Your guide to therapy with Beovu® (brolucizumab) ▼

For the treatment of neovascular (wet) age-related macular degeneration (AMD) and diabetic macular edema (DME)

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions.

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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.

What is diabetic macular edema (DME)?

DME is a progressive disease caused by diabetes, which can lead to irreversible vision loss or blindness. Damaged blood vessels in the eye can cause fluid to leak into the macula. The macula is responsible for central vision and is the part of your eye used for things like reading, driving, and recognizing faces.

Why have I been prescribed Beovu®?

Beovu contains the active substance brolucizumab, which belongs to a group of medicines called anti-neovascularization agents.

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 and DME, which in turn reduces the leakage of fluid or blood in the eye.

How is Beovu administered?

- Beovu is injected into your eye (intravitreal injection) by your doctor
- 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

What to expect after treatment

Sometimes, after an intravitreal injection such as Beovu®, the following may occur:

- An uncommon severe inflammation (endophthalmitis), usually associated with infection, inside the eye or a detachment of one of the layers in the back of the eye (retinal detachment/tear)
- A temporary increase in eye pressure (intraocular pressure), which is common but usually without symptoms; the doctor needs to do measurements of the pressure inside the eye to detect this

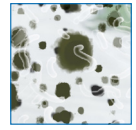
Important risk information

- Inflammation of the blood vessels in the retina (retinal vasculitis) and/or blockage of the blood vessels in the eye (retinal vascular occlusion), or a less severe inflammation in the eye (intraocular inflammation) may occur. You may be more at risk if you are female or of Japanese ethnicity
  - If you have had intraocular inflammation and/or retinal vascular occlusion in the last year, you are at increased risk of developing retinal vasculitis and/or retinal vascular occlusion
- An immune response (immunogenicity) is possible

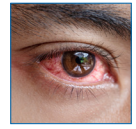
What to expect after treatment (cont)

Seek immediate medical help if you experience any of the following:

A sudden decrease or change in your vision



New or increased number of floaters (small particles in vision)



Overall redness of the eye

New or persistent eye pain or worsening eye discomfort

Flashes of light or increased sensitivity to light (discomfort from bright lights)

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

How to contact your eye care clinic:

Contact: _____

Telephone: _____

Address: _____

E-mail: _____

Suspected Adverse Drug Reactions (side effects) and medication errors may be reported using the Medicines Authority ADR reporting form, which is available online at http://www.medicinesauthority.gov.mt/adrportal and sent by post or email to;

P: Pharmacovigilance Section at Post-Licensing Directorate, Medicines Authority, Sir Temi Zammit Buildings, Malta Life Sciences Park, San Gwann. SGN 3000. E: postlicensing.medicinesauthority@gov.mt.

Healthcare Professionals may also report any adverse events associated with the use of Beovu® to Novartis Pharma Services Inc., Representative Office, Malta, by phone on +356 21222872, online on www.report.novartis.com or by e-mail at drug_safety.malta@novartis.com.

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Local Representative: Novartis Pharma Services Inc., Representative Office Malta. Tel No.: +356 21222872

For electronic copies of this Educational Material, please refer to the Malta Medicines Authority website - http://www.medicinesauthority.gov.mt/rmm - and download the required material with the latest date.

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