HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use BEOVU safely and effectively. See full prescribing information for BEOVU.

BEOVU® (brolucizumab-dbll) injection, for intravitreal use
Initial U.S. Approval: 2019

----------RECENT MAJOR CHANGES----------

Warnings and Precautions, Endophthalmitis and Retinal Detachment (5.1)	6/2020
Warnings and Precautions, Retinal Vasculitis and/or Retinal Vascular Occlusion (5.2)	6/2020

----------INDICATIONS AND USAGE----------
BEOVU is a human vascular endothelial growth factor (VEGF) inhibitor indicated for the treatment of Neovascular (Wet) Age-Related Macular Degeneration (AMD) (1).

----------DOSAGE AND ADMINISTRATION----------
BEOVU is administered by intravitreal injection. The recommended dose for BEOVU is 6 mg (0.05 mL of 120 mg/mL solution) monthly (approximately every 25-31 days) for the first three doses, followed by one dose of 6 mg (0.05 mL) every 8-12 weeks (2.2).

----------DOSAGE FORMS AND STRENGTHS----------
Intravitreal injection: 6 mg/0.05 mL solution in a single-dose vial (3).

----------CONTRAINDICATIONS----------
- Ocular or Periocular Infections (4.1).
- Active Intraocular Inflammation (4.2).
- Hypersensitivity (4.3).

----------WARNINGS AND PRECAUTIONS----------
- Endophthalmitis and retinal detachment may occur following intravitreal injections. Patients should be instructed to report any symptoms suggestive of endophthalmitis or retinal detachment without delay (5.1).
- Retinal vasculitis and/or retinal vascular occlusion, typically in the presence of intraocular inflammation, have been reported following BEOVU injections. Patients should be instructed to report any change in vision without delay (5.2).
- Increases in intraocular pressure (IOP) have been seen within 30 minutes of an intravitreal injection (5.3).
- There is a potential risk of arterial thromboembolic events (ATE) following intravitreal use of VEGF inhibitors (5.4).

----------ADVERSE REACTIONS----------
The most common adverse reactions (≥ 5%) reported in patients receiving BEOVU are vision blurred (10%), cataract (7%), conjunctival hemorrhage (6%), eye pain (5%), and vitreous floaters (5%) (6.1).

To report SUSPECTED ADVERSE REACTIONS, contact Novartis Pharmaceuticals Corporation at 1-888-669-6682 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

See 17 for PATIENT COUNSELING INFORMATION.

Revised: 6/2020

FULL PRESCRIBING INFORMATION: CONTENTS*

*Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

BEOVU® is indicated for the treatment of Neovascular (Wet) Age-related Macular Degeneration (AMD).

2 DOSAGE AND ADMINISTRATION

2.1 General Dosing Information

For ophthalmic intravitreal injection. BEOVU must be administered by a qualified physician.

2.2 Neovascular (Wet) Age-Related Macular Degeneration (AMD)

The recommended dose for BEOVU is 6 mg (0.05 mL of 120 mg/mL solution) administered by intravitreal injection monthly (approximately every 25-31 days) for the first three doses, followed by 6 mg (0.05 mL) by intravitreal injection once every 8-12 weeks.

2.3 Preparation for Administration

Store BEOVU in the refrigerator between 2°C to 8°C (36°F to 46°F); do not freeze. Keep the vial in the outer carton to protect from light.

Prior to use, the unopened glass vial of BEOVU may be kept at room temperature, 20°C to 25°C (68°F to 77°F) for up to 24 hours. After opening the glass vial, proceed under aseptic conditions.

