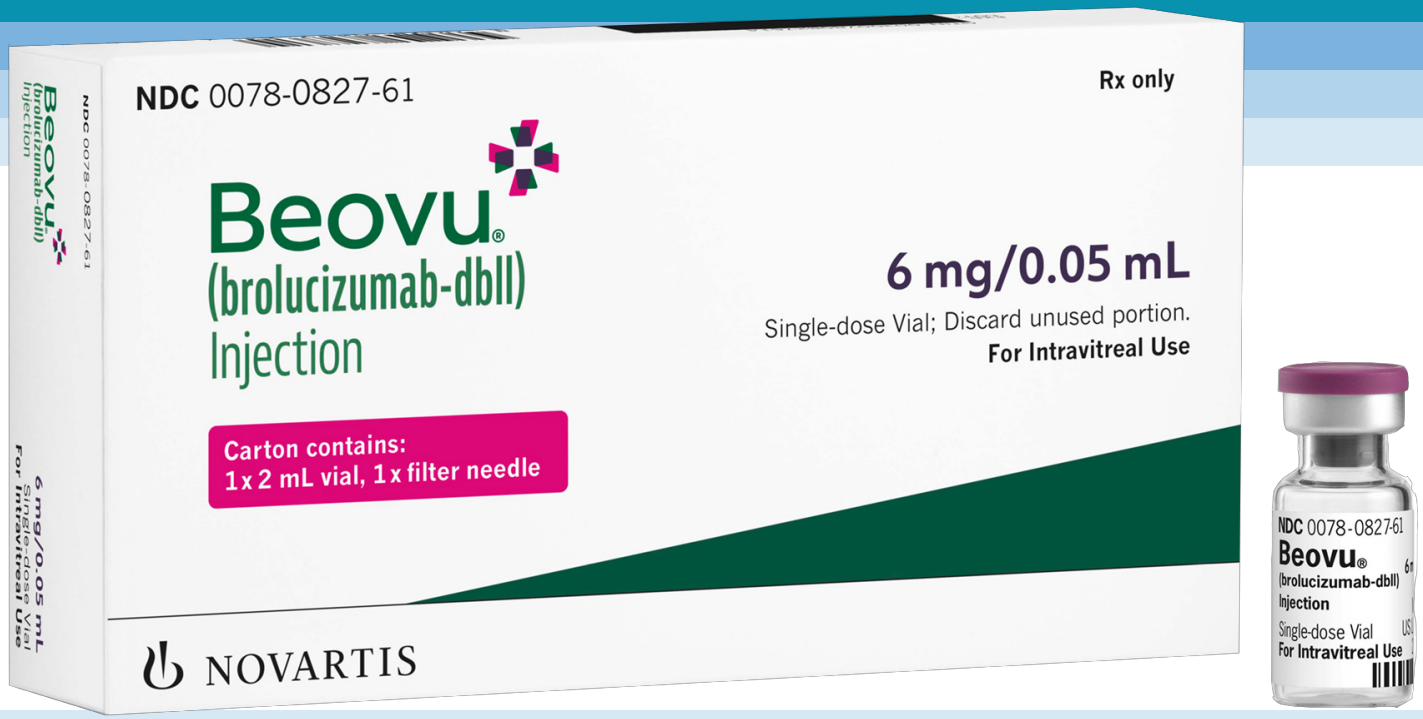
Beovu (brolucizumab-dbll)



