PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

Vabysmo® 6 mg (0.05 mL of 120 mg/ mL solution for injection)

The active substance is Faricimab

Contains Sugar (2.74 mg of D-sucrose)

Read all of this leaflet carefully before you start taking Vabysmo

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- Vabysmo has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What Vabysmo is and what it is used for

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

- neovascular (wet) age-related macular degeneration (nAMD),
- diabetic macular edema (DME).

Vabysmo is used to treat nAMD and DME in adults, 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 DME is caused by leaky blood vessels that cause swelling of the macula.

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.

Other medicines and Vabysmo

Taking other medicines with Vabysmo

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.

The systemic use of vascular endothelial growth factor inhibitors, substances similar to those contained in Vabysmo, 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 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 breastfeeding

Pregnancy

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.

Important information about some of the ingredients of Vabysmo

Vabysmo contains sodium

Vabysmo contains D sucrose. Patients with the rare hereditary conditions of sucrose intolerance should not take Vabysmo.

Vabysmo contains sucrose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

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.

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 determine your treatment interval 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 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 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.

If you miss a dose of Vabysmo

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

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 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.

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

Very Common (may affect up to 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 (intraocular pressure increased)
- 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 (lacrimation increased)

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)
- Red eye (ocular conjunctival / hyperaemia)
- A feeling of having something in the eye
- Pain during the procedure (procedural pain)
- Detachment of the retina

- Decreased sharpness of vision (visual acuity reduced)
- 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

Reporting of side effects

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions to SAHPRA via the "6.04 Adverse Drug Reaction Report Form", found online under SAHPRA's publications:

https://www.sahpra.org.za/Publications/Index/8

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 vial in the original 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.

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 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 120 mg/mL solution for injection 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.

Holder of Certificate of Registration

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