
SUSVIMO (ranibizumab injection), a vascular endothelial growth factor (VEGF) inhibitor, 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 VEGF inhibitor (1.0).

----------DOSAGE AND ADMINISTRATION----------
- For intravitreal use via SUSVIMO ocular implant. (2.1)
- The recommended dose of SUSVIMO (ranibizumab injection) is 2 mg (0.02 mL of 100 mg/mL solution) continuously delivered via the SUSVIMO implant with refills every 24 weeks (approximately 6 months). (2.2)
- Supplemental treatment with 0.5 mg intravitreal ranibizumab injection may be administered in the affected eye if clinically necessary. (2.3)
- Perform the initial implantation, refill-exchange, and implant removal (if necessary) procedures under strict aseptic conditions. (2.4, 2.5, 2.6, 2.7)

----------DOSAGE FORMS AND STRENGTHS----------
Injection: 100 mg/mL solution in a single-dose vial (3)

----------CONTRAINDICATIONS----------
- Ocular or periocular infections (4.1)
- Active intraocular inflammation (4.2)
- Hypersensitivity (4.3)

----------WARNINGS AND PRECAUTIONS----------
- The SUSVIMO implant and/or implant-related procedures have been associated with endophthalmitis, rhegmatogenous retinal detachment, implant dislocation, vitreous hemorrhage, conjunctival retraction, conjunctival erosion, and conjunctival bleb. Patients should be instructed to report signs or symptoms that could be associated with these events without delay. Additional surgical and/or medical management may be required. (5.1, 5.2, 5.3, 5.4, 5.5, 5.6)
- Vitreous Hemorrhage: Temporarily discontinue antithrombotic medication prior to the implant insertion procedure to reduce the risk of vitreous hemorrhage. Vitrectomy may be needed. (5.4)
- Postoperative Decrease in Visual Acuity: A decrease in visual acuity usually occurs over the first two postoperative months. (5.7)

----------ADVERSE REACTIONS----------
The most common adverse reactions were conjunctival hemorrhage (72%), conjunctival hyperemia (26%), iritis (23%) and eye pain (10%) (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Genentech at 1-888-835-2555 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

See 17 for PATIENT COUNSELING INFORMATION and Medication Guide.

Revised: 10/2021

FULL PRESCRIBING INFORMATION: CONTENTS*

*Sections or subsections omitted from the full prescribing information are not list.

FULL PRESCRIBING INFORMATION

WARNING: ENDOPHTHALMITIS

The SUSVIMO implant has been associated with a 3-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 *[see Contraindications (4.1), Warnings and Precautions (5.1)]*.

1 INDICATIONS AND USAGE

SUSVIMO (ranibizumab injection) 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 (VEGF) inhibitor medication.

2 DOSAGE AND ADMINISTRATION

2.1 General Information

For Intravitreal Use via SUSVIMO ocular implant.

The SUSVIMO initial fill and ocular implant insertion and implant removal procedures must be performed under aseptic conditions by a physician experienced in vitreoretinal surgery. The SUSVIMO ocular implant must be surgically implanted in the eye or removed from the eye (if medically necessary) in an operating room using aseptic technique. See SUSVIMO Instructions for Use and the standardized steps to optimize surgical outcomes.

SUSVIMO refill-exchange procedures must be performed under aseptic conditions by a physician experienced in ophthalmic surgery *[see Dosage and Administration (2.7)]*.

Do not administer SUSVIMO (ranibizumab injection) as a bolus intravitreal injection. Do not substitute SUSVIMO (ranibizumab injection) with other ranibizumab products.

Initial Fill: One SUSVIMO initial fill needle (34-gauge, with integrated 5 µm filter and blue cap) is included. A 5-micron sterile filter needle (19-gauge x 1½ inch), and a 1 mL Luer lock syringe are needed but **not included**.

Refill-Exchange: One SUSVIMO refill needle (34-gauge with integrated 5 µm filter and clear cap) is included. A 5-micron sterile filter needle (19-gauge x 1½ inch), and a 1 mL Luer lock syringe are needed but **not included**.

