



Your Guide to the Use of **Vabysmo**[®]

For the treatment of Neovascular (wet)
Age-related Macular Degeneration (nAMD),
Diabetic Macular Edema (DME), Macular edema
secondary to central retinal vein occlusion
(CRVO), Macular edema secondary to branch
retinal vein occlusion (BRVO)



This guide provides you with important safety information, to help you understand the benefits and risks of using Vabysmo.

You can use this guide to obtain more information about your condition, and to learn what to expect from your treatment with Vabysmo. This guide is also for the use of family members and others who support people who are coping with nAMD, DME, CRVO or BRVO. For any other question, you should contact your doctor.

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**:

- A sudden decrease in your vision
- Occurrence of blurred vision, or not seeing as well as usual, including an increased number of small particles in your vision
- Worsening of eye redness, eye pain or increased eye discomfort
- Increased sensitivity to light

2 | What is nAMD?

nAMD is a common cause of vision loss among people aged 60 and over. As nAMD progresses, vision loss becomes more significant. This is a chronic medical condition that requires ongoing treatment.

Macular degeneration occurs when abnormal blood vessels grow in the macula, (the central part of the retina). These blood vessels may bleed, and fluid may leak from them into the back of the eye. This causes swelling of the retina (the light-sensitive layer at the back of the eye) and vision loss.

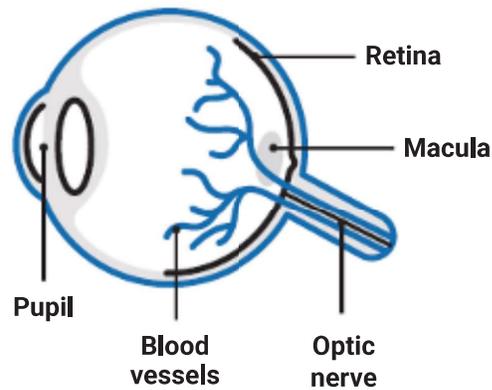
nAMD may affect one or both eyes, but it affects only the central area of vision.

The retina is the layer at the back of the eye that records what we see - and transmits this information to the brain.

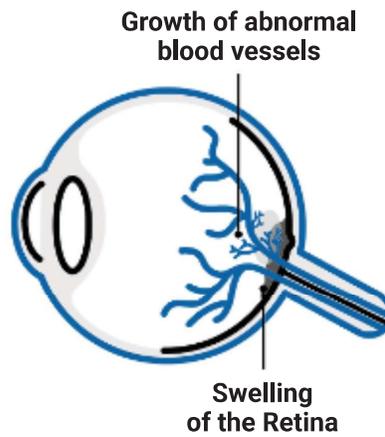
The macula is the central area of the retina, responsible for our sharp vision. This area serves for reading, driving, identifying faces or colours, and seeing objects in fine detail.

2 | What is nAMD? (continued)

Healthy Eye



Eye Affected by nAMD



2 | What is nAMD? (continued)

Symptoms may include



A dark or empty area at the center of your vision



Muted colours



Blurred vision



Objects appearing to have an incorrect shape or size

- Blurred or distorted vision - for example, straight lines appearing wavy
 - Objects appearing to have an incorrect shape or size
 - Colours appearing less bright
 - A dark or empty area at the center of vision
 - Difficulty reading, driving, watching TV or doing other daily tasks
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3 | What is DME?

People with diabetes who have high blood sugar (glucose) levels over a long period of time are at risk for developing DME.

DME occurs when blood vessels in the retina (the light-sensitive layer at the back of the eye) become damaged. Fluid may leak from these damaged vessels into the eye and cause swelling of the macula (the center of the retina) and vision loss.

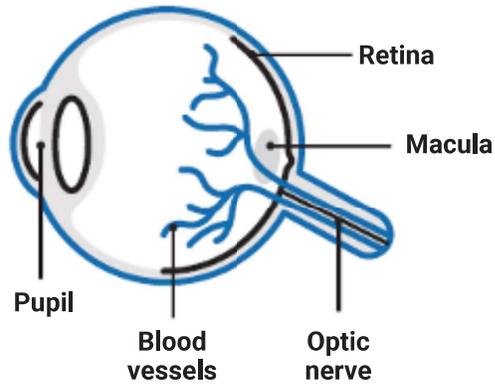
DME is the leading cause of vision loss in people with diabetes.

The retina is the layer at the back of the eye that records what we see - and transmits this information to the brain.

