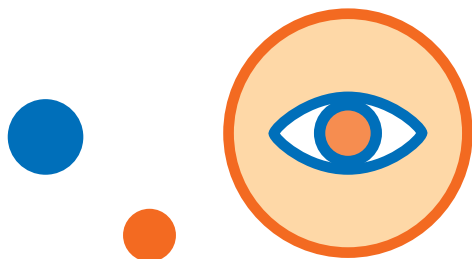


FOR USE IN IRELAND

Roche



Patient/Carer Guide to Vabysmo[®] ▼ (faricimab)

For the treatment of

- Neovascular (wet) Age-Related Macular Degeneration (nAMD)
- Diabetic Macular Edema (DME)
- Macular oedema secondary to Central Retinal Vein Occlusion (CRVO)
- Macular oedema secondary to Branch Retinal Vein Occlusion (BRVO)

Please read this material along with the Package Leaflet supplied with this medicine or also available on www.medicines.ie before taking this medicine.

IE Version 5.1.4

Date of HPRA Approval: February 2025

Contents

1 Summary of Important Safety Information.....	5
2 What is nAMD?.....	6
3 What is DME?	10
4 What is CRVO?	14
5 What is BRVO?.....	18
6 What is Vabysmo?.....	22
7 Treatment with Vabysmo.....	24
8 Recommendation for Adequate After Injection Care	28
9 Reporting of Safety Information.....	30

This guide provides important safety information to assist in your understanding of the benefits and risks associated with Vabysmo.

You can use this guide to learn more about your condition, and what you can expect from your treatment with Vabysmo. This guide is also for family members or carers of people living with nAMD, DME, CRVO or BRVO. For any further questions, you should contact your doctor.

For an audio version and digital version of this information which is available online at www.hpra.ie and www.medicines.ie, please scan this QR code.



1 | Summary of Important Safety Information

Contact your doctor as soon as possible if you experience any of the following symptoms after treatment with Vabysmo:

- Sudden decrease in your vision
- Your vision gets blurred, or you can't see as well as usual including an increased number of small particles in your vision
- Worsening redness of the eye, eye pain, increased eye discomfort
- Increased sensitivity to light

2 | What is Neovascular (wet) Age-Related Macular Degeneration (nAMD)?

nAMD is a common cause of vision loss among people aged 60 years and over. The more that nAMD progresses, the larger the loss of vision becomes. It is a long-term condition and needs ongoing care.

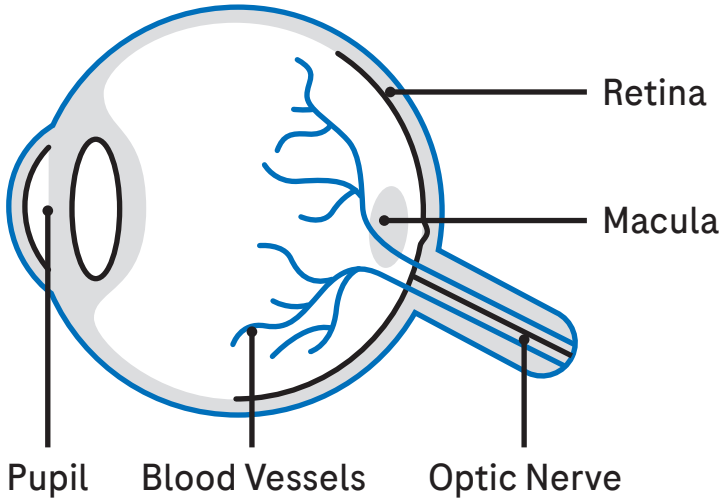
Macular degeneration happens when abnormal vessels grow at the macula (central part of the retina). Abnormal vessels can bleed and leak fluid in the back of the eye, which causes swelling of the retina (the light-sensitive layer at the back of the eye) and vision loss.

nAMD may affect one eye or both but only affects the central part of vision.

