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Yesafili (*aflibercept*)

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

What is Yesafili and what is it used for?

Yesafili 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).

Yesafili is a 'biosimilar medicine'. This means that Yesafili is highly similar to another biological medicine (the 'reference medicine') that is already authorised in the EU. The reference medicine for Yesafili is Eylea. For more information on biosimilar medicines, see here.

Yesafili contains the active substance aflibercept.

How is Yesafili used?

Yesafili 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 doctor who is experienced in giving intravitreal injections.

Yesafili 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 Yesafili, see the package leaflet or contact your doctor or pharmacist.

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How does Yesafili work?

The active substance in Yesafili, 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. By blocking these factors, aflibercept reduces the growth of abnormal blood vessels and controls leakage and swelling.

What benefits of Yesafili have been shown in studies?

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

In addition, a study in 355 patients with diabetic macular oedema showed that Yesafili produced comparable improvements in the condition to those seen with Eylea. In this study, the average number of letters patients could recognise on a standard eye test improved by about 7 in both groups after 8 weeks of treatment.

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

What are the risks associated with Yesafili?

The safety of Yesafili has been evaluated, and on the basis of the study 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 Yesafili, see the package leaflet.

The most common side effects with Yesafili (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, dark shapes moving in the field of 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 (inflammation inside the eye), cataracts, increased intraocular pressure, vitreous haemorrhage (bleeding into the jelly-like fluid in the eye, causing temporary loss of vision) and vitreous or retinal detachment (retina is pulled away from the normal position at the back of the eye).

Yesafili 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 Yesafili authorised in the EU?

The European Medicines Agency decided that, in accordance with EU requirements for biosimilar medicines, Yesafili has a highly similar structure, purity and biological activity to Eylea and is distributed in the body in the same way. In addition, studies in patients with diabetic macular oedema have shown that the safety and effectiveness of Yesafili is equivalent to that of Eylea in this indication.

All these data were considered sufficient to conclude that Yesafili will behave in the same way as Eylea in terms of effectiveness and safety in its authorised uses. Therefore, the Agency's view was that, as for Eylea, the benefits of Yesafili 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 Yesafili?

The company that markets Yesafili 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 Yesafili have also been included in the summary of product characteristics and the package leaflet.

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

Other information about Yesafili

Yesafili received a marketing authorisation valid throughout the EU on 15 September 2023.

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

This overview was last updated in 09-2023.