READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

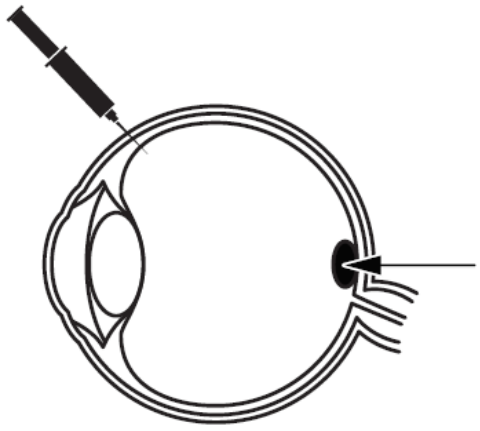
PATIENT MEDICATION INFORMATION

PrBEOVU®
brolucizumab injection
Solution for intravitreal injection

Read this carefully before you start taking **BEOVU®** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **BEOVU**.

What is BEOVU used for?

- BEOVU is a medicine that is injected into the eye by your doctor to treat an eye disorder called neovascular (wet) age-related macular degeneration (AMD).
- BEOVU contains the active substance brolucizumab (bro-loo-siz-u-mab), which belongs to a group of medicines called anti-neovascularization agents ("anti-VEGF", see below "How does BEOVU work").
- BEOVU is used to treat wet AMD, which occurs when abnormal blood vessels form and grow underneath the macula. The macula is located at the back of the eye, and it is responsible for clear vision. These abnormal blood vessels may be weak and leak fluid or blood in the eye. This can interfere with the macula's function, resulting in reduced vision.



How does BEOVU work?

A substance called vascular endothelial growth factor A (VEGF-A) causes the growth of abnormal blood vessels in the eye. By attaching to this substance, BEOVU (anti-VEGF-agent) reduces the growth of abnormal blood vessels, which reduces the leakage of fluid or blood in the eye.

What are the ingredients in BEOVU?

Medicinal ingredient: brolucizumab
Non-medicinal ingredients: polysorbate 80, sodium citrate, sucrose, water for injection

BEOVU comes in the following dosage forms:

Solution for intravitreal injection 6 mg / 0.05 mL in pre-filled syringe

Do NOT use BEOVU if you:

- **Are allergic** (hypersensitive) to brolucizumab or any of the other ingredients in BEOVU.
- **Have** an active or suspected infection in or around the eye.
- **Experience** pain or redness in your eye.

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

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take BEOVU. Talk about any health conditions or problems you may have, including if you:

- Have glaucoma (an eye condition usually caused by high pressure in the eye).
- Have a history of seeing flashes of light or floaters (dark floating spots) and if you have a sudden increase of size and number of floaters.
- Had surgery performed on your eyes within the previous four weeks.
- Have a surgery planned on your eye within the next four weeks.
- Have a prior history of eye conditions or eye treatments.

Tell your doctor immediately if you get any of these symptoms **after BEOVU is injected**:

- 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. All of these could be symptoms of a serious eye condition.
- If you develop signs of a possible allergic reaction. (Ex. fast pulse, low blood pressure, sweating, allergic skin reactions such as rash, itching or stinging)

Furthermore it is important for you to know that:

- The safety and efficacy of administering BEOVU to both eyes at the same time has not been studied. Using BEOVU this way may lead to an increased risk of side effects.
- Injections with BEOVU may cause an increase in eye pressure (intraocular pressure). This can occur in some patients within 30 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 such cases BEOVU must be given with caution.

The use of substances similar to those in BEOVU, is potentially related to the risk of blood clots blocking blood vessels (arterial thromboembolic events). This may lead to heart attack or stroke. There could be a risk of such events following injection of BEOVU into the eye.

Other warnings you should know about:

Children and adolescents (< 18 years)

BEOVU is NOT used in children and adolescents, because wet AMD occurs only in adults.

Older people (≥ 65 years)

BEOVU can be given to elderly people without adjusting the dose.

Pregnancy and breast-feeding

Tell your doctor:

- If you are pregnant or think that you may be or are planning to have a baby. Your doctor will discuss with you whether BEOVU can be administered during your pregnancy.