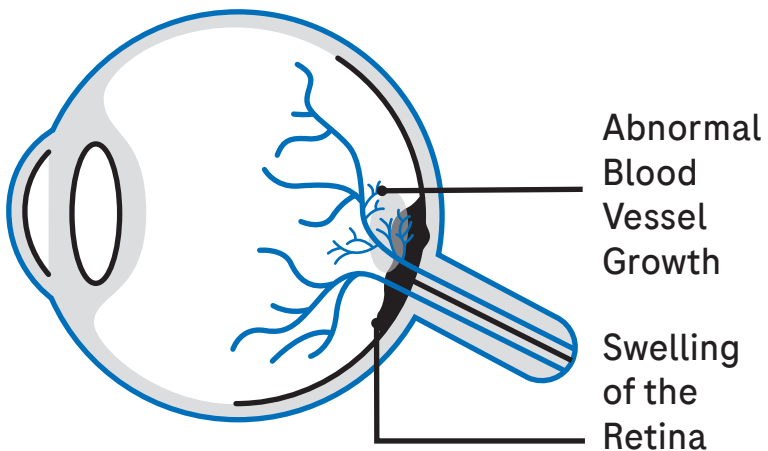
The retina is the back layer inside the eye that records the images we see – and sends them to the brain.

The macula is the central part of the retina, responsible for our sharpest vision. This is used to read, drive a car, recognise faces or colours, and see objects in fine detail.

Healthy Eye



Eye Affected by nAMD



Symptoms may include:



A dark empty area in the centre of vision



Muted colours



Blurred vision



Things appearing as the wrong shape

- Blurry or distorted vision – such as straight lines appearing wavy
- Objects appearing as the wrong shape or size
- Colours seeming less bright
- A dark, empty area in the centre of vision
- Difficulty reading, driving, watching TV, or doing other daily tasks

3 | What is Diabetic Macular Edema (DME)?

People living with diabetes who have high blood sugar (glucose) levels over a long period of the time are at risk of getting **DME**.

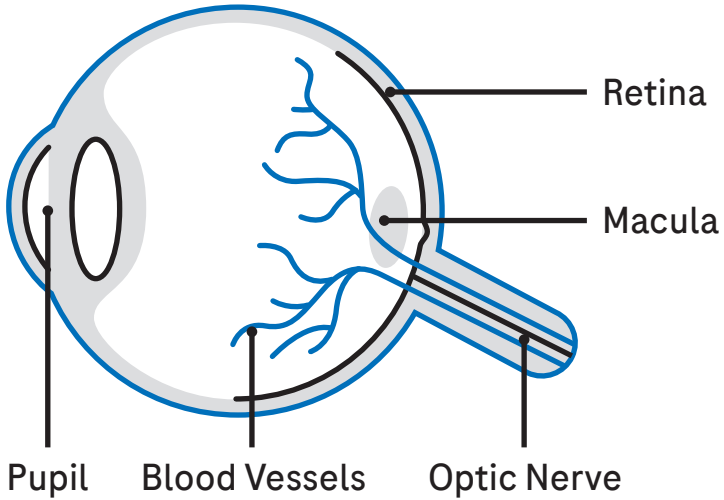
DME is when the blood vessels in the retina (the light sensitive layer at the back of the eye) are damaged which can leak fluid into the eye causing swelling in the macula (the central part of the retina) and vision loss.

DME is the leading cause of vision loss in people living with diabetes.

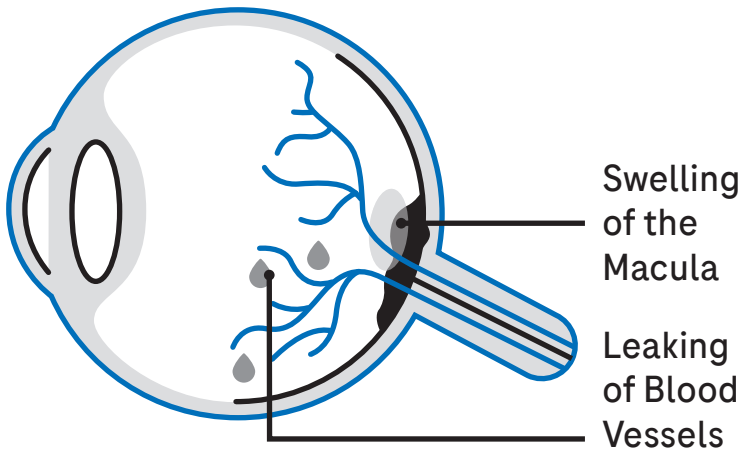
The retina is the back layer inside the eye that records the images we see – and sends them to the brain.

