Package leaflet: Information for the patient

Vabysmo 120 mg/mL solution for injection
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

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 doctor to treat eye disorders in adults called:
- neovascular (wet) age-related macular degeneration (nAMD),
- visual impairment due to diabetic macular oedema (DME).

These disorders 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 DME is caused by leaky blood vessels that cause swelling of the macula.

How Vabysmo works

Vabysmo specifically recognises and blocks the activity of proteins known as angiopoietin-2 and vascular endothelial growth factor A. When these proteins are present at higher levels than normal, they can cause growth of abnormal blood vessels and/or damage to normal vessels, with leakage into the macula, causing swelling or damage that 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 the 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 receiveVabysmo

You should not receive Vabysmo:

- if you are allergic to faricimab or any of the other ingredients of this medicine (listed in section 6).
- 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 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 increased 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 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.

When some medicines that work in a similar way to Vabysmo are given, there is known to be a risk of blood clots blocking blood vessels (arterial thromboembolic events), which may lead to heart attack or stroke. As small amounts of the medicine enter the blood, there is a theoretical risk of such events following injection of Vabysmo into the eye.

There is only limited experience in the treatment of:
- patients with active infections.
- patients with nAMD 85 years or older.
- patients with DME due to type I diabetes.
- diabetics with high average blood sugar values (Hb1Ac over 10%).
- diabetics with an eye disease caused by diabetes called proliferative diabetic retinopathy.
- diabetics with high blood pressure greater than 140/90 mmHg and disease of the blood vessels.
- patients with DME receiving injections less than every 8 weeks over a long period of time.

There is only limited experience in the treatment of patients receiving injections less than every 8 weeks over a long period of time, and these patients may be at greater risk of side effects.

There is no experience in the treatment of:
- diabetics with uncontrolled high blood pressure.

If any of the above applies to you, your doctor will consider this lack of information when treating you with Vabysmo.

Children and adolescents

The use of Vabysmo in children and adolescents has not been studied because nAMD and DME 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.

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 Vabysmo is given

The recommended dose is 6 mg of faricimab.

Neovascular (wet) age-related macular degeneration (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 decide on the frequency of the injections based on the condition of your eye.

Visual impairment due to diabetic macular oedema (DME)
- 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 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 doctor experienced in giving eye injections.

Before the injection your doctor will use a disinfectant eyewash to clean your eye carefully to prevent infection. Your doctor 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 working. 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, increased eye redness, blurred or decreased vision, a higher number of small particles in your vision, or increased sensitivity to light – these are signs of a possible eye infection, inflammation, or allergic reaction.
- a sudden decrease or change in vision.

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):
- Cloudy lens in the eye (cataract)

Common (may affect up to 1 in 10 people*):*
- Tearing of the retina (the layer at the back of the eye that detects light) or one of its layers
- Detachment of the gel-like substance inside the eye (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
- Increased tear production (increased lacrimation)
- Scratched cornea, damage to the clear layer of the eyeball that covers the iris (corneal abrasion)
- Eye irritation

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/red eye (vitritis)
- Inflammation in the iris and its adjacent tissue in the eye (iritis, iridocyclitis, uveitis)
- Bleeding inside the eye (vitreous haemorrhage)
- Eye discomfort
- Itching (eye pruritus)
- 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

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)

When some medicines that work in a similar way to Vabysmo are given, there is known to be a risk of blood clots blocking blood vessels (arterial thromboembolic events), which may lead to heart attack or stroke. As small amounts of the medicine enter the blood, there is a theoretical risk of such events following injection of Vabysmo into the eye.

Reporting of side effects

If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Vabysmo

Your doctor, pharmacist or nurse is responsible for storing this medicine and disposing of any unused product correctly. The following information is intended for healthcare professionals.

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 - 8°C).

Do not freeze.

Keep the vial in the outer carton in order to protect from light.

