

VSIQQ[®]

(brolucizumab)

120 mg/mL solution for injection

Patient Information Leaflet

Document status: Final

Approval date: 15 May 2025

SCHEDULING STATUS: **S4**

VSIQQ® 120 mg/ml solution for injection

brolocizumab

Contains sugar (sucrose) - A vial contains 13,3 mg sucrose.

Read all of this leaflet carefully before you are given VSIQQ

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist, nurse or other health care provider.
- VSIQQ 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 VSIQQ is and what it is used for
2. What you need to know before you are given VSIQQ
3. How VSIQQ is given
4. Possible side effects
5. How to store VSIQQ
6. Contents of the pack and other information

1. What VSIQQ is and what it is used for

What VSIQQ is

VSIQQ, which belongs to a group of medicines called anti-neovascularization agents ("anti-VEGF"), is a prescription medicine that is injected into the eye by your doctor to treat eye conditions which may impact your vision.

What VSIQQ is used for

VSIQQ is used to treat eye conditions in adults, which may cause decreased vision such as:

- wet age-related macular degeneration (wet AMD)
- diabetic macular edema (DME)

How VSIQQ works

VSIQQ may slow down the progression of your eye disease and thereby maintain, or even improve, your vision.

If you have any questions about VSIQQ, how it works or why this medicine has been prescribed for you, ask your doctor.

2. What you need to know before you are given VSIQQ

VSIQQ should not be administered to you:

- if you are allergic (hypersensitive) to brotacizumab or any of the other ingredients of VSIQQ (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.

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

Warnings and precautions

Talk to your doctor before you are given VSIQQ if any of the following applies to you:

- if you have glaucoma.
- 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 a history of eye conditions or eye treatments.
- If you are pregnant or are breastfeeding your baby.

If any of these applies to you, your doctor will decide whether you should be given VSIQQ.

Tell your doctor immediately if you get any of the following symptoms after you have been given VSIQQ:

- if you develop redness of the eye or worsening eye redness, eye pain, increased discomfort, sudden vision loss, blurred or decreased vision, an increased number of small particles in your vision, increased sensitivity to light, nausea or vomiting. All of these could be symptoms of a serious eye condition and may result in your doctor discontinuing your treatment with VSIQQ.

Children and adolescents

VSIQQ is not used in children and adolescents.

Older people (age 65 years and over)

VSIQQ can be given to older people without adjusting the dose.

Other medicines and VSIQQ

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

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think that you may be pregnant or are planning to have a baby, ask your doctor for advice before this medicine is given to you.

Breastfeeding during treatment with VSIQQ and for at least one month after the last injection when stopping treatment with VSIQQ is not recommended because it is not known whether VSIQQ passes into human milk.

Women who could become pregnant must use an effective method of birth control during treatment and for at least one month after the last injection when stopping treatment with VSIQQ. If you become pregnant or think you are pregnant during treatment, tell your doctor right away.

Driving and using machines

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

3. How VSIQQ is used

A trained doctor will inject VSIQQ into your eye.

How much and how often VSIQQ is given

The recommended dose is 6 mg brolucizumab.

Wet AMD

Starting treatment (also called loading treatment)