The macula is the central part of the retina, responsible for our sharpest vision. This is used to read, drive a car, recognise faces or colours, and see objects in fine detail.

Healthy Eye



Eye Affected by DME



Symptoms may include:



Gaps or dark spots



Muted colours



Blurred vision



**Things appearing as
the wrong shape**

- Vision may be blurred or wavy
- Objects may change size
- Colours might appear dull or faded
- Seeing in bright or glaring light may be difficult
- Reading or driving may be difficult
- Gaps or dark spots may appear in your vision

4 | What is Macular oedema secondary to Central Retinal Vein Occlusion (CRVO)?

RVO is a chronic eye condition that can lead to sudden painless vision loss.

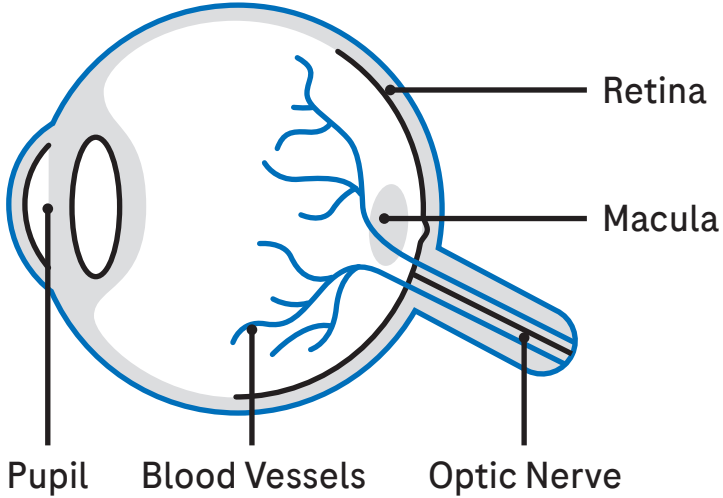
RVO typically affects only one eye. CRVO is due to blockage of the main retinal vein, which transports blood away from the retina.

RVO prevents blood draining from the retina, which leads to bleeding and fluid leakage, causing swelling in the macula.

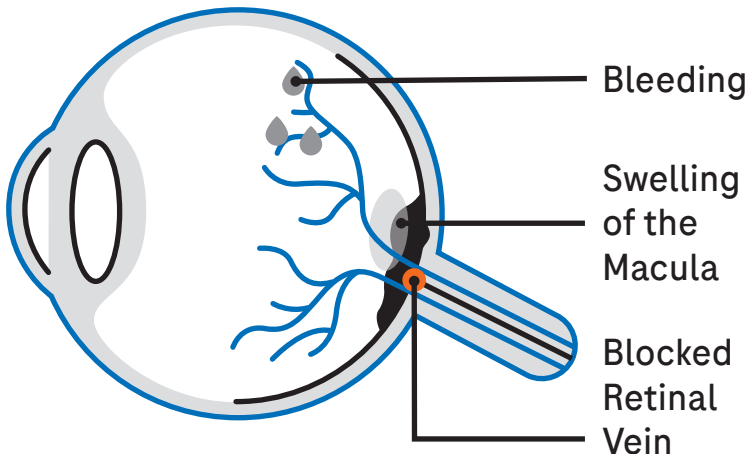
The retina is the back layer inside the eye that records the images we see – and sends them to the brain.

The macula is the central part of the retina, responsible for our sharpest vision. This is used to read, drive a car, recognise faces or colours, and see objects in fine detail.

Healthy Eye



Eye Affected by CRVO



Symptoms may include:



Gaps or dark spots



Muted colours



Blurred vision

- Sudden painless blurring or vision loss in part of or all of one eye
- Dark spots, little squiggles, or lines may appear in your vision
- Colours might appear dull or faded
- Vision may be blurred or wavy
- Reading or driving may be difficult

5 | What is Macular oedema secondary to Branch Retinal Vein Occlusion (BRVO)?

RVO is a chronic eye condition that can lead to sudden painless vision loss.

