swissmedic

Public Summary SwissPAR dated 9 November 2022

Beovu® (active substance: brolucizumab)

Indication extension in Switzerland: 22 June 2022

Medicinal product (solution for injection) for the treatment of diabetic macular oedema (DMA) in adults

About the medicinal product

Beovu, containing the active substance brolucizumab, is a medicinal product for the treatment of adults with diabetic macular oedema. The medicinal product Beovu is injected directly into the eye.

Macular oedema is a disease of the retina. In macular oedema, the retina thickens and fluid builds up in the region of sharpest vision (macula), which can lead to severe visual disturbances and, if left untreated, blindness.

The medicinal product Beovu was authorised by Swissmedic on 16 January 2020 for the treatment of wet age-related macular degeneration (AMD).

The present indication extension means that it can now be used to treat patients with diabetic macular oedema. Diabetic macular oedema is a frequent condition in diabetes patients whose blood glucose levels are elevated or poorly controlled over a longer period.

Mode of action

Macular oedema is caused by an undesired protein called vascular endothelial growth factor A (VEGF-A), which promotes growth of blood vessels in the eye and leaking of fluid and blood. The active substance in Beovu, brolucizumab, is a small monoclonal antibody (a type of protein).

Brolucizumab blocks VEGF-A binding to receptors[1]. This inhibits the formation of harmful blood vessels in the eye and the leaking of fluid in the retina.

[1] A receptor is a protein or a protein complex located on the surface of, or inside, cells. When a specific substance binds to a receptor, a reaction is triggered in the cell.

Use

Beovu, containing the active substance brolucizumab, is a prescription-only medicine.

The medicinal product Beovu is available as a vial or pre-filled syringe for single use for the treatment of a single eye in adult patients. Beovu must be administered by a qualified doctor. The medicinal product is administered as an injection into the vitreous cavity in the eye (intravitreal injection).

The recommended single dose is 6 mg. The first five injections are administered every six weeks. Subsequently, Beovu is administered every 12 weeks (i.e. at three-month intervals). The doctor will adjust the treatment interval based on the patient's disease activity and visual acuity.

Efficacy

The safety and efficacy of Beovu were investigated in two studies (KESTREL and KITE). In these studies, a total of 926 patients were treated for one year with Beovu or a medicinal product containing the active substance aflibercept. The change in best possible corrected visual acuity and the average change in visual acuity were investigated.

Both studies demonstrated that Beovu had positive outcomes with regard to visual acuity. The outcomes were comparable with those for aflibercept.

Precautions, undesirable effects & risks

Beovu may not be used in the event of hypersensitivity to the active substance or any of the excipients, an existing or possible infection in or around the eye or inflammation inside the eye.

The side effects of treatment of diabetic macular oedema with Beovu are comparable with the undesirable effects in the indication wet age-related macular degeneration (AMD), which was already authorised. The most common side effects (in more than 5% of all patients treated with Beovu) were reduced visual acuity, clouding of the lens, conjunctival haemorrhage and vitreous floaters (small dark or transparent dots, spots or thread-like structures in the visual field). The following serious side effects were less frequent (less than 1% of all patients treated with Beovu): endophthalmitis (dangerous eye infection), blindness, retinal artery occlusion and retinal detachment.

You can find out about other possible side effects from healthcare personnel or the Information for healthcare professionals.

All precautions, risks and other possible undesirable effects are listed in the Information for healthcare professionals.

Why the medicinal product has been authorised

Swissmedic considers the benefit/risk ratio of brolucizumab in the indication applied for to be positive. The indication extension for the treatment of patients with diabetic macular oedema is therefore approved for Switzerland.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Beovu®

Healthcare professionals can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Public Summary SwissPAR.

Swissmedic monitors medicinal products authorised in Switzerland. Swissmedic initiates the necessary action in the event of newly discovered adverse drug reactions or other safety-relevant signals. New findings that could impair the quality, efficacy or safety of this medicinal product are recorded and published by Swissmedic. If necessary, the medicinal product information is adapted.