Beovu®
(brolucizumab-dbll)
Injection

NDC 0078-0827-60

Not actual size.

Experience the BEOVU pre-filled syringe

BEOVU is a 6 mg/0.05 mL solution available in a single-dose, pre-filled syringe

- Store BEOVU in the refrigerator between 2°C to 8°C (36°F to 46°F); do not freeze. Keep BEOVU in the outer carton to protect from light
- Prior to use, the unopened glass vial or sealed blister pack 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, proceed under aseptic conditions
- BEOVU solution is clear to slightly opalescent and colorless to slightly brownish yellow
- BEOVU should be inspected visually upon removal from the refrigerator and prior to administration. If particulates, cloudiness, or discoloration is visible, BEOVU must not be used
- Use aseptic technique for preparation of the intravitreal injection

Fewer steps for preparation than the vial[1]

The BEOVU pre-filled glass syringe is sterile and for single use only. It should be inspected visually prior to administration. Do not use if the package or pre-filled syringe is opened, damaged, or expired.

STEP 1
PREPARE

Peel the lid off the blister package and, using aseptic technique, remove the sterile syringe.

STEP 2
SNAP OFF SYRINGE CAP

Snap off the syringe cap and dispose of it.

Do not turn or twist the syringe cap.

STEP 3
ATTACH INJECTION NEEDLE

Aseptically and firmly assemble a 30-gauge x ½-inch sterile injection needle (not included) onto the Luer lock syringe.

STEP 4
DISLODGE AIR BUBBLES

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.

Carefully remove the needle cap by pulling it straight off.

STEP 5
EXPEL AIR AND SET THE DOSE

Hold the syringe at eye level and carefully push the plunger until the edge below the dome of the rubber stopper is aligned with the 0.05 mL dose mark. This will expel the air and excess liquid and set the dose to the 0.05 mL dose mark. The syringe is ready for the injection.

INDICATIONS AND USAGE

BEOVU® (brolucizumab-dbll) injection is indicated for the treatment of Neovascular (Wet) Age-related Macular Degeneration (AMD) and Diabetic Macular Edema (DME).

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

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

Please see additional Important Safety Information on the following page and full Prescribing Information.

IMPORTANT SAFETY INFORMATION (cont)

WARNINGS AND PRECAUTIONS

Endophthalmitis and Retinal Detachment

Intravitreal injections, including those with BEOVU, have been associated with endophthalmitis and retinal detachment. 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.

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. These immune-mediated adverse events may occur following the first intravitreal injection. Discontinue treatment with BEOVU in patients who develop these events. Patients treated with BEOVU who experience intraocular inflammation may be at risk of developing retinal vasculitis and/or retinal vascular occlusion and should be closely monitored. Patients should be instructed to report any change in vision without delay.

Increase in Intraocular Pressure

Acute increases in intraocular pressure (IOP) have been seen within 30 minutes of intravitreal injection, including with BEOVU. Sustained IOP increases have also been reported. Both IOP and perfusion of the optic nerve head must be monitored and managed appropriately.

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 (nAMD) 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.

ADVERSE REACTIONS

Serious adverse reactions, including endophthalmitis, retinal detachment, retinal vasculitis and/or retinal vascular occlusion, increases in intraocular pressure, and arterial thromboembolic events, have occurred following intravitreal injections with BEOVU.

The most common adverse events (≥5% of patients) reported in nAMD clinical studies (HAWK and HARRIER) in patients who received BEOVU were vision blurred, cataract, conjunctival hemorrhage, vitreous floaters, and eye pain. The most common adverse event (≥5% of patients) reported in DME clinical studies (KITE and KESTREL) in patients who received BEOVU was conjunctival hemorrhage.

In a clinical study (MERLIN), patients with nAMD who received BEOVU every 4-week maintenance dosing experienced a higher incidence of intraocular inflammation (including retinal vasculitis) and retinal vascular occlusion than patients who received BEOVU every 8- or 12-week maintenance dosing in the clinical studies (HAWK and HARRIER). The interval between 2 BEOVU doses during maintenance treatment should not be less than 8 weeks.

As with all therapeutic proteins, there is a potential for an immune response in patients treated with BEOVU. Anti-brolucizumab antibodies were detected in the pre-treatment sample of 36% to 64% of treatment-naive patients. After initiation of dosing, anti-brolucizumab antibodies were detected in at least one serum sample in 53% to 76% of patients treated with BEOVU. Intraocular inflammation was observed in 6% of patients with anti-brolucizumab antibodies detected during dosing with BEOVU in clinical trials. Retinal vasculitis and/or retinal vascular occlusion, typically in the presence of intraocular inflammation, are immune-mediated adverse events related to exposure to BEOVU. This treatment-emergent antibody response may develop following the first intravitreal injection. Anti-brolucizumab antibodies were not associated with an impact on clinical efficacy.

Please see full Prescribing Information.

Visit **BEOVUhcp.com/PFS** for more information

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REFERENCE: 1. Beovu [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corp; May 2022.

NOVARTIS

Beovu® (brolucizumab-dbll) Injection

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