swissmedic

Public Summary SwissPAR vom 14.04.2020

Beovu® (active substance: brolucizumab)

First authorisation in Switzerland: 16.01.2020

Medicinal product for the treatment of wet age-related macular degeneration (AMD).

About the medicinal product

Beovu contains the active substance brolucizumab and is available as a vial or pre-filled syringe. Beovu may be administered only by a suitably qualified doctor. Beovu was authorised on 16 January 2020 in Switzerland for the treatment of wet age-related macular degeneration (AMD).

The macula is located at the back of the human retina. It is responsible for central vision, which is needed to make out details for everyday tasks such as driving, reading and recognising faces. The diseases causes the gradual loss of this central vision, leading to a loss of visual acuity in the middle of the visual field.

Mode of action

Wet age-related macular degeneration is caused by an unwanted protein (known as Vascular Endothelial Growth Factor A; VEGF-A) that causes blood vessels to grow in the eye, leading to the leakage of fluid and blood. This damages the macula and reduces visual acuity.

The active substance in Beovu, brolucizumab, is a small monoclonal antibody (a type of protein). It was developed in order to attach to and block the unwanted protein (known as an antigen), thereby inhibiting the formation of new blood vessels and the leakage of fluid from the vessels.

Administration

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 suitably qualified doctor. It is administered as an injection into the vitreous cavity in the eye (intravitreal injection). The recommended single dose is 6 mg. Initially, three injections are administered every 4 weeks. Thereafter, Beovu is injected every 8 to 12 weeks, depending on the activity of the disease and visual acuity. The intravitreal injection must be administered under aseptic conditions. Before the treatment, the skin around the eye, eyelid and surface of the eye is anaesthetised and disinfected. The medicinal product can then be injected slowly.

Efficacy

The efficacy of Beovu has been investigated in two clinical trials over two years with around 1,800 patients who were suffering from wet age-related macular degeneration (AMD). In these trials the efficacy of Beovu was compared with that of a medicinal product that is already authorised in Switzerland for the same indication.

After 48 weeks, the average gain in visual acuity observed for Beovu was similar to that for the comparator product.

Both studies also investigated the maintenance of the effect in the second year of treatment. The studies have shown that a visual acuity gain was still detectable after two years of Beovu treatment.

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 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). Less frequent were the following serious side effects (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.

Why the medicinal product has been authorised

Swissmedic has established that Beovu has been shown to improve visual acuity in patients with wet AMD. The safety of Beovu is similar to that of comparable medicinal products authorised in Switzerland. Therefore, Swissmedic considers the overall benefit/risk ratio of brolucizumab to be positive and has authorised the medicinal product Beovu with the active substance brolucizumab in Switzerland for the above-mentioned indication.

Further information on the medicinal product

Information for healthcare professionals (the english translation was not available at time of publication of this Public Summary SwissPAR):

Healthcare professionals information

Healthcare professionals (doctor, pharmacist, etc.) can answer any other questions.

This information is correct as at the date above. 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.