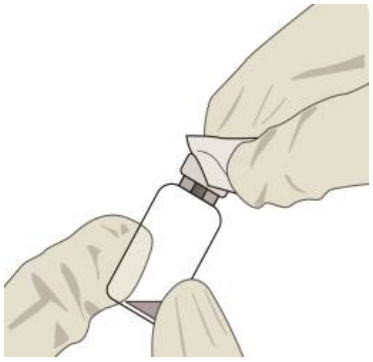
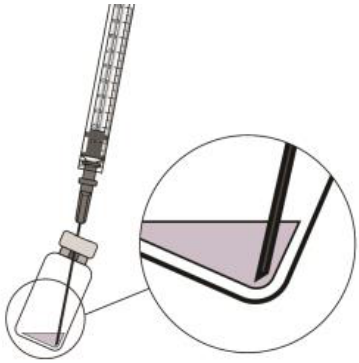
BEOVU is a clear to slightly opalescent and colorless to slightly brownish-yellow solution.

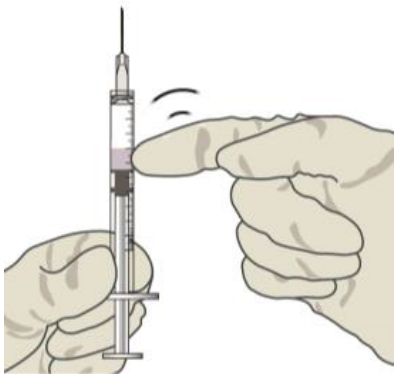
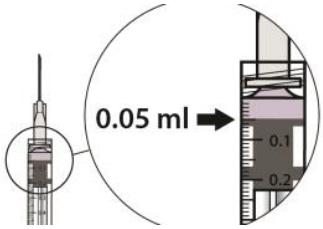
BEOVU should be inspected visually upon removal from the refrigerator and prior to administration. If particulates, cloudiness, or discoloration are visible, the glass vial must not be used.

The BEOVU kit includes the sterile glass vial and filter needle which are for single use only. Do not use if the packaging, vial and/or filter needle are damaged or expired *[see How Supplied/Storage and Handling (16)]*.

Use aseptic technique for preparation of the intravitreal injection.

STEP 1: Gather the supplies needed. • One BEOVU vial (included) • One sterile 5-micron blunt filter needle (18-gauge x 1½ inch, 1.2 mm x 40 mm) (included) • One sterile 30-gauge x ½ inch injection needle **(not included)** • One sterile 1 mL syringe with a 0.05 mL dose mark **(not included)** • Alcohol swab **(not included)**	

STEP 2 Allow vial to come to room temperature and inspect the solution. If particulates, cloudiness, or discoloration are visible, discard the vial and obtain a new vial.	
STEP 3 Remove the vial cap and clean the vial septum (e.g., with alcohol swab) (see Figure 1).	**Figure 1:** 
STEP 4 Assemble the 5-micron filter needle (18-gauge x 1½ inch) onto a 1-mL syringe using aseptic technique.	
STEP 5 Push the filter needle into the center of the vial septum until the needle touches the bottom of the vial.	
STEP 6 To withdraw the liquid, hold the vial slightly inclined and slowly withdraw all the liquid from the vial and filter needle (see Figure 2). Ensure that the plunger rod is drawn sufficiently back when emptying the vial in order to completely empty the filter needle.	**Figure 2:** 
STEP 7 Disconnect the filter needle from the syringe in an aseptic manner and dispose of it. **The filter needle is not to be used for the intravitreal injection**.	
STEP 8 Aseptically and firmly assemble a 30-gauge x ½ inch injection needle onto the syringe.	

STEP 9 Check for air bubbles by holding 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 3).	**Figure 3:** 
STEP 10 Carefully expel the air from the syringe and adjust the dose to the 0.05 mL mark (see Figure 4). The syringe is ready for the injection.	**Figure 4:** 

2.4 Injection Procedure

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

The intravitreal injection procedure must be carried out under aseptic conditions, which includes the use of surgical hand disinfection, sterile gloves, a sterile drape and a sterile eyelid speculum (or equivalent), and the availability of sterile paracentesis equipment (if required). Adequate anesthesia and a broad-spectrum topical microbicide to disinfect the periocular skin, eyelid, and ocular surface should be administered prior to the injection.

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.