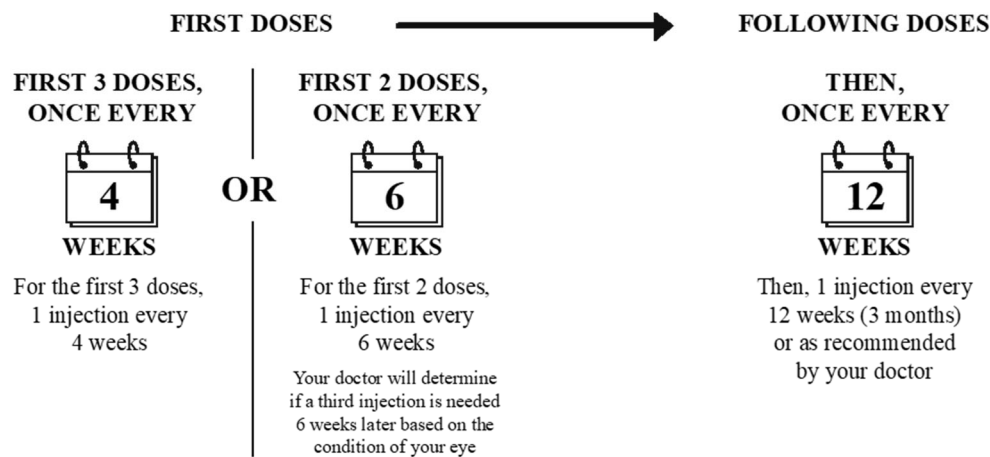
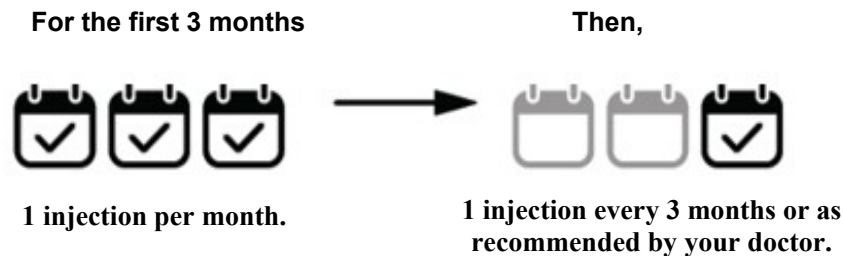
- You will be treated with one injection per month for the first three months.
- Alternatively, you could be treated with one injection every 6 weeks for the first two doses.

Your doctor will determine if a third injection is needed 6 weeks later based on the condition of your eye(s).

Maintenance treatment

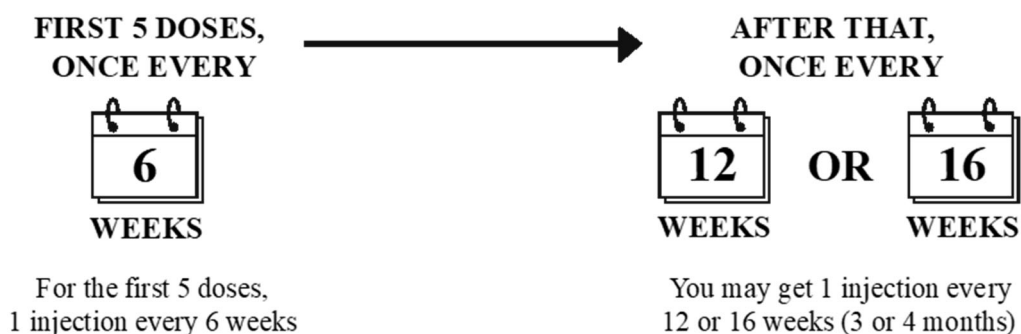
- After that, you may get one injection every twelve weeks (three months). Your doctor will determine your treatment interval based on the condition of your eye; some patients may need treatment every eight weeks (two months). Depending on the condition of your eye, your doctor could extend or shorten your treatment by no more than 4 weeks at a time. The

treatment interval between two doses of VSIQQ should not be less than every eight weeks (2 months).



DME

- You will be treated with one injection every six weeks for the first five injections.
- After that, you may get one injection every twelve or sixteen weeks (3 months or 4 months). Your doctor will determine your treatment interval based on the condition of your eye; some patients may need treatment every eight weeks (2 months).



Once you begin receiving VSIQQ it is important to follow the treatment schedule recommended by your doctor. This could help you receive the full potential benefit of VSIQQ.

Method of administration

VSIQQ is given as an injection into your eye (intravitreal injection).

Before the injection, your doctor will use a disinfectant eyewash to clean your eye carefully, to prevent infection. Your doctor will also give you an eye drop (local anaesthetic) to numb the eye to reduce or prevent any pain you might have with the injection.

How long does VSIQQ treatment last for

VSIQQ is used to treat chronic eye diseases, therefore this is a long-term treatment, possibly continuing for months or years. Your doctor will check that the treatment is having the desired effect during your regular scheduled visits. Your doctor may also check on your eyes during a visit without an injection. If you have questions about how long you will receive VSIQQ, talk to your doctor.

If you forget a scheduled VSIQQ injection

Missing an injection may reverse the visual improvement you may have experienced. If you miss an appointment for VSIQQ treatment, contact your doctor as soon as possible. Your doctor will decide when you should be given your next dose.

