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Beovu (*brolucizumab*)

An overview of Beovu and why it is authorised in the EU

What is Beovu and what is it used for?

Beovu is a medicine used to treat adults with certain sight problems caused by damage to the retina (the light-sensing layer at the back of the eye), and more specifically its central region, known as the macula. The macula provides central vision that is needed to see detail for everyday tasks such as driving, reading and recognising faces. In adults, Beovu is used to treat:

- the 'wet' form of age-related macular degeneration (AMD). The wet form of AMD is caused by choroidal neovascularisation (the abnormal growth of blood vessels under the macula, which may lead to leakage of fluid and blood and cause swelling);
- visual impairment due to macular oedema (swelling of the macula) caused by diabetes (DME).

Beovu contains the active substance brolucizumab.

How is Beovu used?

Beovu is available as prefilled syringes or vials containing a solution for intravitreal injection (injection into the vitreous humour, the jelly-like fluid inside the eye). It can only be obtained with a prescription and must be given by a qualified doctor who is experienced in giving intravitreal injections.

For the treatment of wet AMD, Beovu is injected into the affected eye once a month for the first three doses. Afterwards, Beovu should be given every 8 or 12 weeks, depending on the activity of the disease.

For the treatment of reduced vision due to DME, Beovu is given as an injection into the affected eye, once every 6 weeks for the first five doses. Afterwards, Beovu should be given every 8 or 12 weeks, depending on the activity of the disease.

Treatment with Beovu should be stopped if the patient is not benefitting from it.

For more information about using Beovu, see the package leaflet or contact your doctor or pharmacist.

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How does Beovu work?

The active substance in Beovu, brolucizumab, is a small piece of a monoclonal antibody. A monoclonal antibody is a type of protein that has been designed to recognise and attach to a specific target (called an antigen) that is found in certain cells in the body.

Brolucizumab has been designed to attach to and block a substance called vascular endothelial growth factor A (VEGF-A). VEGF-A is a protein involved in the formation and function of blood vessels. Increased levels of this protein are linked with the development of wet AMD and DME. By blocking VEGF-A, brolucizumab reduces the growth of the blood vessels and controls the leakage and swelling.

What benefits of Beovu have been shown in studies?

Wet AMD

Beovu was investigated in two main studies lasting around 2 years involving a total of around 1,800 patients with the wet form of AMD. The studies compared Beovu (given once a month for 3 months, then every 8 or 12 weeks) with aflibercept (another treatment for AMD) given once a month for 3 months, then every 8 weeks. The main measure of effectiveness was the change in patients' vision after the first year of treatment, measured as the number of letters that they could recognise on a standard eye test. Both studies also looked at the maintenance of the effect in the second year of treatment.

Beovu was shown to be as effective as aflibercept in maintaining vision in patients with wet AMD. In the first study, patient's vision improved on average by 6.4 letters in patients treated with Beovu and by 7 letters in patients given aflibercept. In the second study, the improvement was 6.9 letters for patients given Beovu and 7.6 letters for patients given aflibercept. During the second year of treatment, the effectiveness of Beovu was generally maintained.

DME

Beovu was shown to be effective in treating reduced vision due to DME in two main studies involving a total of 926 patients. These studies compared Beovu given once every 6 weeks for the first five doses and then every 8 or 12 weeks with aflibercept (another treatment for DME) given once a month for five months and then every 8 weeks. The main measure of effectiveness was the change in patients' vision after the first year of treatment, measured as the number of letters that they could recognise on a standard eye test.

In both studies, Beovu was as effective as aflibercept in improving vision in patients after one year of treatment. In the first study, patients treated with Beovu improved on their test score by 9.2 letters on average, compared with 10.5 letters in patients given aflibercept. In the second study, improvement was 10.6 letters for patients treated with Beovu and 9.4 letters for patients treated with aflibercept.

What are the risks associated with Beovu?

The most common side effects with Beovu (which may affect up to 1 in 10 people) are reduced visual acuity, cataract (clouding of the lens in the eye), conjunctival haemorrhage (bleeding at the front of the eye) and vitreous floaters (spots in the vision). The most serious side effects (which may affect up to 1 in 100 people) are blindness, endophthalmitis (an infection inside the eye), retinal artery occlusion (blockage of the artery in the retina) and retinal detachment (separation of the retina from the back of the eye). For the full list of side effects of Beovu, see the package leaflet.

Beovu must not be used in patients active or suspected infection in or around the eye, and in patients with active inflammation inside the eye. For the full list of restrictions, see the package leaflet.

Why is Beovu authorised in the EU?

The European Medicines Agency considered that Beovu was shown to be effective at improving vision in patients with wet AMD and in patients with DME. The safety of Beovu was considered similar to that of medicines of the same type and was considered acceptable. The Agency therefore decided that Beovu's benefits are greater than its risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Beovu?

The company that markets Beovu will provide educational materials for patients with information about wet AMD and DME, how Beovu works and how it is given, and what to expect from the treatment. The patient guide will also include information about Beovu's side effects and on when to seek urgent medical attention after treatment with the medicine.

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Beovu have also been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Beovu are continuously monitored. Side effects reported with Beovu are carefully evaluated and any necessary action taken to protect patients.

Other information about Beovu

Beovu received a marketing authorisation valid throughout the EU on 13 February 2020.

Further information on Beovu can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/beovu.

This overview was last updated in 03-2022.