Immediately following the intravitreal injection, patients should be monitored for elevation in intraocular pressure (IOP). Appropriate monitoring may consist of a check for perfusion of the optic nerve head or tonometry. If required, a sterile paracentesis needle should be available.

Following intravitreal injection, patients should be instructed to report any symptoms suggestive of endophthalmitis or retinal detachment (e.g., eye pain, redness of the eye, photophobia, blurring of vision) without delay *[see Patient Counseling Information (17)]*.

Each vial should only be used for the treatment of a single eye. If the contralateral eye requires treatment, a new vial should be used and the sterile field, syringe, gloves, drapes, eyelid speculum, filter, and injection needles should be changed before BEOVU is administered to the other eye.

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

3 DOSAGE FORMS AND STRENGTHS

Intravitreal injection: 6 mg/0.05 mL, clear to slightly opalescent and colorless to slightly brownish-yellow solution in a single-dose vial.

4 CONTRAINDICATIONS

4.1 Ocular or Periocular Infections

BEOVU is contraindicated in patients with ocular or periocular infections.

4.2 Active Intraocular Inflammation

BEOVU is contraindicated in patients with active intraocular inflammation.

4.3 Hypersensitivity

BEOVU is contraindicated in patients with known hypersensitivity to brolucizumab or any of the excipients in BEOVU. Hypersensitivity reactions may manifest as rash, pruritus, urticaria, erythema, or severe intraocular inflammation.

5 WARNINGS AND PRECAUTIONS

5.1 Endophthalmitis and Retinal Detachment

Intravitreal injections, including those with BEOVU, have been associated with endophthalmitis and retinal detachment *[see Contraindications (4.1) and Adverse Reactions (6.1)]*. Proper aseptic injection techniques must always be used when administering BEOVU. Patients should be instructed to report any symptoms suggestive of endophthalmitis or retinal detachment without delay and should be managed appropriately *[see Dosage and Administration (2.4) and Patient Counseling Information (17)]*.

5.2 Retinal Vasculitis and/or Retinal Vascular Occlusion

Retinal vasculitis and/or retinal vascular occlusion, typically in the presence of intraocular inflammation, have been reported with the use of BEOVU *[see Contraindications (4.2) and Adverse Reactions (6.1)]*. Patients should be instructed to report any change in vision without delay.

5.3 Increase in Intraocular Pressure

Acute increases in intraocular pressure (IOP) have been seen within 30 minutes of intravitreal injection including with BEOVU *[see Adverse Reactions (6.1)]*. Sustained IOP increases have also been reported. Both IOP and perfusion of the optic nerve head must be monitored and managed appropriately *[see Dosage and Administration (2.4)]*.

5.4 Thromboembolic Events

Although there was a low rate of arterial thromboembolic events (ATEs) observed in the BEOVU clinical trials, there is a potential risk of ATEs following intravitreal use of VEGF inhibitors. Arterial thromboembolic events are defined as nonfatal stroke, nonfatal myocardial infarction, or vascular death (including deaths of unknown cause).

The ATE rate in the two controlled 96-week neovascular AMD studies (HAWK and HARRIER) during the first 96-weeks was 4.5% (33 of 730) in the pooled brolucizumab arms compared with 4.7% (34 of 729) in the pooled aflibercept arms *[see Clinical Studies (14.1)]*.

6 ADVERSE REACTIONS

The following potentially serious adverse reactions are described elsewhere in the labeling:

- Hypersensitivity *[see Contraindications (4.3)]*
- Endophthalmitis and Retinal Detachment *[see Warnings and Precautions (5.1)]*
- Retinal Vasculitis and/or Retinal Vascular Occlusion *[see Warnings and Precautions (5.2)]*
- Increase in Intraocular Pressure *[see Warnings and Precautions (5.3)]*
- Thromboembolic Events *[see Warnings and Precautions (5.4)]*

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in one clinical trial of a drug cannot be directly compared with rates in the clinical trials of the same or another drug and may not reflect the rates observed in practice.

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