

Y07 Jun 2024

## DHPC Letter for Vabysmo (faricimab) for tear in primary packaging of Transfer Filter Needle (TFN) co-packaged with vial.

Dear Healthcare Professional,  
Roche would like to inform you of the following:

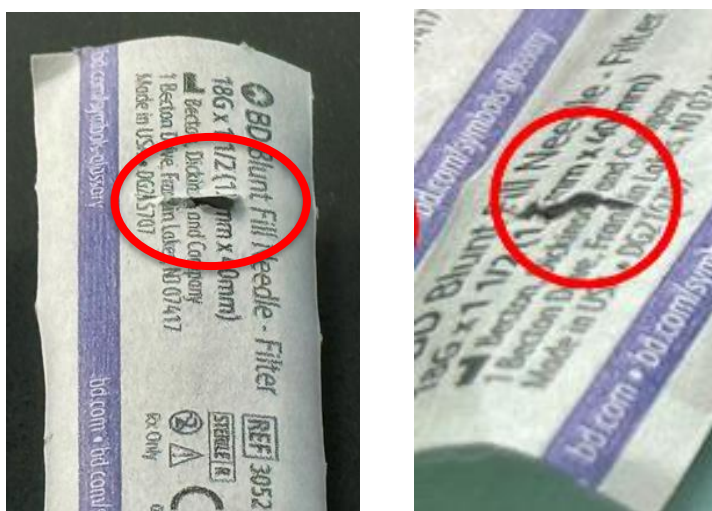
### *Summary*

- On 24 May 2024, Roche identified individual instances of a tear in the primary packaging of the Transfer Filter Needle (TFN) co-packaged with Vabysmo vials.
- The tear is easily detectable to the naked eye.
- To date, this issue has only been found in a limited number of batches at a rate of occurrence of  $\leq 0.26\%$  at the Roche packaging site.
- It is important to examine the TFN packaging prior to use, as instructed in the Vabysmo product leaflet. Please pay special attention to the potential presence of a tear as shown in the images below.
- If the TFN packaging is damaged, the sterility of the TFN cannot be guaranteed and the entire unit of Vabysmo (vial+ damaged TFN pack) must not be used as this may increase the potential risk of infection and/or intraocular inflammation associated with the intravitreal injection.
- To continue with the injection preparation, a new unit (Vabysmo vial co-packaged with TFN) must be used.
- Should you identify a damaged TFN pack within the supplied package of Vabysmo, please report this as a product complaint to Roche at [cac.farmacovigilancia@roche.com](mailto:cac.farmacovigilancia@roche.com) and please send a photograph of the damaged TFN pack and/or the entire unit of Vabysmo to Roche (see details below) so that a replacement unit can be issued.
- To date, there have been no reports of Adverse Events linked to the presence of this issue in any marketed batches of Vabysmo.

## *Background of Issue*

Through the quality assurance measures within Roche, a quality issue linked to the Transfer Filter Needle, which is co-packaged with vials of Vabysmo, was identified on 24 May 2024. The quality checks identified a tear in the primary packaging of one Transfer Filter Needle (TFN). The tear is visible to the naked eye and located close to the needle hub of the TFN. This new issue has not been previously identified within Roche for Vabysmo

## *Background on the Safety Concern*



Vabysmo is a vascular endothelial growth factor (VEGF) and angiopoietin-2 (Ang-2) inhibitor indicated for the treatment of patients with:

- Neovascular (Wet) Age-Related Macular Degeneration (nAMD)
- Diabetic Macular Oedema (DMO)

A TFN from a damaged package may not be sterile and may potentially increase the risk of clinical complications, including infection and/or intraocular inflammation. To date, we have not received any reports of Adverse Events that could be linked to the presence of this issue in any marketed batches of Vabysmo.

For your reference, the identified batch of the Vabysmo drug product, which may contain the described defect in the primary packaging of the transfer filter needle (TFN) and has been distributed in the country, is B1532B10.

## *Recommendations for risk minimisation*

Given that the sterility of the TFN cannot be guaranteed for the damaged TFN pack, the entire Vabysmo product (damaged TFN + the co-packaged vial) must not be used. To further minimise patient safety risk, the following measures are recommended.



### *Instructions to HCPs:*

1. Carefully inspect the TFN packaging for a tear, as highlighted in the image above.
2. If the TFN packaging is intact, continue as per label with injection process.
3. In case of damage to the TFN packaging, do not use either the TFN or vial of Vabysmo. To continue with the injection preparation, a new unit from your supply (Vabysmo vial co-packaged with TFN) must be used.
4. It is imperative you then inform Roche by submitting a product complaint.
5. A photograph of the damaged TFN pack and/or the entire unit of Vabysmo should be sent back to Roche, at [cac.farmacovigilancia@roche.com](mailto:cac.farmacovigilancia@roche.com), so that a replacement batch can then be sent back to you.

### *Call for reporting*

Healthcare professionals should report any product complaints or adverse events suspected to be associated with the use of Vabysmo co-packaged with transfer filter needle according to national reporting requirements and report to Roche at [cac.farmacovigilancia@roche.com](mailto:cac.farmacovigilancia@roche.com)

### *Company contact point*

Should you have any questions regarding the use of Vabysmo, please feel free to contact us at [cac.medical\\_info@roche.com](mailto:cac.medical_info@roche.com)

Yours sincerely,

Dr. Alexandra Hambelant  
Patient Safety Lead  
Roche Servicios S.A.

Dr. Carlos Sandoval  
Country Medical Director  
Roche Servicios S.A.