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Baiama (*aflibercept*)

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

What is Baiama and what is it used for?

Baiama is a medicine used to treat adults with:

- the 'wet' form of age-related macular degeneration (AMD), a disease which affects the central part of the retina (called the macula) at the back of the eye. The wet form of AMD is caused by choroidal neovascularisation (the abnormal growth of blood vessels under the macula), which may leak fluid and blood, causing swelling;
- impaired vision due to macular oedema (swelling) that follows blockage of either the main vein carrying blood from the retina (known as central retinal vein occlusion, CRVO) or of smaller branch veins (known as branch retinal vein occlusion, BRVO);
- impaired vision due to macular oedema caused by diabetes;
- impaired vision due to myopic choroidal neovascularisation (a severe type of short-sightedness where the eyeball continues to grow, becoming longer than it should be).

Baiama contains the active substance aflibercept and is a 'biosimilar medicine'; this means that Baiama is highly similar to another biological medicine (the 'reference medicine') that is already authorised in the EU. The reference medicine for Baiama is Eylea. For more information on biosimilar medicines, see here.

How is Baiama used?

Baiama is available as 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.

Baiama is given as an injection into the affected eye, repeated as appropriate at intervals of a month or more. How often the injections are given depends on the condition being treated and the response of the patient to treatment.

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

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How does Baiama work?

The active substance in Baiama, aflibercept is an engineered protein that has been designed to attach to and block the effects of a substance called vascular endothelial growth factor A (VEGF-A). It can also attach to other proteins such as placental growth factor (PlGF). VEGF-A and PlGF are involved in stimulating the abnormal growth of blood vessels in patients with AMD, certain types of macular oedema and myopic choroidal neovascularisation. By blocking these factors, aflibercept reduces the growth of abnormal blood vessels and controls leakage and swelling.

What benefits of Baiama have been shown in studies?

Laboratory studies comparing Baiama with Eylea have shown that the active substance in Baiama is highly similar to that in Eylea in terms of structure, purity and biological activity. Studies have also shown that giving Baiama results in similar levels of the active substance in the body to when giving Eylea.

In addition, a study in 434 patients with wet AMD showed that Baiama was as effective as Eylea. In this study, the average number of letters patients could recognise on a standard eye test improved by around 7 letters in the Baiama group and 6 letters in the Eylea group after 8 weeks of treatment.

Because Baiama is a biosimilar medicine, the studies on the effectiveness of aflibercept carried out with Eylea do not all need to be repeated for Baiama.

What are the risks associated with Baiama?

The safety of Baiama has been evaluated and, on the basis of all the studies carried out, the side effects of the medicine are considered to be comparable to those of the reference medicine, Eylea.

For the complete list of side effects and restrictions of Baiama, see the package leaflet.

The most common side effects with aflibercept (which may affect more than 1 in 20 people) include conjunctival haemorrhage (bleeding from the small blood vessels on the surface of the eye at the site of injection), retinal haemorrhage (bleeding at the back of the eye), reduced vision, eye pain, vitreous detachment (detachment of the jelly-like substance inside the eye), cataract (clouding of the lens), vitreous floaters (small particles or spots in the vision) and increased intraocular pressure (increased pressure inside the eye).

Serious injection-related side effects (which have occurred in less than 1 in around 2,000 injections in studies) include blindness, endophthalmitis (serious infection or inflammation inside the eye), cataract, increased intraocular pressure, vitreous haemorrhage (bleeding into the jelly-like fluid in the eye, causing temporary loss of vision) and vitreous or retinal detachment.

Baiama must not be used in patients who have or are thought to have ocular or periocular infections (infections in or around the eyes), or in patients who have severe inflammation inside the eye.

Why is Baiama authorised in the EU?

The European Medicines Agency decided that, in accordance with EU requirements for biosimilar medicines, Baiama has a highly similar structure, purity and biological activity to Eylea and is distributed in the body in the same way. In addition, a study in patients with wet AMD has shown that Baiama and Eylea are equivalent in terms of safety and effectiveness in this indication.

All these data were considered sufficient to conclude that Baiama will have the same effects as Eylea in its authorised uses. Therefore, the Agency's view was that, as for Eylea, the benefits of Baiama outweigh the identified risks and it can be authorised for use in the EU.

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

The company that markets Baiama will provide information packs to patients to help them prepare for treatment, recognise serious side effects and know when to seek urgent attention from their doctor. It will also provide material for doctors to minimise the risks associated with the injection in the eye.

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

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

Other information about Baiama

Baiama received a marketing authorisation valid throughout the EU on 13 January 2025.

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

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