How to contact your eye care clinic:

Contact: _

Telephone: _

Address: _

E-mail: _

Your guide to therapy with Beovu® (brolucizumab)

For the treatment of Neovascular (wet) Age-related Macular Degeneration (AMD)

BEOVU®
Important note: Before prescribing, consult full prescribing information. Presentation: Solution for injection. Each vial contains 27.6 mg of brolucizumab in 0.23 mL solution. Each pre-filled syringe contains 19.8 mg of brolucizumab in 0.165 mL solution. Indications: Beovu® is indicated for the treatment of neovascular (wet) age-related macular degeneration (AMD).Dosage regimen and adminis tration: Single-use vial or single-use pre-filled syringe for intravitreal use only. Each vial or pre-filled syringe should only be used for the treatment of a single eye. Beovu® mus t be adminis tered by a qualified physician. Adults: The recommended dose for Beovu® is 6 mg (0.05 mL) adminis tered by intravitreal injection every 4 weeks (monthly) for the firs t three doses. Thereafter, Beovu® is adminis tered every 12 weeks (3 months). The physician may individualize treatment intervals based on disease activity as assessed by visual acuity and/or anatomical parameters. The treatment interval could be as frequent as every 8 weeks (2 months). Special populations: ♦Renal impairment: No dose adjus tment is required. ♦Hepatic impairment: No dose adjus tment is required. ♦Geriatric patients: No dose adjus tment is required. ♦Pediatric patients: Safety and efficacy have not been es tablished. Contraindications: ♦Hypersensitivity to the active subs tance or to any of the excipients. ♦Active or suspected ocular or periocular infection. ♦Active intraocular inflammation. Warnings and precautions: ♦Endophthalmitis, retinal detachment, retinal vasculitis and/or retinal vascular occlusion: Intravitreal injections, including those with Beovu®, have been associated with endophthalmitis and retinal detachment. Proper aseptic injection techniques must always be used when adminis tering Beovu®. Retinal vasculitis and/or retinal vascular occlusion, typically in the presence of intraocular inflammation, have been reported with the use of Beovu®. Patients should be ins tructed to report any symptoms sugges tive of the above mentioned events without delay. ♦Intraocular pressure increases: Transient increases in intraocular pressure have been seen within 30 minutes of injection, similar to those observed with intravitreal administration of other VEGF inhibitors. Sus tained intraocular pressure increases have also been reported. Both intraocular pressure and perfusion of the optic nerve head must be monitored and managed appropriately. ♦Driving and using machines: Patients may experience temporary visual disturbances after an intravitreal injection with Beovu® and the associated eye examination. Advise patients not to drive or use machinery until visual function has recovered sufficiently. Pregnancy, lactation, females and males of reproductive potential Pregnancy: The potential risk of use of Beovu® in pregnancy is unknown. However, based on the anti-VEGF mechanism of action, brolucizumab must be regarded as potentially teratogenic and embryo/fetotoxic. Therefore, Beovu® should not be used during pregnancy unless the expected benefits outweighs the potential risks to the fetus.Lactation: Breas t-feeding is not recommended during treatment and for at leas t one month after the las t dose when s topping treatment with Beovu®. Females and males of reproductive potential: Women of reproductive potential should use effective contraception (methods that result in less than 1% pregnancy rates) during treatment with Beovu® and for at leas t one month after the las t dose when stopping treatment with Beovu®. Adverse drug reactions: Common (1 to 10%): Visual acuity reduced, retinal haemorrhage, uveitis, iritis, vitreous detachment, retinal tear, cataracts, conjunctival haemorrhage, vitreous floaters, eye pain, intraocular pressure increase, conjunctivitis, retinal pigment epithelial tear, vision blurred, corneal abrasion, punctate keratitis, hypersensitivity. Uncommon (<1%): Endophthalmitis, blindness, retinal artery occlusion, retinal detachment, conjunctival hyperaemia, lacrimation increased, abnormal sensation in eye, detachment of retinal pigment epithelium, vitritis, anterior chamber inflammation, irirodyclitis, anterior chamber flare, corneal oedema, vitreous haemorrhage. Frequency not known: Retinal vasculitis, retinal vascular occlusion. Interactions: No formal interaction studies have been performed.

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Scan a QR code to listen to the patient guide

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You can report any problem or adverse events or request additional copies of the materials through:

Patient Safety Department Novartis Pharma AG - Saudi Arabia -.

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What is neovascular (wet) age-related macular degeneration (AMD)?

Wet AMD occurs when abnormal blood vessels form and grow underneath the macula.
The macula, which is at the back of the eye, is responsible for clear vision. The abnormal blood vessels may leak fluid or blood into the eye and interfere with the macula's function, resulting in decreased vision.

Why have I been prescribed Beovu®?

Beovu® contains the active substance brolucizumab, which belongs to a group of medicines called anti-neovascularization agents. Beovu is injected into the eye ("intravitreal injection") by your doctor to treat wet AMD in adults.

A substance called vascular endothelial growth factor A (VEGF-A) causes the growth of blood vessels in the eye. By attaching to VEGF-A, Beovu® blocks its effect and reduces the growth of abnormal blood vessels in wet AMD, which in turn reduces the leakage of fluid or blood in the eye.

After treatment

- Your doctor will do some eye tests after your injection. These tests may include measuring the pressure inside your eye or assessing the condition of your optic nerve
- Sometimes, after an intravitreal injection such as Beovu®, the following may occur:
  - An uncommon but severe inflammation usually associated with infection in the eye called "endophthalmitis"
  - Inflammation of the blood vessels in the retina (retinal vasculitis) and/or blockage of the blood vessels in the back of the eye (retinal vascular occlusion) might occur (Summary of Product Characteristic (SPC) and Patient Information Leaflet (PIL) will be updated)

After treatment (cont)

  - A less severe kind of inflammation called "intraocular inflammation"
  - An immune response (immunogenicity)
  - A temporary increase in eye pressure. This increase is common, but usually has no symptoms
- There is a possibility of getting a retinal detachment (uncommon) or retinal tear (common)
- It is important to contact your doctor immediately if you experience any of these symptoms:
  - A sudden decrease or change in your vision, including an increased number of small particles in your vision
  - Pain, discomfort, or redness in your eye
  - Flashes of light

What can I do after my treatment?

- After your injection, your vision may be temporarily affected (for example, blurred vision). Do not drive or use machines as long as these side effects last

- Be proactive and tell your doctor or nurse if you notice any changes to your vision

- It is important to follow the visit schedule recommended by your doctor