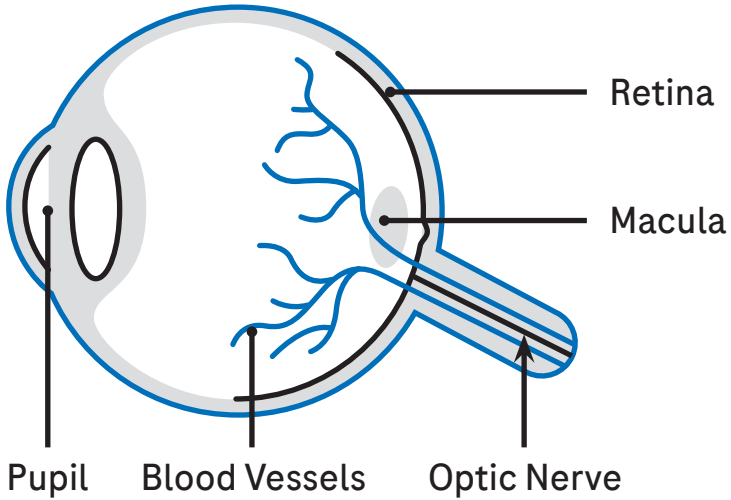
RVO typically affects only one eye. BRVO is due to blockage of one or more branches of the main retinal vein, each of which drains the retina.

RVO prevents blood draining from the retina, which leads to bleeding and fluid leakage, causing swelling in the macula.

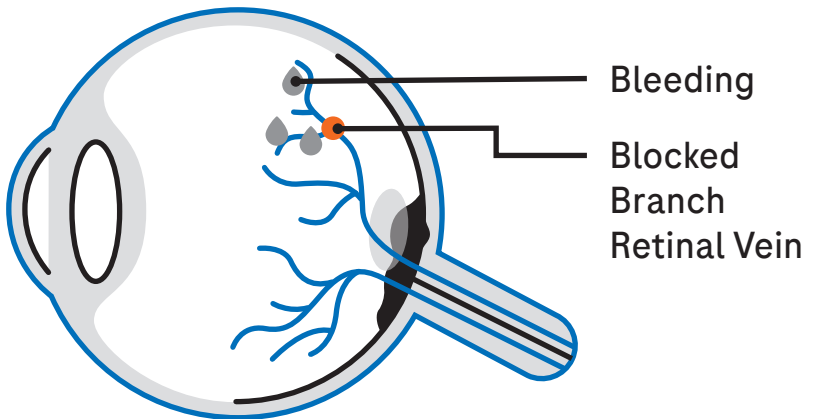
The retina is the back layer inside the eye that records the images we see – and sends them to the brain.

The macula is the central part of the retina, responsible for our sharpest vision. This is used to read, drive a car, recognise faces or colours, and see objects in fine detail.

Healthy Eye



Eye Affected by BRVO



Symptoms may include:



Gaps or dark spots



Muted colours



Blurred vision

- Sudden painless blurring or vision loss in part of or all of one eye
- Dark spots, little squiggles, or lines may appear in your vision
- Colours might appear dull or faded
- Vision may be blurred or wavy
- Reading or driving may be difficult

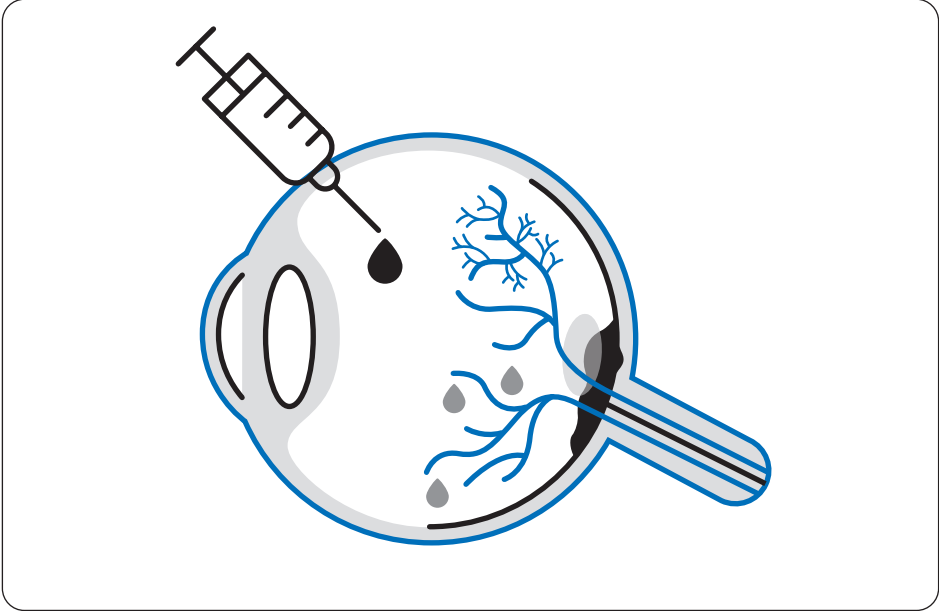
6 | What is Vabysmo?

