▼ This medicinal product is subject to additional monitoring. This allows quick identification of new safety information. Healthcare professionals are asked to report any suspected new or serious adverse effects. See "Adverse effects" for information on reporting adverse effects. **BEOVU®** Important note: **Before prescribing, consult full prescribing information. Presentation:** Solution for injection. 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 administration**: Single-use pre-filled syringe. For intravitreal use only. Each pre-filled syringe may only be used for the treatment of a single eye. Beovu must be administered by a qualified physician. Usual dosage: The recommended dose for Beovu is 6 mg (0.05 ml) administered as an intravitreal injection, with the first three injections taking place at 4-week intervals (monthly). Thereafter, Beovu is administered every 12 weeks (3 months). The physician may individually define treatment intervals based on disease activity as measured by visual acuity and/or anatomical parameters. The treatment interval may be adjusted to every 8 weeks (2 months) (see "Properties/Actions"); however, it should not be less than every 8 weeks (2 months) (see "Warnings and precautions"). To ensure traceability of medicinal products produced using biotechnology, it is recommended that the trade name and batch number be documented at every treatment. **Special dosage instructions:** *Patients with hepatic impairment*: No studies have been performed in patients with hepatic impairment. *Patients with renal impairment*: No dose adjustment is recommended in patients with renal impairment. There are only limited data available in patients with moderate renal impairment and no data in patients with severe renal impairment (see "Properties/Actions"). *Elderly patients*: No dose adjustment is required in patients aged 65 years or above. *Children and adolescents*: The safety and efficacy of Beovu in children and adolescents have not been established. **Method of administration**: As with all medicinal products for intravitreal use, Beovu should be inspected visually prior to administration. The intravitreal injection must be carried out under aseptic conditions. This includes surgical hand disinfection, sterile surgical gloves, a sterile drape and a sterile eyelid speculum (or similar instrument). Sterile paracentesis equipment should be available as a precautionary measure. The patient's medical history should be thoroughly evaluated for possible hypersensitivity reactions prior to the intravitreal injection (see "Contraindications"). Adequate anaesthesia and a broad-spectrum topical antiseptic to disinfect the periocular skin, eyelid and ocular surface should be administered prior to the injection. For information on the preparation of Beovu, see Instructions for use and handling. The injection needle should be inserted 3.5 to 4.0 mm posterior to the limbus into the vitreous cavity, avoiding the horizontal meridian and aiming towards the centre of the globe. The injection volume of 0.05 ml can then be injected slowly. Subsequent injections must be performed at different scleral sites. The safety and efficacy of Beovu treatment in both eyes concurrently have not been studied. **Contraindications:** ♦Hypersensitivity to the active substance or to any of the excipients. ♦Active or suspected ocular or periocular infection. ♦Active intraocular inflammation. Warnings and precautions: ♦Endophthalmitis, intraocular inflammation, retinal detachment, retinal vasculitis and/or retinal vascular occlusion: Intravitreal injections, including those with Beovu, have been associated with endophthalmitis, intraocular inflammation and retinal detachment. Proper aseptic injection techniques must always be used when administering 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 instructed to report any symptoms suggestive of the above mentioned events without delay. In a Phase IIIa 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 pivotal Phase III clinical studies (HAWK and HARRIER). The interval between two Beovu doses during maintenance treatment should not be less than 8 weeks. ♦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. Sustained intraocular pressure increases have also been reported. Both intraocular pressure and perfusion of the optic nerve head must be monitored and managed appropriately. ♦ Systemic effects following intravitreal use: Systemic adverse effects, including non-ocular haemorrhages and arterial thromboembolic events, have been reported following intravitreal injection of VEGF inhibitors. There is a theoretical risk that these may relate to VEGF inhibition. There are only limited safety data on the treatment of patients with AMD with a history of stroke, transient ischaemic attacks or myocardial infarction within the last 3 months. Caution should be exercised when treating such patients. ♦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/Breast-feeding**: *Women of childbearing potential:* Women of childbearing potential must use a reliable method of contraception during treatment with Beovu and for at least one month after stopping treatment with Beovu. *Pregnancy:* There are no adequate and well-controlled studies of Beovu administration in pregnant women. No animal reproduction studies have been conducted. 