Genentech
A Member of the Roche Group

IMPORTANT PRESCRIBING INFORMATION

March 2025

Subject: Update on SUSVIMO® Ocular Implants Voluntarily Recalled in October 2022 - Potential to Affect the Refill-Exchange Procedure

Dear Health Care Provider,

The purpose of this letter is to inform you of additional important safety information about the known risk of septum dislodgement that has the potential to affect the refill exchange procedure in **SUSVIMO® Ocular Implants Voluntarily Recalled in October 2022**. This communication applies only to the SUSVIMO Ocular Implants recalled in 2022.

Additional Important Safety Information About Recalled SUSVIMO® Implants

In a refill-exchange procedure performed as per Section 2.7 of the SUSVIMO Prescribing Information (PI), fluid should immediately collect in the refill needle collection chamber as soon as ranibizumab is administered into the implant. However, cases of lack of fluid return to the refill needle collection chamber during refill-exchange, henceforth referred to in this document as "lack of fluid return", have been reported in implants recalled in 2022, some of which are indicative of a partial septum dislodgement. You are receiving this letter because you may have one or more patients with recalled implants in your clinical practice. Partial septum dislodgement is a precursor to septum dislodgement, which is a known risk with recalled implants. Septum dislodgement is described in the SUSVIMO PI, Section 5.4 Warnings and Precautions.

Which implants are impacted by this issue?

This issue applies only to implants recalled in 2022:

- Phase 3 implants: These implants were used in phase 3 and phase 3 extension trials of SUSVIMO. Most of the patients with these implants are currently enrolled in clinical trials, however, some may have exited early and may be receiving refills in clinical practice.
- Commercial implants recalled in 2022: These implants were released for commercial distribution in December 2021 and recalled from the US market in October 2022. While in commercial distribution prior to the recall, these implants were used to treat patients in the post-marketing setting and in the phase 4 Belvedere (ML43000) study. While the Belvedere study is ongoing, all patients with recalled implants have completed study participation and transitioned into clinical practice.

Which implants are NOT impacted by this issue?

- The updated SUSVIMO Ocular Implants that received FDA approval in July 2024 and are currently in commercial distribution and clinical trial use are NOT impacted by this issue. Laboratory testing of these implants (n=110) showed no septum damage through 50+ years of simulated use**.**
- Phase 2 implants used in the Ladder (GX28228) study are NOT impacted by this issue. All patients with these implants have transitioned into clinical practice.

Clinical presentation and relevant evidence:

- During a refill exchange done per SUSVIMO PI in a recalled implant, the Health Care Provider (HCP) observes a lack of fluid return. This may be indicative of a partial septum dislodgement, a type of damage where the septum may partially detach from the overmold but does not fully dislodge into the implant body.
- In clinical trial cases, a partial septum dislodgment was confirmed only after explanted implants were analyzed in the laboratory at Genentech. HCPs may be able to suspect a partial septum dislodgement but cannot clinically confirm it.
- Summary of cases through January 2025. All reports were from clinical trials.
  - **Recalled Commercial Implants**: One case of a lack of fluid return was reported. A second refill attempt in this patient was successful.
  - **Phase 3 Implants:** 98 cases of lack of fluid return were reported. Second refills were attempted on the same day or after a week in 62 patients of which 56 were successful. Of these 98 cases reporting lack of fluid return,10 were reported as suspected partial septum dislodgement and 3 were confirmed as partial septum dislodgement after explantation and laboratory analysis.

Prescriber Action If Lack of Fluid Return is Observed in a Recalled Implant:

A. Repeat the refill-exchange procedure per SUSVIMO PI Section 2.7. The second refill attempt may be deferred by a week if there are HCP concerns related to dosing errors or adverse events after the first attempt.
B. If a partial septum dislodgement is suspected, refer to Section 5.4 of the SUSVIMO PI, and consistent with that, discontinue treatment with SUSVIMO (ranibizumab injection) following suspected partial septum dislodgement and consider implant removal should the benefit of the removal procedure outweigh the risk.

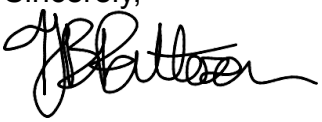
Patient record: It is recommended to save a copy of this letter in the medical records of all patients with recalled SUSVIMO Ocular Implants including Phase 3 implants to enable HCPs who may care for them in the future to have access to this important information.

Reporting Adverse Events / Product Complaints and Company Contact

Health Care Providers should report any adverse events or product complaints suspected to be associated with the use of SUSVIMO to Genentech at 833-EYE-GENE. Alternatively, this information may be reported to FDA's MedWatch reporting system by phone (1-800-FDA-1088) or online (www.fda.gov/medwatch).

Should you have any questions about the information in this letter, returning the product, or the safe and effective use of SUSVIMO, please contact us at 833-EYE-GENE. This letter is not intended as a complete description of the benefits and risks related to the use of SUSVIMO. Please refer to the enclosed full prescribing information for additional information.

Sincerely,



Dr. Toby Patterson, MBBS
Senior Vice President
Head of U.S. Medical