

Package leaflet: Information for the patient

Vabysmo 120 mg/mL solution for injection in pre-filled syringe Faricimab

▼ 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. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Vabysmo is and what it is used for
2. What you need to know before you use Vabysmo
3. How to use Vabysmo
4. Possible side effects
5. How to store Vabysmo
6. Contents of the pack and other information

1. What Vabysmo is and what it is used for

Vabysmo contains the active substance faricimab, which belongs to a group of medicines called antineovascularisation agents. Vabysmo is injected into the eye by your healthcare professional to treat eye disorders called

- neovascular (wet) age-related macular degeneration (nAMD),
- visual impairment due to diabetic macular oedema (DMO).
- visual impairment due to macular oedema secondary to retinal vein occlusion (branch RVO (BRVO) or central RVO (CRVO)).

What Vabysmo is used for

Vabysmo is used in adults to treat nAMD and DMO, which both affect the macula, the central part of the retina (the light-sensitive layer at the back of the eye) that is responsible for fine, central vision. nAMD is caused by the growth of abnormal blood vessels which leak blood and fluid into the macula, and DMO is caused by leaky blood vessels that cause swelling of the macula.

Central RVO is the blockage of the main blood vessel (vein) that transports blood away from the retina, and branch RVO is the blockage of one of the smaller branches of the main blood vessel. Due to the increased pressure within these blood vessels, there is leakage of fluid into the retina, causing swelling of the macula (macular oedema).

How Vabysmo works

Vabysmo specifically recognises and blocks the activity of proteins known as angiopoietin-2 and vascular endothelial growth factor A. In conditions like nAMD, DMO and RVO, these proteins can be present in higher levels than normal, and this can cause the growth of abnormal blood vessels and/or damage to the normal vessels. These changes to the blood vessels can result in leakage into the retina,

causing swelling of the retina or damage to the layers of the retina, which can negatively affect a person's vision. By attaching to these proteins, Vabysmo can block their actions and prevent abnormal vessel growth, leakage and swelling. Vabysmo may improve disease and/or slow down worsening of the disease and thereby maintain, or even improve, your vision.

2. What you need to know before you use Vabysmo

Do not use Vabysmo:

- if you have an active or suspected infection in or around the eye.
- if you have pain or redness in your eye (eye inflammation).
- if you are allergic to faricimab or any of the other ingredients of this medicine (listed in section 6).

If any of these apply to you, tell your doctor. You should not be given Vabysmo.

Warnings and precautions

Talk to your doctor before receiving Vabysmo:

- if you have glaucoma (an eye condition usually caused by high pressure in the eye).
- if you have a history of seeing flashes of light or floaters (dark floating spots) and if you have a sudden increase in the size and number of floaters.
- if you have had eye surgery in the last four weeks or if eye surgery is planned in the next four weeks.
- if you have ever had any eye diseases or eye treatments.

Tell your doctor immediately if you:

- develop sudden vision loss.
- develop signs of a possible eye infection or inflammation, such as worsening redness of the eye, eye pain, increased eye discomfort, blurred or decreased vision, an increased number of small particles in your vision, increased sensitivity to light.

Furthermore it is important for you to know that:

- the safety and efficacy of Vabysmo when administered to both eyes at the same time has not been studied and use in this way may lead to an increased risk of experiencing side effects.
- injections with Vabysmo may cause a temporary increase in eye pressure (intraocular pressure) in some patients within 60 minutes of the injection. Your doctor will monitor this after each injection.
- your doctor will check whether you have other risk factors that may increase the chance of a tear or detachment of one of the layers at the back of the eye (retinal detachment or tear, and retinal pigment epithelial detachment or tear), in which case Vabysmo must be given with caution.

Injecting vascular endothelial growth factor inhibitors, substances similar to those contained in Vabysmo, directly into the bloodstream is potentially related to the risk of blood clots blocking blood vessels (arterial thromboembolic events), which may lead to heart attack or stroke. There is a theoretical risk of such events following injection of Vabysmo into the eye.

Children and adolescents

The use of Vabysmo in children and adolescents has not been studied because nAMD, DMO and RVO occur mainly in adults.

Other medicines and Vabysmo

Tell your doctor if you are using, have recently used or might use any other medicines.

Pregnancy and breast-feeding

Vabysmo has not been studied in pregnant women. Vabysmo should not be used during pregnancy unless the potential benefit to the patient outweighs the potential risk to the unborn child. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before this medicine is given to you.