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 must not be administered during pregnancy unless absolutely necessary. *Breast-feeding*: It is unknown if brolucizumab is transferred into human milk after administration of Beovu. There are no data on the effects of Beovu on the breast-fed infant or milk production. Because of the potential for adverse drug reactions in breast-fed infants breast-feeding is not recommended during treatment and for at least one month after stopping treatment with Beovu. Fertility: No relevant data are available. **Adverse drug reactions:** *Common*: Reduced visual acuity, cataract, conjunctival haemorrhage, vitreous floaters, eye pain, retinal haemorrhage, vitreous detachment, increased intraocular pressure, conjunctivitis, retinal pigment epithelial tear, blurred vision, uveitis, corneal abrasion, punctate keratitis, iritis, retinal tear. *Uncommon*: Conjunctival hyperaemia, increased lacrimation, blindness, retinal artery occlusion, abnormal sensation in eye, endophthalmitis, retinal detachment, detachment of retinal pigment epithelium, vitritis, anterior chamber inflammation, iridocyclitis, anterior chamber flare, corneal oedema, vitreous haemorrhage. a) Including urticaria, rash, pruritus, erythema. Adverse drug reactions from spontaneous reports and literature cases (frequency not known) The following adverse drug reactions are from spontaneous reports and literature cases associated with post-marketing experience with Beovu. Because these effects are reported voluntarily from a population of unknown size, it is not always possible to reliably estimate their frequencies. Therefore, these adverse drug reactions have been assigned the frequency category "not known". Adverse drug reactions are listed by MedDRA system organ class. Within each system organ class adverse drug reactions are listed in order of decreasing seriousness. *Eye disorders Not known*: Retinal vascular occlusion, retinal vasculitis Intraocular inflammation The results of a retrospective real-world evidence analysis in nAMD patients who were evaluated for up to 6 months after starting treatment with Beovu suggest that patients with a history of intraocular inflammation and/or retinal vascular occlusion in the year prior to treatment with Beovu were more likely to present with similar events after Beovu injection than nAMD patients with no history of these events. *Immunogenicity* As with all therapeutic proteins, there is also a potential risk of an immune response in patients treated with Beovu. The immunogenicity of Beovu was evaluated in serum samples. The immunogenicity data reflect the percentage of patients whose test results were considered positive for antibodies to Beovu in immunoassays. The detection of an immune response is highly dependent on the sensitivity and specificity of the assays used, sample handling, timing of sample collection, concomitant medications and underlying disease. For these reasons comparison of the incidence of antibodies to Beovu with the incidence of antibodies to other products may be misleading. Antibodies, including single-chain antibodies, to a variety of therapeutic proteins produced using biotechnology have been detected in treatment-naive patients before the start of treatment. The pre-treatment incidence of anti-brolucizumab antibodies was 35-52%. After administration of Beovu for a period of 88 weeks treatment-emergent anti-brolucizumab antibodies were detected in 23-25% of patients. Anti-brolucizumab antibodies were not associated with an impact on clinical efficacy. Among patients with treatment-emergent antibodies a higher number of intraocular inflammation events were observed. The clinical significance of anti-brolucizumab antibodies on safety is unclear at this time. Product class-related adverse effects There is a theoretical risk of arterial thromboembolic events, including stroke and myocardial infarction, following intravitreal use of VEGF inhibitors. A low incidence rate of arterial thromboembolic events was observed in the brolucizumab clinical studies in patients with AMD. There were no major differences between the groups treated with brolucizumab and the comparator. **Interactions**: No formal interaction studies have been performed. **Packs and prices:** Country-specific**. Legal classification:** Country-specific. **BSS version**: 1.4 (2021-PSB/GLC-1225-e). **Leaflet revision date:** July 2021