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Opuviz (*aflibercept*)

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

What is Opuviz and what is it used for?

Opuviz 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 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).

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

How is Opuviz used?

Opuviz 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.

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

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How does Opuviz work?

The active substance in Opuviz, 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 Opuviz have been shown in studies?

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

In addition, a study of 449 patients with wet AMD showed that Opuviz 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 both groups after 8 weeks of treatment.

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

What are the risks associated with Opuviz?

The safety of Opuviz 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 Opuviz, see the package leaflet.

The most common side effects with Opuviz (which may affect more than 1 in 10 people) are 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 and eye pain. Other common side effects (which may affect up to 1 in 10 people) are 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) are 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.

Opuviz 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 Opuviz authorised in the EU?

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

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

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

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

Other information about Opuviz

Opuviz received a marketing authorisation valid throughout the EU on 13 November 2024.

Further information on Opuviz can be found on the Agency's website:

ema.europa.eu/medicines/human/EPAR/opuviz

This overview was last updated in 11-2024.