Prior to use, the unopened vial may be kept at room temperature, 20°C to 25°C, for up to 24 hours.

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 vial contains 28.8 mg faricimab in 0.24 mL solution. This provides a usable amount to deliver a single dose of 0.05 mL solution containing 6 mg of faricimab.
- 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 is a clear to opalescent, colourless to brownish-yellow solution.

Pack size of one glass vial and one sterile 5 µm blunt transfer filter needle (18-gauge x 1½ inch, 1.2 mm x 40 mm) for single-use only.

Marketing Authorisation Holder

Roche Registration GmbH
Emil-Barell-Strasse 1
79639 Grenzach-Wyhlen
Germany

Manufacturer

Roche Pharma AG
Emil-Barell-Str 1
79639 Grenzach-Whylen
Germany

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

België/Belgique/Belgien
N.V. Roche S.A.
Tél/Tel: +32 (0) 2 525 82 11

България
Рош България ЕООД
Тел: +359 2 474 5444

Lietuva
UAB “Roche Lietuva”
Tel: +370 5 2546799

Luxembourg/Luxemburg
(Voir/siehe Belgique/Belgien

Česká republika
Roche s. r. o.
Tel: +420 - 2 20382111

Danmark
Roche Pharmaceuticals A/S
Tlf: +45 - 36 39 99 99

Deutschland
Roche Pharma AG
Tel: +49 (0) 7624 140

Eesti
Roche Eesti OÜ
Tel: + 372 - 6 177 380

Ελλάδα
Roche (Hellas) A.E.
Τηλ: +30 210 61 66 100

España
Roche Farma S.A.
Tel: +34 - 91 324 81 00

France
Roche
Tél: +33 (0)1 47 61 40 00

Hrvatska
Roche d.o.o.
Tel: + 385 1 47 22 333

Ireland
Roche Products (Ireland) Ltd.
Tel: +353 (0) 1 469 0700

Ísland
Roche Pharmaceuticals A/S
c/o Icepharma hf
Sími: +354 540 8000

Italia
Roche S.p.A.
Tel: +39 - 039 2471

Κύπρος
Γ.Α.Σταμάτης & Σια Λτδ.
Τηλ: +357 - 22 76 62 76

Latvija
Roche Latvija SIA
Tel: +371 - 6 7039831

Magyarország
Roche (Magyarország) Kft.
Tel: +36 - 1 279 4500

Malta
(See Ireland)

Nederland
Roche Nederland B.V.
Tel: +31 (0) 348 438050

Norge
Roche Norge AS
Tlf: +47 - 22 78 90 00

Österreich
Roche Austria GmbH
Tel: +43 (0) 1 27739

Polska
Roche Polska Sp.z o.o.
Tel: +48 - 22 345 18 88.

Portugal
Roche Farmacêutica Química, Lda
Tel: +351 - 21 425 70 00

România
Roche România S.R.L.
Tel: +40 21 206 47 01

Slovenija
Roche farmacevtska družba d.o.o.
Tel: +386 - 1 360 26 00

Slovenská republika
Roche Slovensko, s.r.o.
Tel: +421 - 2 52638201

Suomi/Finland
Roche Oy
Puh/Tel: +358 (0) 10 554 500

Sverige
Roche AB
Tel: +46 (0) 8 726 1200

United Kingdom (Northern Ireland)
Roche Products (Ireland) Ltd.
Tel: +44 (0) 1707 366000

This leaflet was last revised in

Detailed information on this medicine is available on the European Medicines Agency web site: https://www.ema.europa.eu/en.

<---------->

The following information is intended for healthcare professionals only:

Before you start:

- Read all the instructions carefully before using Vabysmo.
- The Vabysmo kit includes a glass vial and transfer filter needle. The glass vial is for a single dose only. The filter needle is for single use only.
- Vabysmo should be stored refrigerated at temperatures between 2ºC to 8ºC.