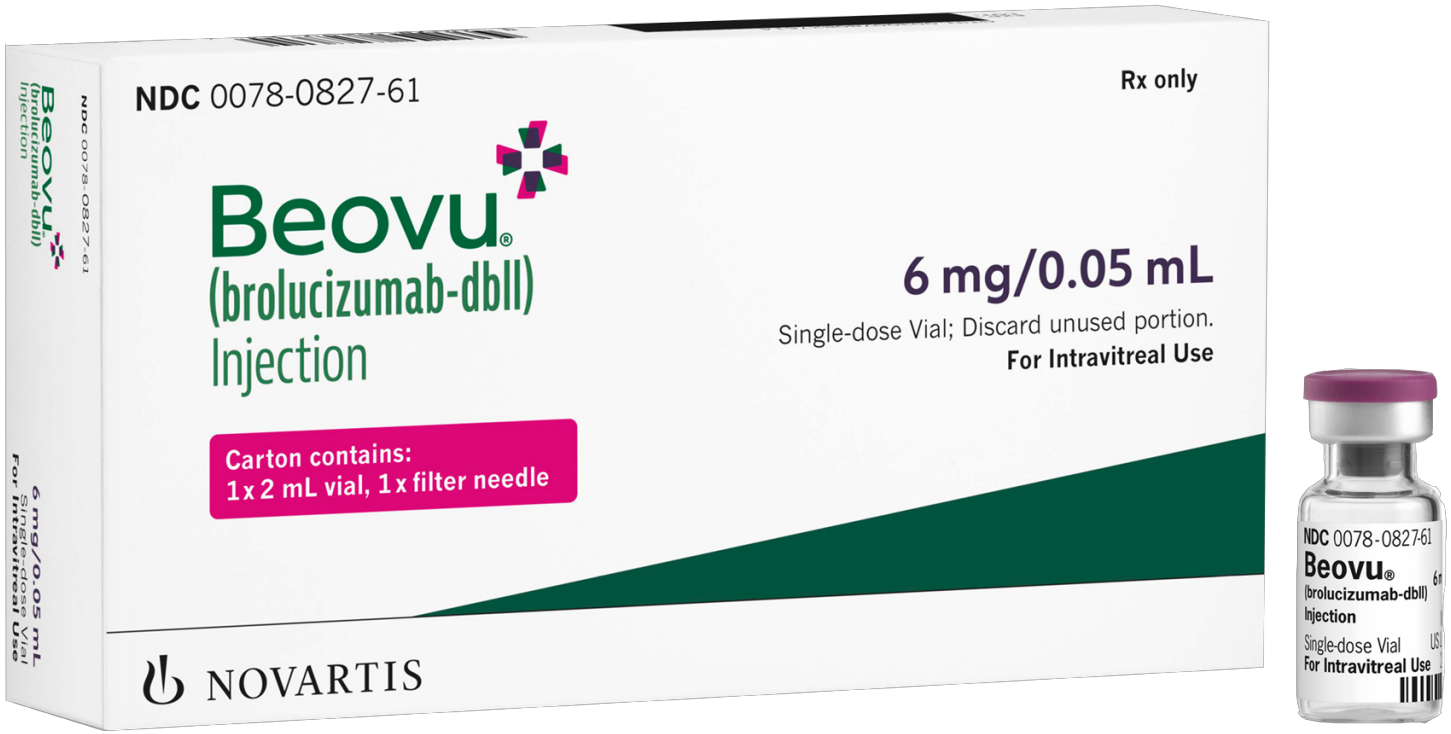
NEW PRODUCT SLIDESHOW

MPR

Introduction

- **Brand name:** Beovu
- **Generic name:** Brolucizumab-dbll
- **Pharmacological class:** Vascular endothelial growth factor (VEGF) inhibitor
- **Strength and Formulation:** 6mg/0.05mL solution for ophthalmic intravitreal injection; preservative-free
- **Manufacturer:** Novartis
- **How supplied:** Single-dose vial—1 (w. needle)
- **Legal Classification:** Rx

Beovu


NDC 0078-0827-61
Rx only
Beovu®
(brolucizumab-dbll)
Injection
6 mg/0.05 mL
Single-dose Vial; Discard unused portion.
For Intravitreal Use
Carton contains:
1 x 2 mL vial, 1 x filter needle
NOVARTIS
NDC 0078-0827-61
Beovu®
(brolucizumab-dbll)
Injection
Single-dose Vial
For Intravitreal Use

