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. If you get any side effects, talk to your doctor, pharmacist or nurse. By reporting side effects, you can help provide more information on the safety of this medicine. You can report side effects directly via HPRA Pharmacovigilance, website: www.hpra.ie. Side effects could also be reported to Novartis preferably via www.report.novartis.com, or by email to drugsafety.dublin@novartis.com or by calling 01 2080 612.

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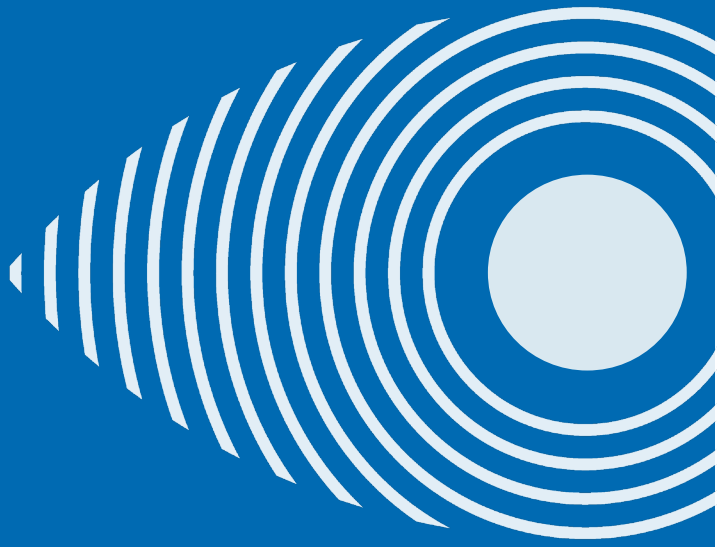
This booklet has been created to help you better understand Beovu® when used for the treatment of neovascular (wet) age-related macular degeneration (AMD) and diabetic macular edema (DME).



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 recognising faces.

Why have I been prescribed Beovu®?

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

Beovu® may slow down disease progression and thereby maintain, or even improve, your vision.

How is Beovu® administered?

- Before the injection, your doctor will clean your eye carefully, to prevent infection. Your doctor will also give you an eye drop (local anaesthetic) to numb the eye to reduce or prevent pain from the injection
- 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

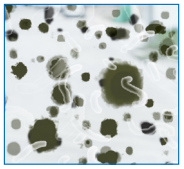
What to expect after treatment

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

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 photophobia which is increased sensitivity to light (discomfort from bright lights)

Important risk information

Please be aware that the following might occur:

- An immune response (immunogenicity) is possible. It can occur as 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)
- You may be more at risk of developing similar events if you are female or of Japanese ethnicity, or if you have had intraocular inflammation and/or retinal vascular occlusion in the last year

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
- Speak with your doctor before stopping treatment. Stopping treatment may increase your risk of vision loss and your vision may worsen.

How to contact your eye care clinic:

Contact: _____

Telephone: _____

Address: _____

E-mail: _____

Stamp

Electronic versions of the educational materials can be obtained at www.hpra.ie and electronic versions of the product information can be obtained at www.ema.europa.eu/en/medicines.

If copies of the audio CD's are required please contact Novartis Medical Information.

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