

MEDICATION GUIDE
SUSVIMO™ (suss-VIH-moh)
(ranibizumab injection)

for intravitreal use via SUSVIMO ocular implant

What is the most important information I should know about SUSVIMO?

SUSVIMO (ranibizumab injection) is delivered into the eye using the SUSVIMO implant. The SUSVIMO implant and the procedures to insert, fill, refill and remove the eye (ocular) implant can cause 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. **Call your healthcare provider right away if you have increasing eye pain, vision loss, sensitivity to light, or redness in the white of the eye.** 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. **Call your healthcare provider right away if you have a sudden feeling that something is in your eye, if you have eye discharge, or watering of the eye.** 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. **Call your healthcare provider right away if you have a sudden feeling that something is in your eye, if you have eye discharge, or watering of the eye.** Conjunctival retraction may require surgical treatment.

See “**What are the possible side effects of SUSVIMO?**” for other serious side effects that may happen while in treatment with SUSVIMO.

To help prevent or keep these side effects from becoming more serious follow all post-procedure instructions your healthcare provider gives you. See “How will I receive SUSVIMO?”.

What is SUSVIMO?

SUSVIMO (ranibizumab injection) is a prescription medicine used to treat adults with Neovascular (wet) Age-related Macular Degeneration (AMD) who have responded to at least two injections of a Vascular Endothelial Growth Factor (VEGF) inhibitor in the gel-like part of the eye (intravitreal).

It is not known if SUSVIMO is safe and effective in children.

Do not receive SUSVIMO if you:

- have an infection in or around your eye.
- have active swelling around your eye that may include pain and redness.
- are allergic to ranibizumab or any of the ingredients in SUSVIMO. See the end of this Medication Guide for a complete list of ingredients in SUSVIMO.

Talk to your healthcare provider before receiving this SUSVIMO if you have any of these conditions.

Before receiving SUSVIMO, tell your healthcare provider about all of your medical conditions, including if you:

- are currently taking or have recently taken medicines that lower the chance of blood clots forming in the body such as warfarin, low or regular doses of aspirin, or nonsteroidal anti-inflammatory drugs (NSAID).
- are pregnant or plan to become pregnant. It is not known if SUSVIMO will harm your unborn baby. You should use birth control during your treatment with SUSVIMO and for 12 months after your last dose of SUSVIMO.
- are breastfeeding or plan to breastfeed. It is not known if SUSVIMO passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you receive SUSVIMO.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How will I receive SUSVIMO?

- SUSVIMO is implanted through the white part of the eye (sclera) by your healthcare provider.
- Your healthcare provider will refill your implant device every 6 months (about every 24 weeks).
- If you miss a scheduled refill, call your healthcare provider as soon as possible to reschedule your refill. Your next refill should be given 6 months after your last refill.

Your healthcare provider will give you instructions to follow after the implant insertion, the refill procedure, and the implant

removal. The instructions may include:

After the Implant Insertion:

- **Positioning of your head**
 - Keep your head above shoulder level for the rest of the day.
 - Sleep with your head on 3 or more pillows during the day and night after your implant insertion.
- **How to care for your eye**
 - **Do not** remove the eye shield from your eye until you are told to by your healthcare provider. At bedtime, continue to wear an eye shield for **at least 7 nights** following the implant insertion.
 - Take all post-operative eye medicines as your healthcare provider tells you to.
 - **Do not** push on the eye, rub the eye, or touch the area of the eye where the implant is located (underneath the eyelid in the upper and outer part of your eye) for **30 days** following the implant insertion.
 - **Do not** participate in strenuous activities until 1 month after the implant insertion or after talking to your healthcare provider.
- **Magnetic Resonance Imaging (MRI) Implant Card**
 - Get your implant card from your healthcare provider after receiving the implant and keep the card in a safe place for future reference. The implant card contains important information about your SUSVIMO implant.
 - Show your current and future healthcare providers your implant card. This is important if you need to have an MRI. You may only receive an MRI under very specific conditions if you have the SUSVIMO implant. Your healthcare provider will review the information on the implant card and will let you know if you should receive an MRI.

After the Refill Procedure:

- **Do not** push on the eye, rub the eye, or touch the area of the eye where the implant is located (underneath the eyelid in the upper and outer part of your eye) for **7 days** following the refill procedure.
- Take eye drops exactly as your healthcare provider tells you to take them.

After the Implant Removal:

- Keep your head above shoulder level for the rest of the day.
- Sleep with your head on 3 or more pillows if lying down during the day and night after implant removal.
- Wear an eye shield for **at least 7 nights** following the implant removal.
- Do not participate in strenuous activities until **14 days** following the implant removal.
- Give all post-operative drops, as told by your healthcare provider.

These are not all the instructions you may receive from your healthcare provider. Following all post-procedure instructions may help prevent serious side effects or keep side effects from becoming more serious. See **“What is the most important information I should know about SUSVIMO?”**.

What should I avoid while receiving SUSVIMO?

- **Do not** drive or use machinery until the eye shield can be removed and you can see.
- **Avoid** rubbing your eye or touching the area of your eye where the implant is located as much as possible while the implant is in place. If you have to rub or touch your eye, wash your hands first.

What are the possible side effects of SUSVIMO?

See **“What is the most important information I should know about SUSVIMO?”** on the first page.

In addition to those side effects listed on page one, the SUSVIMO implant and the procedures to insert, fill, refill and remove the eye (ocular) implant can cause other serious side effects including:

- **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. Call your healthcare provider or go to the emergency room right away if you see flashing lights, see a curtain or veil covering part of your vision, have a change in your vision, or a loss of vision. Rhegmatogenous retinal detachment requires surgical treatment.
- **Implant movement (Implant dislocation):** Tell your healthcare provider right away if you notice that the implant has moved out of place. 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. Call your healthcare provider right away if you have an increase in moving spots or what looks like spider webs in your vision as you may need 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. Call your healthcare provider right away if you have a sudden feeling that something is in your eye (foreign body sensation), see a bulge over the white part of your eye, if you have eye discharge, or watering in the eye. You may need medical or surgical treatment.

- **Temporary decrease in vision after the SUSVIMO procedure.**

The most common side effects of SUSVIMO include:

- blood on the white of the eye
- eye pain
- redness in the white of the eye
- sensitivity to light

These are not all the possible side effects of SUSVIMO.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

You may also report side effects to Genentech at 1-888-835-2555.

General information about the safe and effective use of SUSVIMO.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. You can ask your pharmacist or healthcare provider for information about SUSVIMO that is written for health professionals.

What are the ingredients in SUSVIMO (ranibizumab injection)?

Active ingredient: ranibizumab

Inactive ingredients: histidine HCl, polysorbate 20, sucrose.

Manufactured by: **Genentech, Inc.**, A Member of the Roche Group, 1 DNA Way, South San Francisco, CA 94080-4990
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