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Eyluxvi (*aflibercept*)

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

What is Eyluxvi and what is it used for?

Eyluxvi is a medicine used to treat adults with:

- the 'wet' form of age-related macular degeneration (AMD), a disease that 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 and cause 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).

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

How is Eyluxvi used?

Eyluxvi is available as 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.

Eyluxvi 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 patient's response to treatment.

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

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

How does Eyluxvi work?

The active substance in Eyluxvi, aflibercept, is an engineered protein that has been designed to attach to and block the effects of a protein 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 proteins, aflibercept reduces the growth of abnormal blood vessels and controls leakage and swelling.

What benefits of Eyluxvi have been shown in studies?

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

In addition, a study involving 431 patients with wet AMD showed that treatment with Eyluxvi resulted in improvements that were comparable to those seen with Eylea. After 8 weeks of treatment, the average number of letters patients could recognise on a standard eye test improved by around 6 letters for those given Eyluxvi compared with around 8 letters for those given Eylea.

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

What are the risks associated with Eyluxvi?

The safety of Eyluxvi 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 Eylea.

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

The most common side effects with Eyluxvi (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).

Some side effects can be serious. Serious side effects related to the injection (which have occurred in less than 1 in around 2,000 aflibercept injections in studies) include blindness, endophthalmitis (serious infection or 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.

Eyluxvi 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 Eyluxvi authorised in the EU?

The European Medicines Agency decided that, in accordance with EU requirements for biosimilar medicines, Eyluxvi 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 Eyluxvi and Eylea are equivalent in terms of safety and effectiveness in this use.

All these data were considered sufficient to conclude that Eyluxvi will have the same effects as Eylea in its authorised uses in adults. Therefore, the Agency's view was that, as for Eylea, the benefits of Eyluxvi 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 Eyluxvi?

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

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

Other information about Eyluxvi

Eyluxvi received a marketing authorisation valid throughout the EU on 15 September 2025.

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

This overview was last updated in 11-2025.