



INFORMATION FOR PATIENTS

Your Guide to VABYSMO® ▼ (faricimab)

For the treatment of visual impairment due to diabetic macular oedema (DMO)

This guide provides important safety information for people living with DMO, who have been prescribed VABYSMO.

This material is applicable across the United Kingdom.

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See **page 15** for how to report side effects.

This educational material is developed and provided by Roche Products Limited and mandatory as a condition of the Marketing Authorisation in order to further minimise important selected risks.

You can use this guide to learn more about your condition, what to expect from your treatment with VABYSMO, and important safety information. This guide is also for carers and families of people living with DMO who have been prescribed VABYSMO.

This guide does not replace the advice from a healthcare professional. For any further questions regarding your treatment or your condition, you should contact your eye doctor.

Please also read the patient leaflet that comes with your medicine. This can be requested from anyone in your eye care team or accessed by scanning the QR codes on **page 3**. For any further questions, you should contact your eye department.

Your eye department contact details:

Your eye department:

Contact name:

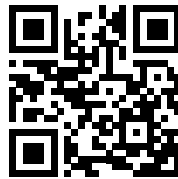
Contact number:

Contact email:

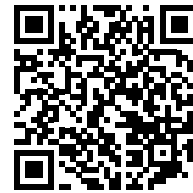


To access an online version of the patient leaflet that comes with your medicine, VABYSMO, scan the QR codes below or visit <https://emclink.uk/VBD5> (VABYSMO 120 mg/mL solution for injection) or <https://emclink.uk/VBS1> (VABYSMO 120 mg/mL solution for injection in pre-filled syringe). Large print, Braille, or audio CD may be available via these links

**VABYSMO 120 mg/mL
solution for injection**



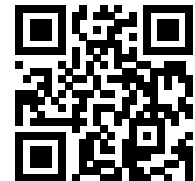
**VABYSMO 120 mg/mL solution
for injection in pre-filled syringe**



For a digital version of the information in this guide, please scan this QR code
<https://emclink.uk/VBD1>



For an audio version of the information in this guide, please scan this QR code
<https://emclink.uk/VBD3>



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1. Summary of important safety information

Contact your eye doctor urgently if you have any of the following, which could be signs of a serious treatment complication:

- Eye pain, increased discomfort, worsening eye redness
- Blurred vision or you can't see as well as usual
- Increased sensitivity to light
- A sudden loss, decrease or change in vision
- An increase or sudden appearance of floaters or flashes of light

For a list of all potential side effects, please read the patient leaflet that comes with your medicine, VABYSMO. This can be accessed by scanning the QR code on page 3 of this guide or asking your eye department.

2. What is diabetic macular oedema (DMO)?

DMO is a leading cause of vision loss in people living with diabetes. People living with Type 1 or Type 2 diabetes are at risk of getting DMO.

DMO happens when the blood vessels in the **retina** become damaged. These blood vessels can leak fluid into the eye, causing swelling in the **macula** leading to vision loss. Usually the condition is painless and affects what you can see directly in front of you.

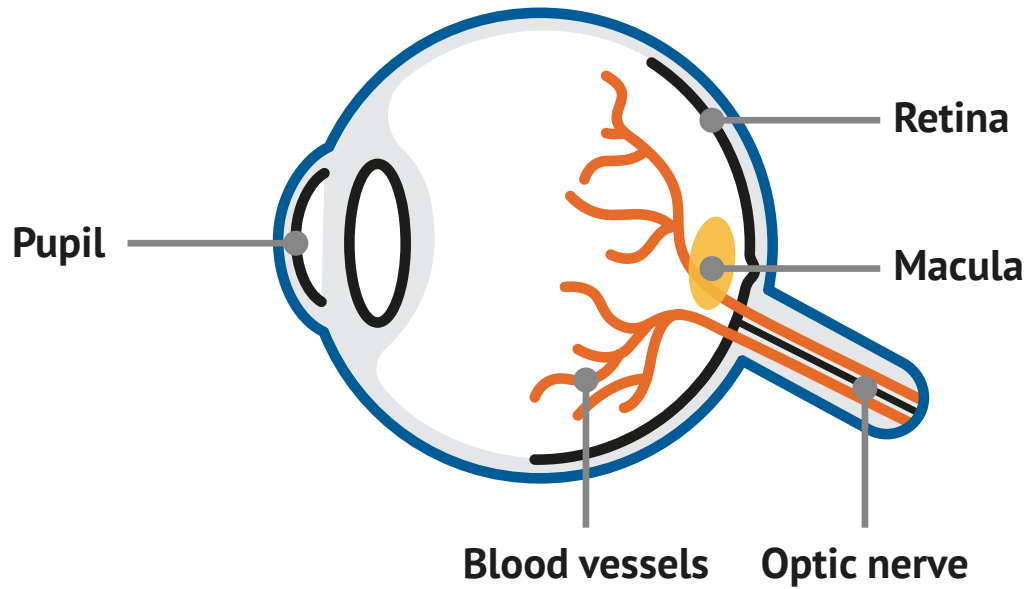
Although you may not experience symptoms immediately, the disease may still be progressing. Therefore, it is important for you to attend every appointment for a check-up.