Indication

- Neovascular (wet) age-related macular degeneration (AMD)

Dosage & Administration

- Give by intravitreal injection
- 6mg (0.05mL) once monthly (approx. 25–31 days) for the first 3 doses, followed by 6mg (0.05mL) once every 8–12 weeks

Considerations for Special Populations

- **Pregnancy:** may pose risk to human embryo-fetal development
- **Nursing mothers**: not recommended during treatment and for at least 1 month after last dose
- **Pediatric**: not established
- **Geriatric:** no significant differences in efficacy, safety

Contraindications

- Ocular or periocular infections
- Active intraocular inflammation

Warnings/Precautions

- Must only be administered by a qualified physician
- Monitor for endophthalmitis, retinal detachments, elevation in intraocular pressure, and perfusion of optic nerve head following injection
- Potential risk of arterial thromboembolic events (eg, nonfatal stroke or MI, vascular death)
- Advise females of reproductive potential to use effective contraception during and for ≥1 month after the last dose

Adverse Reactions

- **Most common (≥5%)**: blurred vision, cataract, conjunctival hemorrhage, eye pain, vitreous floaters

Mechanism of Action

- Brolucizumab is a human vascular endothelial growth factor (VEGF) inhibitor
- Brolucizumab binds to the 3 major isoforms of VEGF-A, thereby preventing interaction with receptors VEGFR-1 and VEGFR-2
- By inhibiting VEGF-A, brolucizumab suppresses endothelial cell proliferation, neovascularization, and vascular permeability

Clinical Trials

- Safety and efficacy of brolucizumab were assessed in 2 randomized, multicenter, double-masked, active-controlled studies (HAWK - NCT02307682 and HARRIER - NCT02434328) in patients with neovascular AMD
- A total of 1817 patients were treated in these studies for 2 years (1088 on brolucizumab and 729 on control)

Clinical Trials

- **HAWK:**
  - Brolucizumab 3mg administered every 8 or 12 weeks after the first 3 monthly doses
  - Brolucizumab 6mg administered every 8 or 12 weeks after the first 3 monthly doses
  - Aflibercept 2mg administered every 8 weeks after the first 3 monthly doses
- **HARRIER:**
  - Brolucizumab 6mg administered every 8 or 12 weeks after the first 3 monthly doses
  - Aflibercept 2mg administered every 8 weeks after the first 3 monthly doses

Clinical Trials

- Both studies demonstrated efficacy in the **primary end point** defined as the change from baseline in Best Corrected Visual Acuity (BCVA) at Week 48, measured by the Early Treatment Diabetic Retinopathy Study (ETDRS) Letter Score

- In both studies, brolucizumab-treated patients had a similar mean change from baseline in BCVA as the patients treated with aflibercept 2mg (fixed every 8 weeks)

Clinical Trials

Mean change from baseline in BCVA at Week 48

- **HAWK:**
  - Brolucizumab (n=360): 6.6
  - Aflibercept (n=360): 6.8
  - Difference: -0.2 (95% CI: -2.1, 1.8)
- **HARRIER:**
  - Brolucizumab (n=370): 6.9
  - Aflibercept (n=369): 7.6
  - Difference: -0.7 (95% CI: -2.4, 1.0)

Clinical Trials

- Through Week 48, 56% (HAWK) and 51% (HARRIER) of patients remained on brolucizumab every 12 weeks
- The proportion of patients who were maintained on every 12 week dosing through Week 96 was 45% and 39% in HAWK and HARRIER, respectively
- The probability of remaining on every 12 week dosing from Week 20 to Week 48 was 85% and 82%, and from Week 48 to Week 96 was 82% and 75% in HAWK and HARRIER, respectively

New Product Monograph

- For more information view the product monograph available at:

  https://www.empr.com/drug/beovu/