19th June 2024

Direct Healthcare Professional Communication (DHPC)

VABYSMO®▼(faricimab): tear in primary packaging of Transfer Filter Needle (TFN) co-packaged with vial; localised in Northern Ireland

Dear Healthcare Professional,

Roche Products Ltd, in agreement with the Medicines and Healthcare Products Regulatory Agency (MHRA) 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 (faricimab) vials; this issue is believed to be localised in stock provided in Northern Ireland.**
- **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. Therefore the entire unit of VABYSMO (vial plus damaged TFN pack) must not be used. We have issued this DHPC letter as an additional precaution to encourage extra vigilance and minimise any potential risk to patients.**
- **The tear is easily detectable to the naked eye.**
- **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.**
- **In case of damage to the TFN packaging, do not use either the TFN or vial of VABYSMO and to continue with the injection preparation, a new unit (VABYSMO vial co-packaged with TFN) must be used.**
- **To date, this issue has only been found in a limited number of batches at a rate of occurrence of ≤0.26% at the Roche packaging site. All instances of tears should be reported to Roche.**
- **To date, there have been no reports of Adverse Events linked to the presence of this issue in any marketed batches of VABYSMO.**

DHPC Letter Distribution:

This communication is directed to the Chief Pharmacist/Pharmacy department across affected centres in Northern Ireland, to distribute to all medical retina ophthalmology consultants and ophthalmology nurses. Please also cascade this information to any additional HCPs involved with the preparation of the procedure and product and administration of the intravitreal injection. Roche will request confirmation of receipt via email from the Chief Pharmacist/Pharmacy department across affected centres in Northern Ireland.

Roche Products Limited
M-GB-00018150
June 2024

6 Falcon Way, Shire Park
Welwyn Garden City AL7 1TW,
United Kingdom

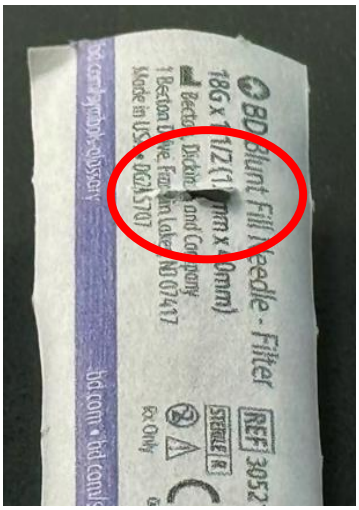
Registered in England
No. 100674

Medical Information
Tel +44(0)800 328 1629
Email: medinfo.uk@roche.com

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 administered via intravitreal injection 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)

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.

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 minimise patient safety risk, carefully inspect the TFN packaging for a tear, as highlighted in the image above. If the TFN packaging is intact, continue as per label with injection process. 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.

It is imperative you then inform Roche by submitting a product complaint using the contact information listed in the call for reporting section and company contact information.

Report any adverse events to the Yellow Card scheme (details below), mentioning any associated with this issue if relevant.

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Call for reporting

VABYSMO is subject to additional monitoring. This will allow quick identification of new safety information.

Please report ANY suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme.

Please report:

- All suspected ADRs that are serious or result in harm. Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason
- All suspected ADRs associated with new drugs identified by the black triangle ▼

You can report via:

- the Yellow Card website
- the free Yellow Card app available from the Apple App Store or Google Play Store
- some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals

Alternatively, you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm.

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, timing onset, treatment dates, and product brand name.

Company contact point

Should you identify a damaged TFN pack within the supplied package of VABYSMO, please report this as a product complaint to Roche Quality Team via email to global.welwyn_complaints@roche.com. 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.

Should you have any questions regarding the use of VABYSMO, please feel free to contact:

Roche Medical Information by phone on +44(0)800 328 1629 or via e-mail medinfo.uk@roche.com.

Adverse events should also be reported to Roche Products Ltd. Please contact Roche Drug Safety Centre by emailing welwyn.uk_dsc@roche.com or calling +44 (0)1707 367554.

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Annexes

1. VABYSMO Summary of Product Characteristics (SmPC)
   Great Britain: https://www.medicines.org.uk/emc#gref
   Northern Ireland: https://www.emcmedicines.com/en-gb/northernireland/

Please kindly acknowledge receipt of this communication by replying to this email at your earliest convenience.

Yours faithfully,

Roche Products Limited

DocuSigned by:
Gregory Thomas
96F45953BC0C445...

Gregory Thomas

on behalf of Medical Cluster Lead/Chief Medical Officer

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