2.2 Neovascular (Wet) Age-Related Macular Degeneration (AMD)

The recommended dose of SUSVIMO (ranibizumab injection) is 2 mg (0.02 mL of 100 mg/mL solution) continuously delivered via the SUSVIMO ocular implant with refills administered every 24 weeks (approximately 6 months).

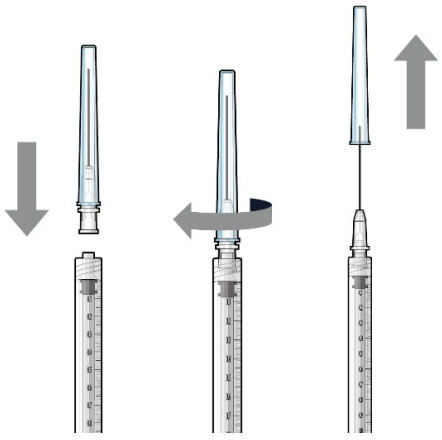
2.3 Supplemental Treatment with Intravitreal Ranibizumab Injection

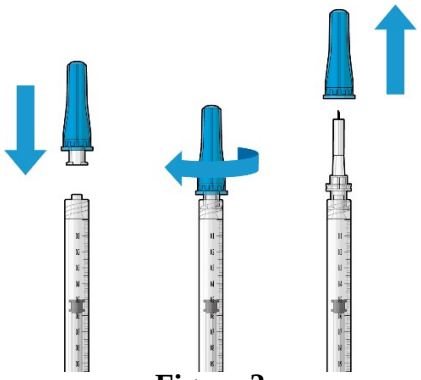
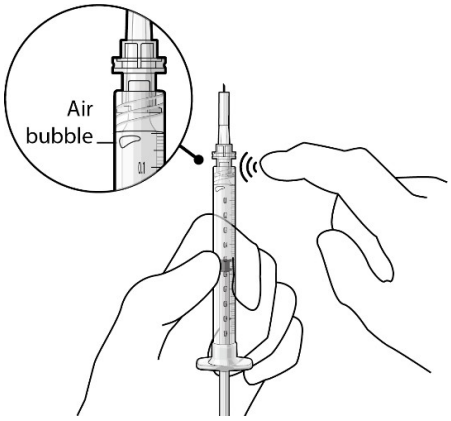
Supplemental treatment with 0.5 mg (0.05 mL of 10 mg/mL) intravitreal ranibizumab injection may be administered in the affected eye while the SUSVIMO implant is in place and if clinically necessary *[see Clinical Studies (14)]*.

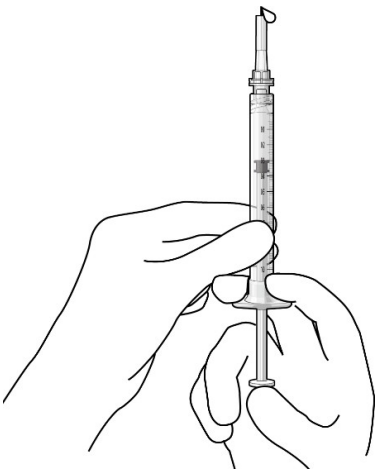
2.4 Ocular Implant Initial Fill

The implant initial fill procedure must be performed by a physician experienced in vitreoretinal surgery *[*see *Dosage and Administration (2.1)]*. The implant will be filled using aseptic technique with 0.02 mL of SUSVIMO (ranibizumab injection) prior to insertion of the implant into the patient's eye *[see Dosage and Administration (2.5)]*. Refer to the complete SUSVIMO Instructions for Use for the initial fill and implant procedure included in the insertion tool assembly carton for further details.