  Do not freeze.

  Do not shake.
- Allow Vabysmo to reach room temperature, 20°C to 25°C before proceeding with the administration. Keep the vial in the original carton to protect from light.
- The Vabysmo vial may be kept at room temperature for up to 24 hours.
- The Vabysmo vial should be inspected visually prior to administration. Vabysmo is a clear to opalescent and colorless to brownish-yellow liquid solution.

  Do not use if particulates, cloudiness, or discoloration are visible.

  Do not use if the packaging, vial and/or transfer filter needle are expired, damaged, or have been tampered with (see **Figure A**).
- Use aseptic technique to carry out the preparation of the intravitreal injection.

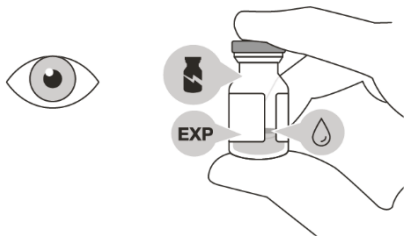

Figure A

Instructions for use of vial:

1. Gather the following supplies:

- One Vabysmo vial (included)
- One sterile 5-micron blunt transfer filter needle 18-gauge x 1½ inch, 1.2 mm x 40 mm (included)
- One sterile 1 mL Luer lock syringe with a 0.05 mL dose mark (**not included**)
- One sterile injection needle 30-gauge x ½ inch (**not included**)

  Note that a 30-gauge injection needle is recommended to avoid increased injection forces that could be experienced with smaller diameter needles.
- Alcohol swab (**not included**).

2. To ensure all liquid settles at the bottom of the vial, place the vial upright on a flat surface (for about 1 minute) after removal from packaging (see **Figure B**). Gently tap the vial with your finger (see **Figure C**), as liquid may stick to the top of the vial.

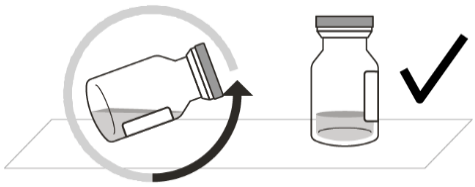

Figure B

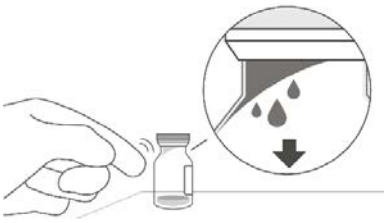

Figure C

3. Remove the flip-off cap from the vial (see **Figure D**) and wipe the vial septum with an alcohol swab (see **Figure E**).

Figure D

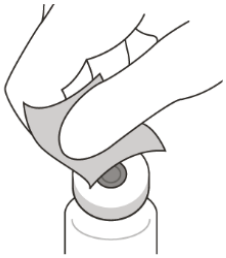

Figure E

4. Aseptically and firmly attach the included 18-gauge x 1½ inch transfer filter needle onto a 1 mL Luer lock syringe (see **Figure F**).

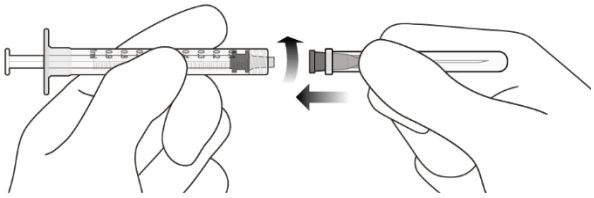

Figure F

5. Using aseptic technique, push the transfer filter needle into the center of the vial septum (see **Figure G**), push it all the way in, then tilt the vial slightly so that the needle touches the bottom edge of the vial (see **Figure H**).

