

December 2023

**Vabysmo® (faricimab) 120 mg/mL solution for injection**

**ואביסמו**

צוות רפואי נכבד,

הנדון: סיכון לדלקת של כלי דם ברשתית ו/או חסימה של כלי דם ברשתית בשימוש ב-Vabysmo® (faricimab)

חברת רוש פרמצבטיקה (ישראל) בע"מ, בשיתוף משרד הבריאות, מעוניינת להביא לידיעתך את המידע הבא הנוגע לבטיחות השימוש בתרופה Vabysmo

להלן עיקרי הדברים:

- דלקת כלי דם ברשתית (**Retinal Vasculitis**) ו/או חסימה של כלי דם ברשתית (**Retinal Vascular Occlusion**) דווחו בחולים שטופלו ב-Vabysmo.
- דלקת כלי דם ברשתית עם או ללא חסימה הינה תופעת לוואי חמורה שיכולה לגרום לאובדן ראייה בלתי הפיך.
- הדיווחים התקבלו לאחר תחילת השיווק של התכשיר ונכון לאוגוסט 2023 שיעור הדיווח מוערך ב- 0.17 ל-10,000 זריקות עבור דלקת כלי דם ברשתית עם וללא חסימה מתוכם שיעור הדיווח של דלקת כלי דם ברשתית עם חסימה מוערך ב-0.06 ל-10,000 זריקות.

הנחיות לצוות הרפואי:

- יש ליידע את המטופל אודות היתרונות והחסרונות של הטיפול ב-Vabysmo, כולל הסיכון להופעת דלקת של כלי דם ברשתית עם או ללא חסימה של כלי הדם.
- יש להדריך את המטופל לדווח על כל שינוי בראייה ללא דיחוי, ולפנות מייד לרופא עיניים במקרה של הופעת אדמומיות בעין, רגישות לאור, כאב או שינויים בראייה.
- יש להפסיק את הטיפול ב-Vabysmo במטופל שפיתח תופעות אלה.
- המידע לעיל עודכן בעלון בפרק אזהרות ופרק תופעות הלוואי.
- למידע נוסף אודות התכשיר יש לפנות לעלון.

December 2023

Subject: VABYSMO® (faricimab), New Warnings and Precautions: Retinal Vasculitis and/or Retinal Vascular Occlusion

Dear Health Care Provider:

The purpose of this letter is to inform you of the updated safety information for VABYSMO. 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 Edema (DME)

### **Risk of Retinal Vasculitis and/or Retinal Vascular Occlusion**

An update to the Warnings and Precautions (section 5.4) and Adverse Reactions (section 6) - Postmarketing Experience (section 6.2) sections of the physician leaflet has been made following spontaneous post-marketing reports of retinal vasculitis with or without occlusion in patients treated with VABYSMO. Patient leaflet have been updated accordingly in section 4, "Adverse Reactions". Retinal vasculitis with or without occlusion is a serious event that can cause permanent vision loss.

As of the end of August 2023, with 1.5 million vials dosed globally, the estimated reporting rate of retinal vasculitis with occlusion is 0.06/10,000 injections (for retinal vasculitis with or without occlusion: 0.17/10,000 injections).

Please also refer to section 6.2 in the physician leaflet:

The following adverse reactions have been identified during postapproval use of VABYSMO. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Eye disorders: retinal vasculitis with or without retinal vascular occlusion.

The benefit-risk profile of VABYSMO for all its approved indications continues to be favorable.

### **Prescriber Action**

- Counsel patients about the benefits and risks of VABYSMO, including the risk of retinal vasculitis with or without retinal vascular occlusion.
- Patients treated with VABYSMO should be instructed to report any changes in vision without delay to permit prompt and appropriate management [see Patient leaflet]. If the eye becomes red, sensitive to light, painful, or develops a change in vision, advise the patient to seek immediate care from an ophthalmologist.
- VABYSMO should be discontinued in patients who develop these events.
- Prescribers should refer to the Warnings and Precautions Section 5.4 of the physician leaflet.

## **Call for reporting**

Healthcare professionals should report any adverse events, which are suspected to be associated with the use of Vabysmo, to the Israeli Ministry of Health by using an online form:

<https://sideeffects.health.gov.il>


It could also be reported to Roche Israel drug safety department at 09-9737722 or [israel.drugsafety@roche.com](mailto:israel.drugsafety@roche.com).

## **Company contact point**

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

Roche Pharmaceuticals (Israel) Ltd.,  
[Israel.drugsafety@roche.com](mailto:Israel.drugsafety@roche.com)  
09-9737777.

Yours sincerely,

DocuSigned by:  
  
Signer Name: Tamar Birenboim-Gal  
Signing Reason: I approve this document  
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Dr. Tamar Birenboim-Gal  
Medical Director

Siyona Kolatkar  
Qualified Person for Pharmacovigilance

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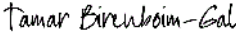
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