Breast-feeding is not recommended during treatment with Vabysmo because it is not known whether Vabysmo passes into human milk.

Women who could become pregnant must use an effective method of birth control during treatment and for at least three months after stopping treatment with Vabysmo. If you become pregnant or think you are pregnant during treatment, tell your doctor right away. Ask your doctor for advice before starting Vabysmo treatment.

Driving and using machines

After your injection with Vabysmo, you may have temporary vision problems (for example blurred vision). Do not drive or use machines as long as these last.

Vabysmo contains sodium

The medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially “sodium-free”.

3. How to use Vabysmo

How much and how often Vabysmo is given

The recommended dose is 6 mg of faricimab.
The frequency of injections will be determined by your doctor.

nAMD

- You will be treated with one injection every month for the first 4 months.
- After that, you may receive injections up to every 4 months. Your doctor will determine your treatment interval based on the condition of your eye.

DMO

- You will be treated with one injection every month for the first 4 months.
- After that, you may receive injections from every month to every 4 months. Your doctor will determine your treatment interval based on the condition of your eye.

RVO

- You will be treated with one injection every month for at least 3 months
- After that, you may receive injections less frequently. Your doctor will decide on the frequency of the injections based on the condition of your eye.

Method of administration

Vabysmo is injected into your eye (intravitreal injection) by a healthcare professional experienced in giving eye injections.

Before the injection your healthcare professional will use a disinfectant eyewash to clean your eye carefully to prevent infection. Your healthcare professional will give you an eye drop (local anaesthetic) to numb the eye to reduce or prevent pain from the injection.

How long does Vabysmo treatment last for

This is a long-term treatment, possibly continuing for months or years. Your doctor will regularly monitor your condition to check that the treatment is having the desired effect. Depending on how you respond to the treatment with Vabysmo, your doctor may ask you to change to a more or less frequent dose.

If you miss a dose of Vabysmo

If you miss a dose, schedule a new appointment with your doctor as soon as possible.

If you stop using Vabysmo

Speak with your doctor before stopping treatment. Stopping treatment may increase your risk of vision loss and your vision may worsen.

If you have any further questions on the use of this medicine, ask your doctor.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The side effects with Vabysmo injection are either from the medicine itself or from the injection procedure and they mostly affect the eye.

Some side effects could be serious

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

- eye pain, increased discomfort, worsening eye redness, blurred or decreased vision, a higher number of small particles or floaters in your vision, or increased sensitivity to light – these are signs of a possible eye infection or inflammation.
- a sudden decrease or change in vision.

Please tell your doctor immediately if you develop any of these side effects.

Other possible side effects

Other side effects which may occur after Vabysmo treatment include those listed below.

Most of the side effects are mild to moderate and will generally disappear within a week after each injection.

Contact your doctor if any of the following side effects become severe.

Very common (may affect more than 1 in 10 people):

- None

Common (may affect up to 1 in 10 people):

- Cloudy lens in the eye (cataract)
- Tear of one of the layers in the back of the eye (retinal pigment epithelial tear - nAMD only)
- Detachment of the gel-like substance inside the eye (posterior vitreous detachment)
- Increase in pressure inside the eye (increased intraocular pressure)
- Bleeding from small blood vessels in the outer layer of the eye (conjunctival haemorrhage)
- Moving spots or dark shapes in your vision (vitreous floaters)
- Eye pain

Uncommon (may affect up to 1 in 100 people):

- Serious inflammation or infection inside the eye (endophthalmitis)
- Inflammation of the gel-like substance inside the eye (vitritis)
- Inflammation in the iris and its adjacent tissue in the eye (iritis, iridocyclitis, uveitis)
- Bleeding in the eye (vitreous haemorrhage)
- Eye discomfort
- Itching (eye pruritus)
- Tearing of the retina (the back of the eye that detects light) • Red eye (ocular/conjunctival hyperaemia)
- A feeling of having something in the eye
- Blurred vision
- Decreased sharpness of vision (visual acuity reduced)
- Pain during the procedure (procedural pain)
- Detachment of the retina
- Increased tear production (increased lacrimation)
- Scratched cornea, damage to the clear layer of the eyeball that covers the iris (corneal abrasion)
- Eye irritation

Rare (may affect up to 1 in 1,000 people):

- Temporary decreased sharpness of vision (visual acuity reduced transiently)
- Clouding of the lens due to injury (traumatic cataract)

Not known

- Retinal vasculitis (inflammation of blood vessels in the back of the eye)
- Retinal occlusive vasculitis (blockage of blood vessels in the back of the eye, typically in presence of inflammation)

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Vabysmo

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and label after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C to 8°C).

