Volume of Vabysmo for Single-Dose Intravitreal Injection

This article responds to your request for information on the preparation of Vabysmo® (faricimab) for a single-dose intravitreal injection.

In brief

- Each glass vial of Vabysmo contains 28.8 mg of Vabysmo in 0.24 mL solution. This provides a usual amount to deliver a single dose of 0.05 mL solution containing 6.0 mg of Vabysmo.
- Vabysmo intravitreal injection must be prepared according to the instructions for use. If the instructions are correctly followed, it is not possible to split the vial contents for multiple doses.
    - Withdraw Vabysmo from the vial using the single-use transfer filter needle to ensure removal of sub-visible particles in the product.

Volume amount in vial

The contents of the Vabysmo vial and the co-packaged transfer filter needle are sterile and for single use only.[1]

Each glass vial contains 28.8 mg of Vabysmo in 0.24 mL solution. This provides a usable amount to deliver a single dose of 0.05 mL solution containing 6.0 mg of Vabysmo.[1]

Rationale for volume amount

Each glass vial contains 0.24 mL, the minimum fill volume that allows for administration of a single 0.05-mL dose of solution containing 6.0 mg of Vabysmo. In addition to delivering the 0.05-mL dose, the volume is sufficient to

- fill the dead volume of the transfer filter needle,
- fill the the dead volume of the injection needle, and
- allow for priming of the syringe.[2]

In alignment with regulatory guidance, information on overage or overfill amounts is not provided.[3]

Caution around vial splitting for multiple doses

Prepare Vabysmo intravitreal injection according to the instructions for use to minimize risk to patients. If the instructions are followed correctly, vial contents cannot be split for multiple doses.[2]

Deviations from the instructions for use can result in potential risk to patients.[4,5]

Importance of the transfer filter needle

Withdraw Vabysmo from the vial using with the single-use transfer filter needle to ensure removal of sub-visible particles in the product.[5] Omission of this step can cause an increased risk of endophthalmitis,

intraocular inflammation, increase in intraocular pressure and vitreous floaters, due to presence of sub-visible particles.[4]

References

1. Roche Internal Technical Report (Accessed on 26 July 2023).

2. Roche Internal Communication (Accessed on 26 July 2023).

3. European Commission. A guideline on summary of product characteristics (SmPC). Available at https://health.ec.europa.eu/system/files/2016-11/smpc_guideline_rev2_en_0.pdf. Accessed on July 26, 2023.

4. Roche Internal Communication (Accessed on 9 February 2023) .

5. Roche Internal Regulatory Report (Accessed on 21 March 2023).