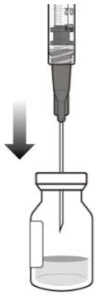

Figure G

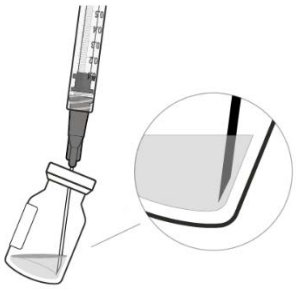

Figure H

6. Hold the vial slightly inclined and **slowly** withdraw all the liquid from the vial (see **Figure I**). Keep the bevel of the transfer filter needle submerged in the liquid, to avoid introduction of air.

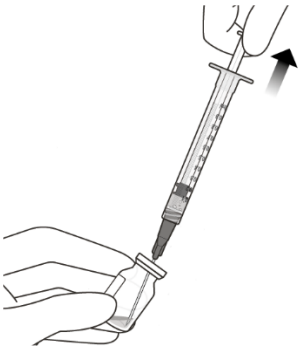

Figure I

7. Ensure that the plunger rod is drawn sufficiently back when emptying the vial, in order to completely empty the transfer filter needle (see **Figure I**).
8. Disconnect the transfer filter needle from the syringe and dispose of it in accordance with local regulations.

   Do not use the transfer filter needle for the intravitreal injection.
9. Aseptically and firmly attach a 30-gauge x ½ inch injection needle onto the Luer lock syringe (see **Figure J**).

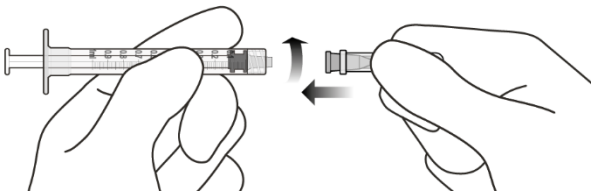

Figure J

10. Carefully remove the plastic needle shield from the needle by pulling it straight off.
11. To check for air bubbles, hold the syringe with the needle pointing up. If there are any air bubbles, gently tap the syringe with your finger until the bubbles rise to the top (see **Figure K**).

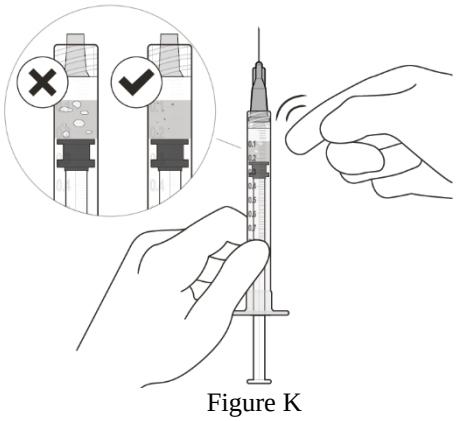

Figure K

12. Carefully expel the air from the syringe and needle, and **slowly** depress the plunger to align the rubber stopper tip to the 0.05 mL dose mark. The syringe is ready for the injection (see **Figure L**). Ensure that the injection is given **immediately** after preparation of the dose.

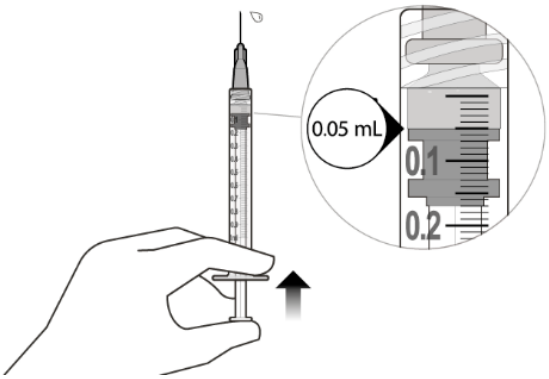

Figure L

13. Inject slowly until the rubber stopper reaches the end of the syringe to deliver the volume of 0.05 mL. Confirm delivery of the full dose by checking that the rubber stopper has reached the end of the syringe barrel.

Excess volume should be expelled prior to injection. The injection dose must be set to the 0.05 ml dose mark to avoid overdose.

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