Do not freeze.

Keep the sealed tray in the original carton to protect the pre-filled syringe from light.

The pre-filled syringe may be kept at room temperature, 20°C to 25°C, in the original carton for up to 24 hours.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away any medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Vabysmo contains

- The active substance is faricimab. One mL solution for injection contains 120 mg faricimab. Each pre-filled syringe contains 21 mg faricimab in 0.175 mL solution. This provides a usable amount to deliver a single dose of 0.05 mL solution containing 6 mg of faricimab. The excess volume must be discarded prior to administration.
- The other ingredients are: L-histidine, acetic acid 30%, L-methionine, sodium chloride, sucrose, polysorbate 20, water for injections.

What Vabysmo looks like and contents of the pack

Vabysmo 120 mg/mL solution for injection is a clear to opalescent, colourless to brownish-yellow solution.

Pack size of one pre-filled syringe and one sterile 5 µm Extra Thin Wall injection filter needle (30-gauge x ½ inch, 0.30 mm x 12.7 mm) for single-use only.

Marketing Authorisation Holder and Manufacturer

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The following information is intended for healthcare professionals only: Instructions for use of pre-filled syringe:

Before you start



Read all the instructions carefully before using Vabysmo.

The Vabysmo carton includes:



A sterile pre-filled syringe in a sealed tray. The pre-filled syringe is for a single dose only.



A sterile, 30-gauge x ½ inch, ETW (Extra Thin Wall) injection filter needle with an integrated filter in the hub. The injection filter needle is for single use only.

Only use the provided injection filter needle for the administration, as it was designed to ensure safe ophthalmic use of the medicinal product.



Vabysmo should be refrigerated at temperatures between 2°C to 8°C .

Do not freeze.



Allow Vabysmo to reach room temperature, 20°C to 25°C before proceeding with the administration.



Prior to use, keep the sealed tray in the original carton to **protect the pre-filled syringe from light**. The pre-filled syringe may be kept at room temperature in the original carton for up to **24 hours**.



Vabysmo should be inspected visually prior to administration.

Do not use if the carton seals have been tampered with.

Do not use if the packaging, pre-filled syringe, injection filter needle is expired, damaged, or have been tampered with.

Do not use if the injection filter needle is missing.

Do not remove the finger grip from the syringe.

Do not use if the syringe cap is detached from the Luer lock.

Do not use if particulates, cloudiness, or discolouration are visible. Vabysmo is a clear to opalescent and colourless to brownish-yellow liquid solution.

Carton contents

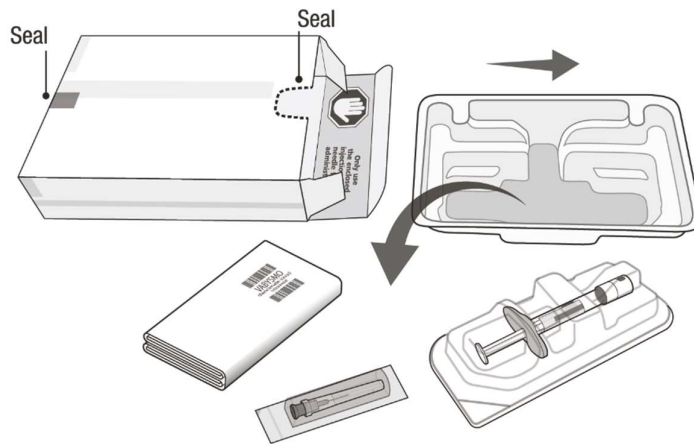
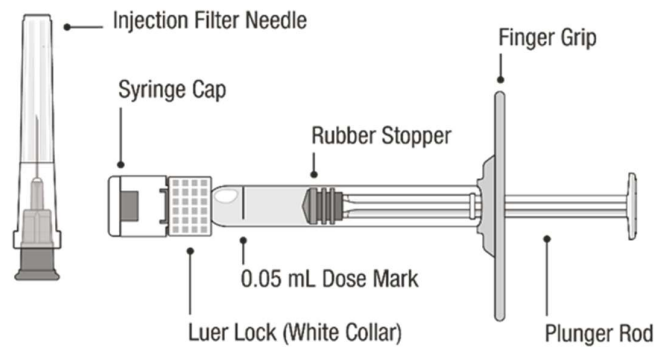


Figure A

Device description

Figure B



Removal of the syringe from the syringe tray (step 1) and all subsequent steps should be done using aseptic technique.

