Susvimo (ranibizumab injection for intravitreal use via Susvimo ocular implant)

NEW PRODUCT SLIDESHOW

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Introduction

- **Brand name:** Susvimo
- **Generic name:** Ranibizumab
- **Pharmacologic class:** Vascular endothelial growth factor (VEGF) inhibitor
- **Strength and Formulation:** 100mg/mL; solution for intravitreal use via ocular implant; preservative-free
- **Manufacturer:** Genentech
- **How supplied:** Susvimo insertion tool assembly (1 insertion tool assembly + 1 implant); Kit–Initial fill needle + 1 single-dose vial (100mg/mL); Refill needle carton–1; Single-dose vial carton–1
- **Legal Classification:** Rx

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Indication

- Treatment of patients with **neovascular (wet) age-related macular degeneration (AMD)** who have previously responded to at least 2 intravitreal injections of a VEGF inhibitor.

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Dosage and Administration

- Perform all procedures (initial fill, ocular implant insertion, refill-exchange, implant removal) under aseptic conditions.
- For intravitreal use via ocular implant.
- Ocular implant must be surgically implanted in eye.
- **Recommended dose**: 2mg (0.02mL of 100mg/mL solution) continuously delivered via implant.
- Refills every 24 weeks (approx. 6 months).
- **Supplemental treatment**: 0.5mg (0.05mL of 10mg/mL) intravitreal ranibizumab injection into affected eye while implant is in place, as clinically needed.
- No more than 30mins between initial fill of the ocular implant and insertion into patient's eye.

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Dosage and Administration

- Do not administer as bolus intravitreal injection.
- Do not substitute with other ranibizumab products.
- Monitor routinely following insertion.
- **Withhold dose (refill-exchange)** if intraocular inflammation ≥1+ cells or flare, sight threatening events, local infections of either eye, infectious endophthalmitis, or severe systemic infection.
- **Withhold dose (refill-exchange) and consider implant removal** if observed damage to the implant.
- If planned dose (refill-exchange) is missed, it should be administered as soon as possible and subsequent refill-exchange should be performed 24 weeks thereafter.

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Susvimo Ocular Implant

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Contraindications

- Ocular or periocular infections.
- Active intraocular inflammation.
- Hypersensitivity to ranibizumab or excipients in Susvimo.

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Considerations for Specific Populations

- **Pregnancy**: Insufficient data to inform drug-related risks.
- **Nursing mothers**: No data on presence of ranibizumab in human milk; consider benefits of breastfeeding along with mother's clinical need and potential adverse effects.
- **Females of reproductive potential**: Use effective contraception during and for at least 12 months after last dose.
- **Pediatric**: Not established.
- **Geriatrics**: No notable differences in treatment effect or safety.
- **Renal impairment**: No clinically significant differences.

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Boxed Warning

- **Endophthalmitis**
  - The Susvimo implant has been associated with a 3-fold higher rate of endophthalmitis than monthly intravitreal injections of ranibizumab.
  - In clinical trials, 2% of patients receiving the implant experienced an episode of endophthalmitis.

Warnings and Precautions

- Endophthalmitis: treat promptly; delay dose until resolution.
- Rhegmatogenous retinal detachment: treat promptly; delay dose in presence of retinal detachment or retinal break.
- Evaluate retinal periphery; prior to implant insertion, treat suspected areas of abnormal vitreo-retinal adhesion.
- Risk of implant dislocation, vitreous hemorrhage, conjunctival bleb, conjunctival erosion or retraction.
- Decreased visual acuity for 2 months post-op.
- Improper filling of the implant due to air bubbles; see full labeling.
- Deflection of the implant due to eye procedures (eg, B-scan ultrasound, scleral depression, gonioscopy).

Interactions

- Increased risk of vitreous hemorrhage with antithrombotic medication (eg, oral anticoagulants, aspirin, NSAIDs); temporarily interrupt these prior to implant insertion procedure.

Adverse Reactions

- **Most common**: Conjunctival hemorrhage (72%), conjunctival hyperemia (26%), iritis (23%), eye pain (10%).
- **Others**: Conjunctival edema, vitreous floaters, foreign body sensation in eyes, headache, hypotony of eye, vitreous detachment, corneal disorder/abrasion/edema.
- **Serious**: Endophthalmitis, rhegmatogenous retinal detachment, implant dislocation, vitreous hemorrhage, conjunctival erosion or retraction.

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Mechanism of Action

- Ranibizumab binds to the receptor binding site of multiple biologically active forms of VEGF-A, including $VEGF_{110}$.
- The binding of ranibizumab to VEGF-A prevents the interaction of VEGF-A with its receptors (VEGFR1 and VEGFR2) on the surface of endothelial cells, reducing endothelial cell proliferation, vascular leakage, and new blood vessel formation.

Pharmacokinetics

- Following implant insertion:
  - Max ranibizumab serum concentration (C_{max}): 0.48 (±0.17) ng/mL
  - Median time to max serum concentration (T_{max}): 26 (range: 1–89) days
  - Terminal half-life: Approximately 25 weeks

Clinical Trial

- Approval was based on a randomized, visual assessor-masked, active treatment-controlled study (Archway, ClinicalTrials.gov Identifier: NCT03677934).
- Patients (N=415) were diagnosed with nAMD within 9 months prior to screening and received ≥3 doses of anti-VEGF intravitreal agents in the study eye within the last 6 months prior to screening.
- Patients were randomly assigned 3:2 to receive continuous delivery of Susvimo via the Susvimo implant (n=248) every 24 weeks or intravitreal ranibizumab injections every 4 weeks (n=167).
- First 24 weeks, 1.6% of Susvimo group received supplemental treatment (intravitreal ranibizumab 0.5mg inj); following 24 weeks, 5.4% received supplemental treatment.

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Clinical Trial

- **Primary efficacy endpoint**: Change from baseline in distance Best Corrected Visual Acuity (BCVA) score averaged over week 36 and week 40.

Visual acuity outcomes at week 40			
Outcome Measure	Susvimo n=248	Intravitreal ranibizumab n=167	Difference (95% CI)
Adjusted mean change from baseline in BCVA score averaged over weeks 36 and 40	0.2	0.5	-0.3 (-1.7 to 1.1)

Clinical Trial

- Results showed that Susvimo was equivalent to intravitreal ranibizumab injections administered every 4 weeks.
- Consistent results were observed across patient subgroup analyses (age, gender, number of prior anti-VEGF intravitreal injections, and baseline BCVA score).

New Product Monograph

- For more information view the product monograph available at:

  https://www.empr.com/drug/susvimo/