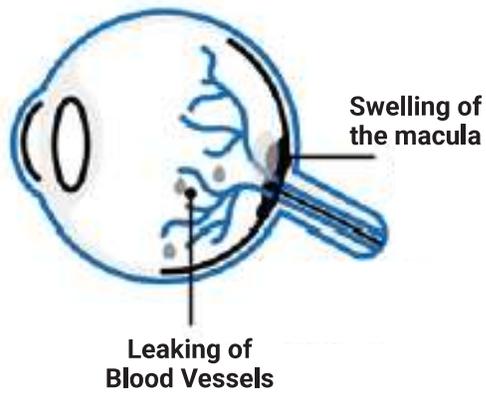
The macula is the central area of the retina, responsible for our sharp vision. This area serves for reading, driving, identifying faces or colours, and seeing objects in fine detail.

3 | What is DME? (continued)

Healthy Eye



Eye Affected by DME



3 | What is DME? (continued)

Symptoms May Include



A dark or empty area at the center of your vision



Muted colours



Blurred vision



Objects appearing to have an incorrect size or shape

- Vision may be blurred or wavy
- Objects may appear to have a different size
- Colours may look dull or faded
- There may be difficulty seeing in bright light or glare
- There may be difficulty with reading or driving
- Gaps or dark spots may appear in your vision

4 | What is 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.

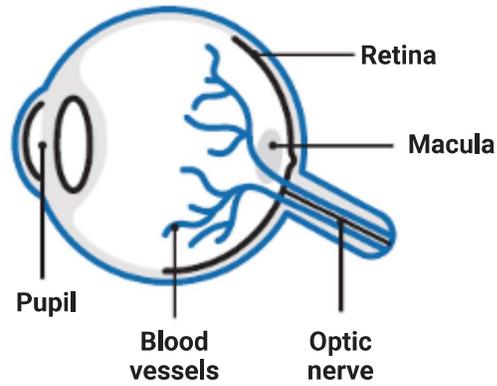
A condition of RVO may prevent blood draining from the retina, which leads to bleeding and fluid leakage, causing swelling in the macula.

The retina is the layer at the back of the eye that records what we see - and transmits this information to the brain.

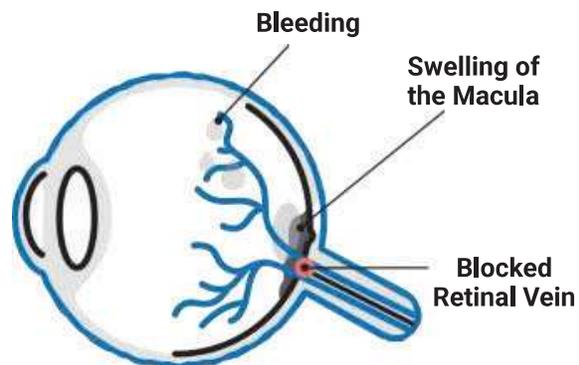
The macula is the central part of the retina, responsible for our sharp vision. This area serves for reading, driving, identifying faces or colours, and seeing objects in fine detail.

4 | What is CRVO? (continued)

Healthy Eye



Eye Affected by CRVO



4 | What is CRVO? (continued)

Symptoms May Include



A dark or empty area at the center of your vision



Muted colours



Blurred vision

- Sudden appearance of painless blurring or vision loss in part or all of the field of vision of one eye
- Dark spots, little squiggles or lines may appear in your vision
- Colours may look dull or faded
- Blurred or distorted vision – for example, straight lines appearing wavy
- There may be difficulty with reading or driving

5 | What is 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.

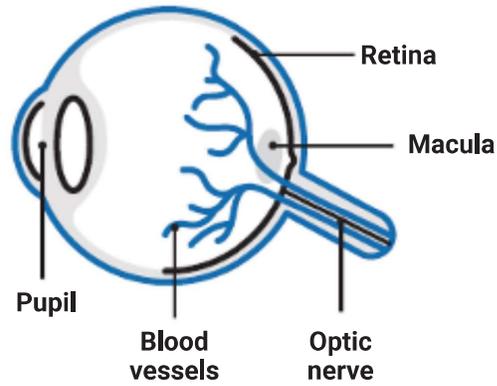
A condition of RVO may prevent blood draining from the retina, which leads to bleeding and fluid leakage, causing swelling in the macula.

The retina is the layer at the back of the eye that records what we see - and transmits this information to the brain.

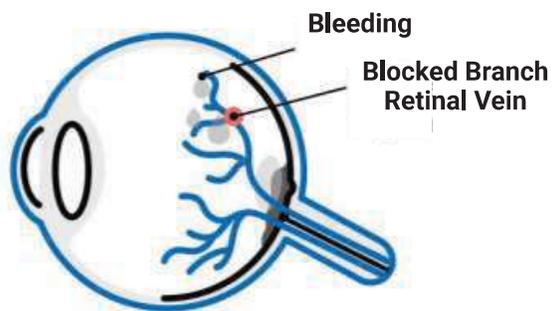
The macula is the central part of the retina, responsible for our sharp vision. This area serves for reading, driving, identifying faces or colours, and seeing objects in fine detail.