Note: the dose must be set to the 0.05 mL dose mark.

Open tray and remove syringe cap

- 1 Peel the lid off the syringe tray and aseptically remove the pre-filled syringe.
- 2 Hold the syringe by the white collar; snap off the syringe cap (see Figure C).

Do not twist off the cap.

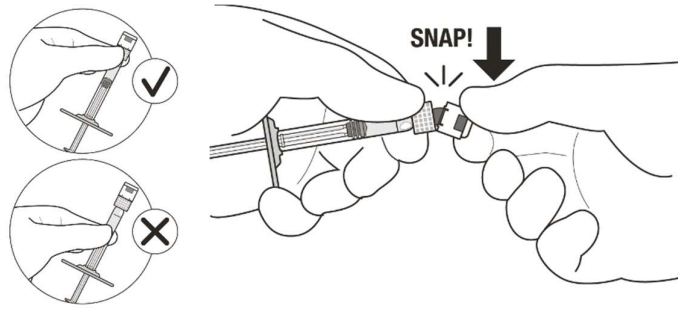


Figure C

Attach injection filter needle

- 3 Aseptically remove the injection filter needle from its packaging.
- 4 Aseptically and firmly attach the injection filter needle onto the syringe Luer lock (see **Figure D**).

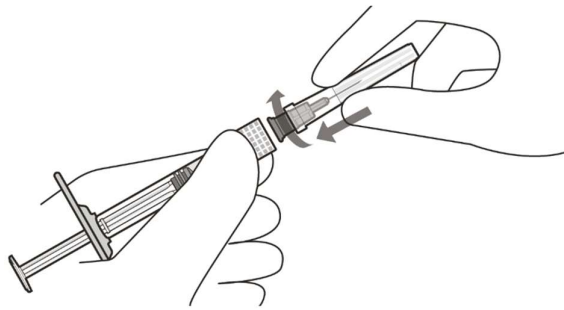


Figure D

Only use the provided injection filter needle for the administration

- 5 Carefully remove the needle cap by pulling it straight off.

Dislodge air bubbles

- 6 Hold the syringe with the injection filter needle pointing up. Check the syringe for air bubbles.
- 7 If there are any air bubbles, gently tap the syringe with your finger until the bubbles rise to the top (see **Figure E**).

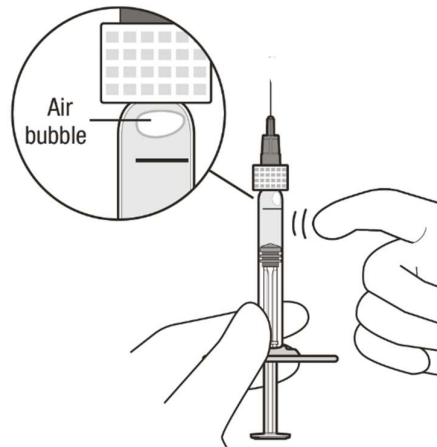


Figure E

Adjust medicinal product dose and expel air

- 8 Hold the syringe at eye level and **slowly** push the plunger rod until the **lower edge of the rubber stopper's dome** is aligned with the 0.05 mL dose mark (see Figure F). This will expel the air and the excess solution and set the dose to 0.05 mL.

Ensure that the injection is given **immediately** after preparation of the dose.

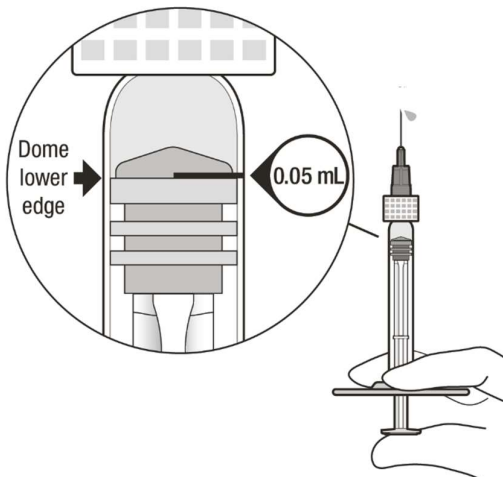


Figure F

Injection procedure

- 9 The injection procedure should be carried out under aseptic conditions.
Inject **slowly** until the rubber stopper reaches the bottom of the syringe to deliver the volume of 0.05 mL.
Do not recap or detach the injection filter needle from the syringe.

Any unused medicinal product or waste material should be disposed of in accordance with local regulations.