Vabysmo is an eye injection containing the active substance **faricimab**.

Certain proteins in higher than normal levels can cause the growth of abnormal blood vessels or cause the damage to the normal vessels at the back of the eye. These abnormal or damaged vessels can leak fluid into the eye causing swelling and vision loss.

By blocking these proteins, Vabysmo helps reduce the leakage and thereby maintain, or even improve, your vision.

Your condition will be regularly monitored by your doctor to make sure the treatment is working properly.



7 | Treatment with Vabysmo

Preparing for Your Treatment Day

- Have a family member or supporter take you to and from your appointment. This will not only help you with logistics but might also support you in keeping all the information given / in conversation with your doctor.
- Avoid wearing makeup on the day of your injection.
- Take dark glasses with you as your eyes may be sensitive to light after the injection.

On Treatment Day

Before the Injection

- Vabysmo is injected into your eye (intravitreal injection) by a doctor experienced in giving eye injections. Before the injection, your doctor will use a disinfectant eyewash to clean your eye carefully to prevent infection.
- It is understandable to worry about such injection, your doctor will give you an eye drop (local anaesthetic) to numb the eye to reduce or prevent pain from the injection.
- Your eyelid will be kept open using a tool to stop you from blinking.

Tell your doctor before having Vabysmo if:

- You have an infection in or around the eye.
- You have pain or redness in your eye (eye inflammation).
- You are allergic to faricimab or any of the other ingredients of this medicine. The full list can be found in the patient information leaflet available online at www.medicines.ie or www.hpra.ie

During the Injection

- The injection will only take a few minutes.
- You will be awake.
- You may feel pressure during the injection, but you should feel no pain.

After the Injection

- Ask your doctor if you should avoid any particular activities.
- Use any treatment given to you by your eye doctor.
- Try to rest your eyes as much as possible – and for at least a few hours at first.
- 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.

8 | Recommendation for Adequate After Injection Care

After the injection, you will probably have blurred eyesight and small particles in your vision. This is normal and should only last a few days.

Sometimes, after Vabysmo intravitreal injection you may experience:

- Inflammation inside the eye
- An uncommon but severe infection inside the eye called “endophthalmitis”

Contact your doctor immediately if you have any of the following, which are signs of allergic reactions, inflammation, or infections:

- Sudden vision loss
- Worsening redness of the eye, eye pain, or increased eye discomfort
- Blurred or decreased vision
- An increased number of small particles in your vision that don't go away after a few days
- Increased sensitivity to light

It is important to follow the treatment schedule recommended by your doctor. Ask for your doctor's advice before stopping the treatment.

9 | Reporting of Safety Information

Reporting of side effects

▼ This medicine 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. If you experience any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the patient information leaflet. You can also report side effects directly (see details below).

Please report side effects to:

The Drug Surveillance Centre
Roche Products (Ireland) Limited
3004 Lake Drive, Citywest, Naas Road, Dublin 24.
Telephone: (01) 4690700
Email: ireland.drug_surveillance_centre@roche.com

Or report to:

HPRA Pharmacovigilance
Website: www.hpra.ie

By reporting side effects, you can help provide more information on the safety of this medicine.

For additional safety information, please talk to your doctor and see the accompanying Vabysmo full Prescribing Information.

Further Information

Talk to your doctor, nurse or pharmacist if you have any questions or concerns.

IE Version 5.1.4

M-IE-00001314

Date of Preparation: July 2024

Date of HPRA Approval: February 2025

Copyright ©2025 by Roche Products (Ireland) Limited. All rights reserved.