Use aseptic technique to carry out the following preparation steps prior to insertion of the ocular implant into the patient's eye:

Step 1: Gather the supplies needed. • One SUSVIMO ocular implant with insertion tool assembly (included) • One SUSVIMO initial fill needle (34-gauge with integrated 5 µm filter) with blue cap (included) • One SUSVIMO (ranibizumab injection) 100 mg/mL vial (included) • One sterile 5-micron filter needle (19-gauge x 1½ inch) **(not included)** • One sterile 1 mL Luer Lock syringe **(not included)**	
Step 2: Transfer Dose from Vial to Syringe **Note:** Use the filter needle (not included) to withdraw SUSVIMO (ranibizumab injection) from the vial. **Do not** use the SUSVIMO initial fill needle for this step. • Prepare SUSVIMO (ranibizumab injection) vial by removing the flip-off cap and disinfecting the rubber vial septum with alcohol. • Attach a filter needle to the syringe by screwing it tightly onto the Luer lock (see Figure 1). • Carefully remove the needle cap by pulling it straight off. • Using aseptic technique, withdraw all of the contents of the SUSVIMO (ranibizumab injection) vial through the	 **Figure 1**

filter needle into the syringe. • Remove and properly dispose of the filter needle after withdrawal of the vial contents.	
Step 3: Attach SUSVIMO Initial Fill Needle **<u>Do not</u>** use the filter needle to fill the implant. • Attach the SUSVIMO initial fill needle (included) firmly onto the syringe by screwing it tightly onto the Luer lock (see Figure 2). Ensure that the initial fill needle is attached to the syringe. • Carefully remove the needle cap by pulling straight off. • **Do not** wipe the needle at any time.	 **Figure 2**
Step 4: Remove Air from Syringe • Hold the syringe with the needle pointing up. If there are any air bubbles, gently tap the syringe with your finger until the bubbles rise to the top (see Figure 3). • Slowly push the plunger rod just until all air is expelled from the syringe and needle, and a drop of drug solution is seen at the needle tip (see Figure 4). **Note:** It is important to preserve as much drug as possible in order to completely fill the implant.	 **Figure 3**

<table>
<tr><td></td><td> 
Figure 4</td></tr>
<tr><td>Step 5: Inspect the Syringe for Air Bubbles
• Inspect the syringe and the needle hub to ensure that no air bubbles are present (see Figure 5).
• If air bubbles are present, continue to remove air from the syringe and reinspect.

Note: Use the syringe within <u>15 minutes</u> of removing all air to avoid ranibizumab drying in the needle and impeding fluid flow.

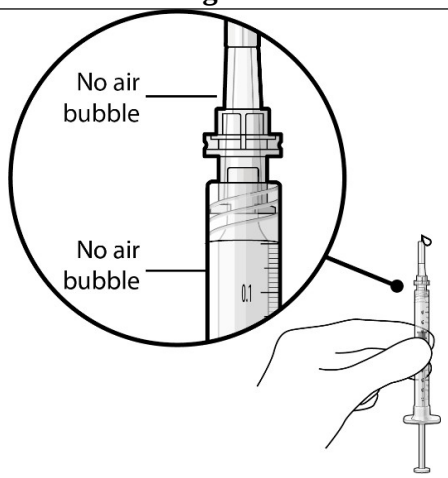
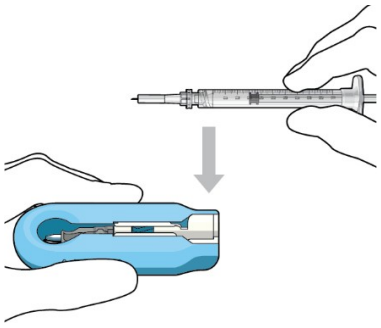
Do not use the initial fill needle if the needle is clogged.</td><td> 

Figure 5</td></tr>
<tr><td>Step 6: Load Syringe into the Carrier

Do not hold or push on the plunger rod of the syringe while inserting the needle into the implant septum.

• Retrieve insertion tool carrier with pre-positioned implant from the inner tray.
• Align the syringe Luer lock above the Luer lock slot in the carrier to protect the needle from being damaged.
• Lower the syringe into the carrier (see Figure 6).
• Push the syringe forward until it stops, taking care to avoid touching the plunger rod (see Figure 7)</td><td> 
Figure 6: Align and lower the syringe into the carrier</td></tr>
</table>

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.