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Pavblu (*aflibercept*)

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

What is Pavblu and what is it used for?

Pavblu 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 choroidal neovascularisation in people with myopia (short-sightedness).

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

How is Pavblu used?

Pavblu can only be obtained with a prescription and must be given by a qualified doctor who is experienced in giving intravitreal injections (injection into the vitreous humour, the jelly-like fluid inside the eye). The medicine is available as a solution for intravitreal injection.

Pavblu is given as an intravitreal injection into the affected eye, repeated as appropriate at intervals of one 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 how Pavblu is used, see the package leaflet or contact your doctor or pharmacist.

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How does Pavblu work?

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

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

In addition, a study involving 579 adults with wet AMD found that Pavblu was as effective as Eylea. In this study, the average number of letters patients could recognise on a standard eye test improved by around 6.5 letters in both groups after 8 weeks of treatment.

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

What are the risks associated with Pavblu?

The safety of Pavblu 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 Pavblu, see the package leaflet.

The most common side effects with Pavblu (which may affect more than 1 in 10 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 and eye pain.

Other common side effects (which may affect up to 1 in 10 people) include 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 injection-related side effects (which have occurred in less than 1 in around 2,000 aflibercept 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.

Pavblu 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 Pavblu authorised in the EU?

The European Medicines Agency decided that, in accordance with EU requirements for biosimilar medicines, Pavblu 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 wet AMD has shown that Pavblu and Eylea are equivalent in terms of safety and effectiveness in this condition.

All these data were considered sufficient to conclude that Pavblu 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 Pavblu 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 Pavblu?

The company that markets Pavblu will provide up-to-date educational material for doctors to minimise the risks associated with the injection in the eye, and for patients to provide instructions on how to use the medicine, precautions to take and how to recognise serious side effects and know when to seek urgent attention from their doctor.

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

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

Other information about Pavblu

Pavblu received a marketing authorisation valid throughout the EU on 04 April 2025.

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

This overview was last updated in 04-2025.