5 | What is BRVO? (continued)

Healthy Eye



Eye Affected by BRVO



5 | What is BRVO? (continued)

Symptoms May Include



A dark or empty area at the center of your vision



Muted colours



Blurred vision

- Sudden appearance of painless blurring or vision loss in part or all of your field of vision in one eye
- Dark spots or lines may appear in your vision
- Colours may look dull or faded
- Blurred or distorted vision – for example, straight lines appearing wavy
- There may be difficulty with reading or driving

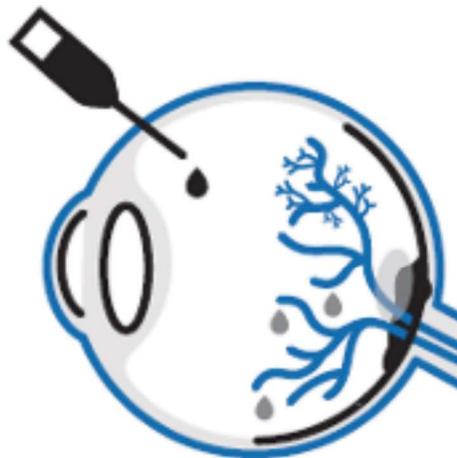
6 | What is Vabysmo?

Vabysmo is a medicine injected into the eye, which contains the active ingredient Faricimab.

Abnormally high levels of specific proteins could cause the growth of abnormal blood vessels or cause damage to the normal blood vessels at the back of the eye. This can lead to leakage of fluids from these blood vessels into the eye cavity, and cause swelling and vision loss.

By blocking these proteins, Vabysmo helps reduce the leakage of fluids, thus preserving, or even improving, your vision.

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



7 | Treatment with Vabysmo

Preparing for your treatment day

- Ask a family member, or someone else who can help you, to take you to and from the appointment. This will be helpful logistically, and may also help you to remember all of the information provided during the discussion with your doctor.
- Avoid wearing makeup on the day that you receive the injection
- Bring sunglasses, as your eyes may be sensitive to light following the injection.

7 | Treatment with Vabysmo (continued)

On the day of your treatment

Before the injection

- Vabysmo is injected into your eye (an intravitreal injection) by a doctor who is experienced in giving eye injections. Before the injection, your doctor will use a disinfectant eyewash to clean your eye well to prevent infection.
- It is understandable to worry about such an injection. Your doctor will use eye drops (local anesthetic) to numb your eye and to reduce or prevent pain from the injection.
- Your eyelid will be kept open using an instrument that prevents you from blinking.

Before being given Vabysmo, tell your doctor if:

- You have an infection in or around your eye.
- You have pain or redness in the eye (eye inflammation)
- You are allergic to Faricimab or to any of the other ingredients of this medicine. You can find the full list in the leaflet found in the medicine package.

During the injection

- The injection procedure will only take a few minutes. You will be awake during the procedure.
- You may feel pressure during the injection, but you shouldn't feel pain

After the injection

- Ask your doctor whether you need to avoid certain activities.
 - Use any treatment that your eye doctor prescribes for you.
 - Try to rest your eyes as much as possible - at least for the first few hours following the injection.
 - You may experience temporary vision problems (such as blurred vision) after the Vabysmo injection. **Do not drive or operate machines as long as these effects last.**
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8 | Recommendation for After the Injection

After the injection, you will probably experience blurred vision and see small particles in your vision. This is normal, and should pass within a few days.

Sometimes after a **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 experience any of the following, which are signs of allergic reaction, inflammation or infections:

- Sudden vision loss
- Worsening of eye redness, eye pain or increased eye discomfort
- Blurred or decreased vision
- A large 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 schedule of treatment prescribed by your doctor. Consult your doctor before you stop treatment.

9 | Reporting safety information

If you experience any side effects, contact your doctor as soon as possible. This includes possible side effects not listed in the medicine's leaflet that you received with this guide.

Side effects can be reported to the Ministry of Health, using the online form for reporting side effects on the Ministry of Health homepage www.health.gov.il or using the link: <https://sideeffects.health.gov.il/>, or to Roche at email address Israel.DrugSafety@roche.com

Reporting side effects can provide additional information about the safety of this medicine.

For more information about safety, speak with your doctor and read the **Vabysmo** leaflet.

The exact instructions can be found in the medicine's leaflet on the Ministry of Health website or on the Roche website at web address www.roche.co.il

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