Extended In-Use Stability of Vabysmo

This letter responds to your request for information on extended in-use stability of Vabysmo® (faricimab) solution for intravitreal injection (single dose vial).

Please refer to the stability information provided in the manufacturers label. Any deviation from this information is considered off-label and any treatment decisions based on such deviations are the full responsibility of the prescribing physician.

Drug preparation and administration precaution

Vabysmo solution for intravitreal injection (single dose vial) does not contain any antimicrobial preservative. Therefore, sterility of the solution must be ensured during in-use handling by maintaining appropriate aseptic conditions.

Recommendation for use of prepared Vabysmo injection

The prepared injection solution should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user.[1]

If storing prepared Vabysmo injection

If the prepared Vabysmo intravitreal injection cannot be immediately administered, cap the drug-filled syringe with a combi-stopper and store in a refrigerator at 2°C to 8°C (36°F to 46°F) for up to 24 hours.

In-use storage and stability considerations

The combi-stopper cap minimizes potential risk of contamination. Identify on the cap the date and time of preparation.[2]

Within the 24 hour in-use storage period, the drug-filled syringe may be held at 9°C to 25°C (47°F to 77°F) up to a maximum cumulative time of 6 hours, including the time required for warming up the syringe to room temperature.[2]

Do not attach the 30G injection needle the syringe until the Vabysmo injection is ready for administration.

In-use stability reported from external *in vitro* studies

Gjolberg et al. reported results of an *in vitro* study that evaluated the effects of storing prepared Vabysmo injection syringes.[3] Vabysmo was withdrawn under aseptic conditions into silicone oil-free syringes, and a 33G, 9 mm needle was attached.

Prepared Vabysmo injection syringes demonstrated uncompromised protein concentration, aggregation, and thermal stability up to 7 days when stored in a sterile plastic bag at 4°C in the dark.[3]

Jørstad et al. reported the results of an *vitro* study that evaluated compounding and storing Vabysmo in pre-filled syringes, and the impact this had on the stability and bi-specific binding properties of faricimab.[4] Vabysmo was compounded into silicone-oil free syringes and stored in the dark at 4° for 7, 14, or 37 days. Syringes stored for 7 days were stored with either a 30G, 13 mm needle or a Luer Lock cap. Syringes stored for 14 or 37 days were all stored with a Leur Lock cap.

The protein concentration, stability and integrity, and binding capacity of faricimab to vascular endothelial growth factor A (VEGF-A) and angiopoietin-2 (Ang-2) was measured.[4] The prefilled syringes were not

assessed clinically, or for sterility and microbiological safety. Withdrawal and storage of Vabysmo in syringes for up to 37 days was not found to impair the stability or binding properties of faricimab.

References

1. Roche Internal Regulatory Document (Vabysmo CDS). Accessed on 9 August 2023.

2. Roche Internal Technical Report. Accessed on 9 August 2023.

3. Gjolberg T, Mester S, Foss S, et al. Compounding and storage of faricimab in a new syringe developed for intravitreal injections of antibody-based biologics: VEGF, Ang-2, and FcRn binding properties. Presented at the EURETINA Congress in Amsterdam, NL; October 5-8, 2023.

4. Jørstad Ø, Foss S, Gjølberg T, et al. Pharmaceutical compounding and storage of faricimab in a syringe for intravitreal injection do not impair stability and bi-specific binding properties. Int J Retina Vitreous 2023;9:65. https://www.ncbi.nlm.nih.gov/pubmed/37936232