You should not breast-feed your child:

- During BEOVU treatment; and
- For at least one month after the last injection when stopping treatment with BEOVU.

Women of child-bearing potential

Women who could become pregnant must use an effective birth control:

- During BEOVU treatment; and
- For at least one month after the last injection when stopping treatment with BEOVU.

If you become pregnant or think you are pregnant, tell your healthcare professional right away.

Driving and using machines

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

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

How to take BEOVU:

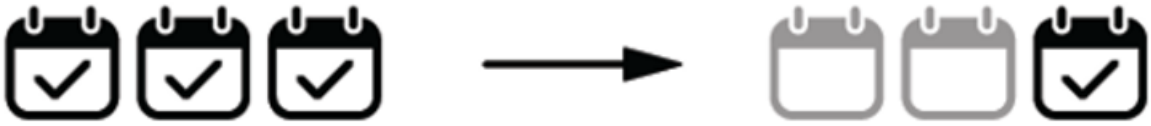
A trained doctor will inject BEOVU into your eye.

Usual dose:

The recommended dose is 6 mg of BEOVU (brolucizumab).

- You will be treated with one injection per month for the first three months.
- After that, you may get one injection every twelve weeks (3 months) or every eight weeks (2 months). Your doctor will determine your treatment interval based on the condition of your eye.

For the first 3 months **Then,**



1 injection per month

or

1 injection every 3 months or 2 months as recommended by your doctor

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

How is BEOVU given

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

Before the injection, your doctor will:

- Clean your eye with a disinfectant eyewash to prevent infection.
- Give you an eye drop (local anesthetic) to numb the eye, to reduce or prevent any pain you might have with the injection.

How long does BEOVU treatment continue

Wet AMD is a chronic disease. Your doctor will check if the treatment is having the desired effect during your regularly scheduled visits. Your doctor may also check your eyes during a visit without an injection. **If you have questions about how long you will receive BEOVU, talk to your doctor.**

Before stopping BEOVU 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**.

Overdose:

If you think you have been given too much BEOVU, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

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

What are possible side effects from using BEOVU?

These are not all the possible side effects you may feel when taking BEOVU. The side effects associated with the administration of BEOVU are either due to the medicine itself or the injection procedure. If you experience any side effects not listed here, contact your healthcare professional.

If these side effects become severe, please tell your doctor.

Common: *may affect up to 1 in every 10 people*

- 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 eye lens (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)

Uncommon: *may affect up to 1 in every 100 people.*

- 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 (lacrimation increased)
- 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 center 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)

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
UNCOMMON Inflammations or infections (redness of the eye, eye pain, increased discomfort, blurred or decreased vision, increased number of small particles in your vision, increased sensitivity to light)		✓	
Tear or detachment of one of the layers at the back of the eye (a sudden decrease or change in vision, flashing lights, black spots)		✓	
Cataract (clouded, blurred or dim vision)		✓	
Increased pressure in the eye		✓	
Allergic reactions (fast pulse, low blood pressure, sweating, allergic skin reactions such as rash, itching or stinging)		✓	
Signs of stroke (weakness or paralysis of limbs or face, difficulty speaking or understanding, sudden blurring or loss of vision)*		✓	
UNKNOWN Sudden vision loss due to blockage of blood vessels in the back of the eye		✓	
Inflammation of blood vessels in the back of the eye		✓	

* There is a potential risk of Arterial Thromboembolic Events (ATEs), including stroke, following injection of BEOVU into the eye.

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects
You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

The information on how to store BEOVU is meant for your doctor. Your doctor will be storing, handling, and injecting BEOVU.

- Store in a refrigerator (2°C to 8°C).
- Do NOT freeze.
- Prior to use, the unopened blister may be kept at room temperature (25°C) for up to 24 hours.
- Keep the pre-filled syringe in its sealed blister and in the carton in order to protect from light.
- Do not use if the packaging, or pre-filled syringe is damaged or expired.

Keep out of reach and sight of children.

If you want more information about BEOVU:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (https://www.canada.ca/en/health-canada.html); the manufacturer's website (www.novartis.ca), or by calling 1-800-363-8883.

This leaflet was prepared by Novartis Pharmaceuticals Canada Inc.

Last Revised: Aug 18, 2021

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