Definitions

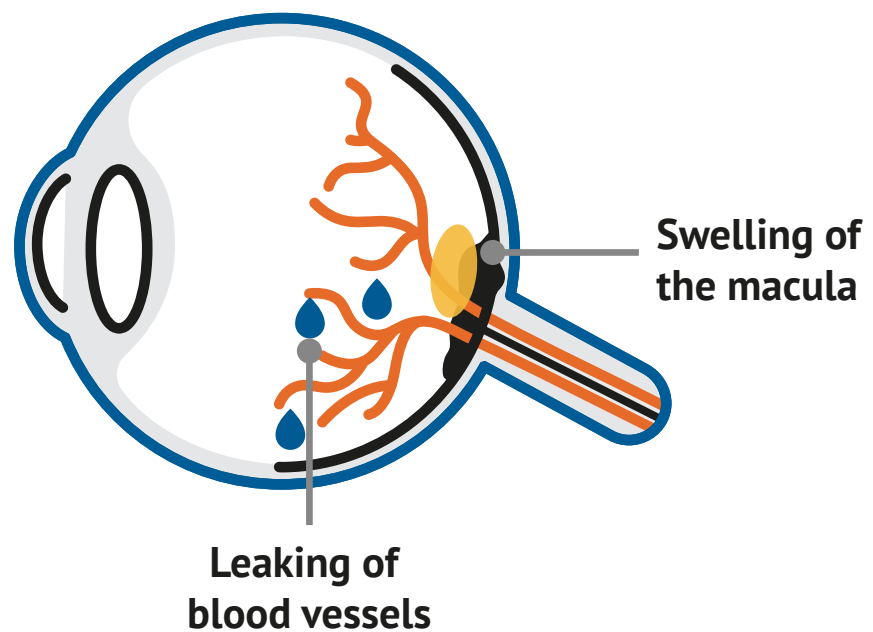
The **retina** is the light-sensitive layer at the back of the eye that records the images we see and sends them to the brain.

The **macula** is a small but important area located at the centre of the retina. It is responsible for our central vision as well as our sharpest vision.

Healthy eye



Eye affected by DMO



Symptoms may include:

- Gaps or dark spots may appear in your vision **(A)**
- Colours may seem faded **(B)**
- Blurred vision **(C)**
- Objects may appear as the wrong shape, size or colour—for example, straight lines appearing bent or wavy **(D)**
- Difficulty reading, driving or seeing in bright or glaring light

A)



Gaps or dark spots may appear in your vision

B)



Colours may seem faded

C)



Blurred vision

D)



Objects may appear as the wrong shape, size or colour

3. What is VABYSMO and how does it work?

VABYSMO [vab·EYES·mo] is an eye injection that contains the active ingredient **faricimab** [FA·rissi·mab].

Based on evidence from clinical trials, VABYSMO has been approved to treat visual impairment due to DMO.

VABYSMO specifically recognises two proteins known as **angiopoietin-2 (Ang-2)** and **vascular endothelial growth factor A (VEGF-A)**. In DMO, Ang-2 and VEGF-A are present in higher levels than normal. These two proteins are involved in causing abnormal blood vessel growth or damage to normal blood vessels.

By attaching to these proteins, VABYSMO can block their actions and help prevent abnormal blood vessel growth and leakage of fluid into the eye and may thereby maintain, or even improve, your vision.

4. Treatment with VABYSMO

VABYSMO is injected into the corner of your eye (intravitreal injection), after it has been numbed, by an eye specialist who is experienced in giving eye injections.

When you start treatment with VABYSMO, you may receive loading doses—this is usually one injection every 4 weeks, for the first few doses. After that, the time between injections may be gradually extended. Your eye doctor will determine your treatment interval based on the condition of your eye.

VABYSMO is a long-term treatment and your condition will be regularly monitored by your eye doctor to make sure the treatment is working properly.





