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.

----------RECENT MAJOR CHANGES----------

Dosage and Administration (2.4, 2.7)	**4/2022**
Warnings and Precautions (5.4)	**4/2022**

----------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, septum dislodgement, 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, 5.7)
- Vitreous Hemorrhage: Temporarily discontinue antithrombotic medication prior to the implant insertion procedure to reduce the risk of vitreous hemorrhage. Vitrectomy may be needed. (5.5)
- Postoperative Decrease in Visual Acuity: A decrease in visual acuity usually occurs over the first two postoperative months. (5.8)

----------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: 4/2022

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).

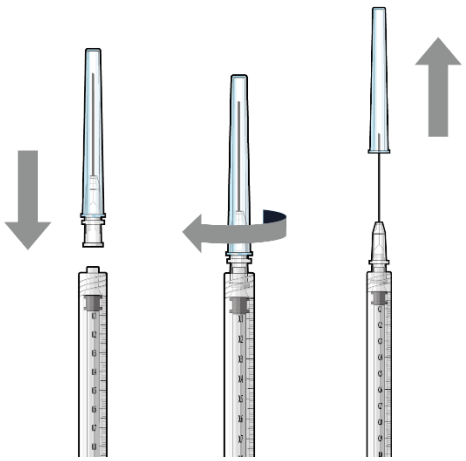
2.3 Supplemental Treatment with Intravitreal Ranibizumab Injection

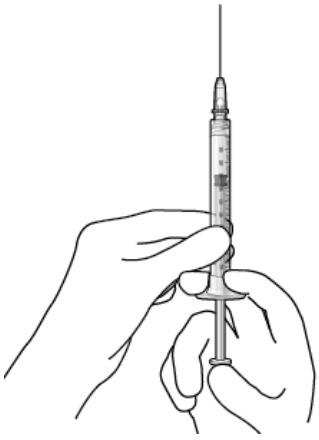
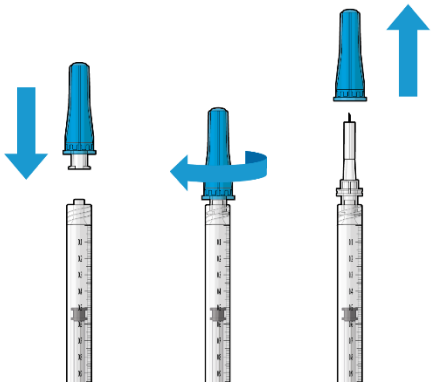
Supplemental treatment with 0.5 mg (0.05 mL of 10 mg/mL) intravitreal ranibizumab injection may be administered in the affected eye while the SUSVIMO implant is in place and if clinically necessary *[see Clinical Studies (14)]*.

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. **<u>Do not</u>** 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	 **Figure 1**

the contents of the SUSVIMO (ranibizumab injection) vial through the filter needle into the syringe.	
Step 3: Remove Air from Syringe • With the filter needle attached, 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 (Figure 2). • Slowly push the plunger rod just until all air is expelled from the syringe and needle. It is important to preserve as much drug as possible in order to completely fill the implant. • Remove and properly dispose of the filter needle after air is removed from syringe.	 **Figure2**
Step 4: 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 3). 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 3**

Step 5: Remove Any Remaining Air from Syringe

- With the initial fill needle attached, 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 4).
- 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 5).

Note: It is important to preserve as much drug as possible in order to completely fill the implant.

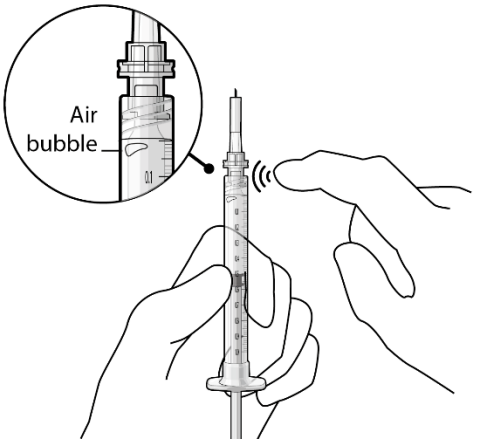


Figure 4

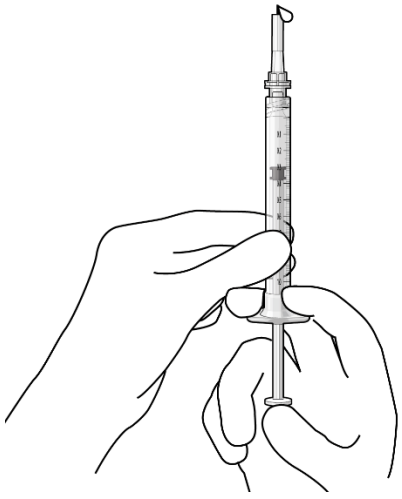


Figure 5

DOCKET ALARM

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