If you are given more VSIQQ than you should

Since a health care provider will administer VSIQQ, he / she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you stop VSIQQ treatment

Speak with your doctor before stopping treatment. Stopping treatment may increase your risk of vision loss and reverse the visual improvement you may have experienced.

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

4. Possible side effects

This medicine can cause side effects. The side effects associated with the administration of VSIQQ are either due to the medicine itself or the injection procedure and mostly affect the eye.

Not all side effects reported for VSIQQ are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking VSIQQ, please consult your health care provider for advice.

Some side effects could be serious

Seek immediate medical help if you experience any of the following, which are signs of allergic reactions, inflammations or infections:

- a sudden decrease or change in vision

- pain, discomfort, redness in your eye

If you experience any serious side effects, tell your doctor immediately.

Other side effects which may occur following VSIQQ treatment include the following listed below. If these side effects become severe, please tell your doctor.

Frequent

- inflammation of the middle layer of tissue of the eye wall (uveitis)
- detachment of one of the layers at the back of the eye (vitreous detachment)
- tear of the retina that is located in the back of the eye (retinal tear)
- reduced sharpness of vision (visual acuity reduced)
- bleeding in the retina (retinal haemorrhage)
- inflammation of the iris (iritis)
- clouding of the lens of the eye (cataract)
- bleeding from small blood vessels in the white of the eye (conjunctival haemorrhage)
- moving spots in your vision (vitreous floaters)
- eye pain
- increase in eye pressure (intraocular pressure increase)
- redness in the white of the eye (conjunctivitis)
- tear of one of the layers in the back of the eye (retinal pigment epithelial tear)
- blurred or unclear vision
- scratched cornea, damage to the clear layer of the eyeball that covers the iris (corneal abrasion)
- damage to the clear layer of the eyeball that covers the iris (punctate keratitis)
- allergic reactions (hypersensitivity)

Less frequent

- severe inflammation inside the eye (endophthalmitis)
- blindness
- sudden vision loss due to blockage of an artery in the eye (retinal artery occlusion)
- detachment of one of the layers in the back of the eye (retinal detachment)
- redness of the eye (conjunctival hyperaemia)
- increased tear production (increased lacrimation)
- abnormal feeling in the eye
- detachment of one of the layers in the back of the eye (detachment of retinal pigment epithelium)
- inflammation of the gel that fills the centre of the eyeball (vitritis)
- inflammation of the front of the eye (anterior chamber inflammation or flare)
- inflammation in the iris and its adjacent tissue in the eye (iridocyclitis)
- swelling of the cornea, the clear layer of the eyeball (corneal oedema)
- bleeding in the eye (vitreous haemorrhage)

Frequency not known: frequency cannot be estimated from the available data

- sudden vision loss due to blockage of blood vessels in the back of the eye (retinal vascular occlusion)
- inflammation of blood vessels in the back of the eye (retinal vasculitis)
- inflammation of the white part of the eye (scleritis)

*The side effects of iridocyclitis, vitreous haemorrhage and retinal vascular occlusion were observed at a common frequency in clinical trials in patients with DME

Reporting of side effects

If you get side effects, talk to your doctor. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of VSIQQ.

5. How to store VSIQQ

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

Store in a refrigerator between 2 °C – 8 °C.

Do not freeze.

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

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

6. Contents of the pack and other information

What VSIQQ contains

- The active substance is brolucizumab. Each ml contains 120 mg of brolucizumab.
- The other ingredients are: sodium citrate, sucrose, polysorbate 80, water for injection.

What VSIQQ looks like and contents of the pack

VSIQQ is a solution for injection in a vial. One vial contains 0,230 ml sterile solution. The vial is for single use only.

Pack size of 1 vial and 1 blunt filter needle (18 G x 1½", 1,2 mm x 40 mm, 5 µm).

Holder of certificate of registration

Novartis South Africa (Pty) Ltd

Magwa Crescent West

Waterfall City, Jukskei View

Johannesburg

2090

South Africa

+27 11 347 6600

This leaflet was last revised in

15 May 2025

Registration number

54/15.4/0489