Preparing for your treatment visit

- Have a family member or carer take you to your appointment. This will not only help you with travel, but may be helpful for you to understand and retain all the information you receive and in conversation with your eye doctor
- Avoid wearing make-up on the day of your injection
- Bring a list of your medication history (prescription or non-prescription medicines) for your eye doctor to look at
- Take dark glasses with you to your appointment as your eyes may be sensitive to light after the injection
- Bring a snack to help regulate your blood sugar levels


Tell your eye doctor or eye specialist team before receiving VABYSMO if:

- You have an infection in or around your eye
- You have pain or redness in your eye
- You are allergic to faricimab or any of the other ingredients in this medicine. The full list of ingredients can be found in the patient leaflet that comes with your medicine, VABYSMO. This can be accessed by scanning the QR code on **page 3** of this guide or asking your eye department
- You have had any eye diseases or eye treatments
- Any medication has changed since your last visit
- You are pregnant or think you may be pregnant, you are breast-feeding or are planning to have a baby




During your treatment visit

Before the injection




You will have a full eye examination including a scan that will take a picture of the back of your eye. This is called an optical coherence tomography (OCT) scan



It is normal to feel worried ahead of an injection procedure but you will be given the opportunity to ask your eye specialist any questions before you consent to the injection


During the injection




You will be given an eye drop of local anaesthetic to numb your eye




Your eye will be cleaned carefully with a disinfectant eye wash to prevent infection



Your eyelid will be kept open using a tool to stop you from blinking








The injection procedure should only take a few minutes and you should only feel a light pressure against the eye when injected



You will be awake but you should not see the needle as the injection is in the corner of the eye



After your treatment

-  Use any treatment given to you by your eye department during your visit
-  You may be given an eye lubricant to keep your eye comfortable, which you should use as directed by your eye specialist
-  Ask your eye specialist if you should avoid any particular activities
-  Try to rest your eyes as much as possible—and for at least the first few hours after the injection
-  You may have temporary vision problems (for example, blurred vision) after your injections with VABYSMO.
Do not drive or use machines as long as these last

5. Important safety information

Like any medicines or medical procedures, your eye injection with VABYSMO may cause side effects, which affect people differently and not everyone will experience side effects.

After the eye injection with VABYSMO, you will probably have blurred eyesight and some floaters in your vision. This is to be expected but should only last a few days.

If your symptoms do not go away or are getting worse, contact your eye doctor or eye department as soon as possible.

Contact your eye doctor urgently if you have any of the following, which could be signs of a serious treatment complication:

- Eye pain, increased discomfort, worsening eye redness
- Blurred vision or you can't see as well as usual
- Increased sensitivity to light
- A sudden loss, decrease or change in vision
- An increase or sudden appearance of floaters or flashes of light

These are signs of potentially sight-threatening complications of the injection (infection and inflammation in the eye, tear or detachment of the retina) that require immediate medical care.

For a list of all potential side effects, please read the patient leaflet that comes with your medicine, VABYSMO. This can be accessed by scanning the QR code on page 3 of this guide or asking your eye department.

Missed dose or appointment

It is important to follow the treatment schedule recommended by your eye doctor. If you miss a dose or check-up, schedule a new appointment with your eye department as soon as possible. Ask for your eye doctor's advice before stopping treatment with VABYSMO.

6. Reporting side effects

If you get any side effects, talk to your eye doctor, pharmacist or nurse. This includes any possible side effects not listed in the patient leaflet.

Please report suspected side effects to the MHRA through the Yellow Card scheme. You can report via:

- the Yellow Card website [**www.mhra.gov.uk/yellowcard**](http://www.mhra.gov.uk/yellowcard)
- the free Yellow Card app available from the **Apple App Store** or **Google Play Store**.

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. You can leave a message outside of these hours.

When reporting please provide as much information as possible. By reporting side effects, you can help provide more information on the safety of this medicine.

You should also report side effects to Roche Products Ltd by emailing the Roche Drug Safety Centre at **welwyn.uk_dsc@roche.com** or calling **+44 (0)1707 367554**.

7. Additional resources and support

You can always contact your eye department with questions or contact the Macular Society or the Royal National Institute of Blind People (RNIB). Please note, these are independent organisations and Roche Products Limited is not responsible for the content of their website or the advice they provide.

Macular Society

Advice and Information: **0300 3030 111**

Email: **help@macularsociety.org**

Website: **https://www.macularsociety.org/**

Macular Society
Beating Macular Disease

RNIB

Helpline: **0303 123 9999**

Email: **helpline@rnib.org.uk**

Website: **https://www.rnib.org.uk/**

R N I B

See differently

