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Vislyfa (ranibizumab)

A plain-language overview of Vislyfa and why it is authorised in the EU

What is Vislyfa and what is it used for?

Vislyfa is a medicine used to treat adults with certain sight problems caused by damage to the retina (the light-sensing layer at the back of the eye), and more specifically its central region, known as macula. The macula provides the vision needed to see detail for everyday tasks such as driving, reading and recognising faces. Vislyfa is used to treat:

- 'wet' form of age-related macular degeneration (AMD). The wet form of AMD is caused by choroidal neovascularisation (abnormal growth of blood vessels beneath the retina, which may leak fluid and blood and cause swelling);
- macular oedema (swelling of the macula) caused by diabetes or by occlusion (blockage) of the veins behind the retina;
- proliferative diabetic retinopathy (growth of abnormal tiny blood vessels in the eye, associated with diabetes);
- other sight problems associated with choroidal neovascularisation.

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

How is Vislyfa used?

Vislyfa can only be obtained with a prescription. It is given by intravitreal injection (an injection into the vitreous humour, the jelly-like fluid in the eye) by a qualified eye doctor who is experienced in giving intravitreal injections.

Treatment with Vislyfa is started with one injection every month, with regular checks of the patient's vision and examination of the back of the eye, until maximum vision is achieved and/or there are no signs of disease activity. The interval between two injections of Vislyfa must be at least 4 weeks. The doctor will adjust the interval between doses after assessing the patient's vision and disease activity. Treatment should be stopped if the patient is not benefiting from it.

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

How does Vislyfa work?

The active substance in Vislyfa, ranibizumab, is a type of antibody produced in the laboratory. Antibodies are proteins that recognise and attach to specific targets in the body.

Ranibizumab has been designed to attach to and block a substance called vascular endothelial growth factor A (VEGF-A). VEGF-A is a protein that makes blood vessels grow and leak fluid and blood, damaging the macula. By blocking VEGF-A, ranibizumab reduces the growth of the blood vessels and controls the leakage and swelling.

What benefits of Vislyfa have been shown in studies?

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

In addition, a study involving 600 people with the wet form of AMD showed that Vislyfa was as effective as Lucentis. In the study, the average number of letters patients could recognise on a standard eye test improved by about 11 in both patients treated with Vislyfa and those given Lucentis after 12 months of treatment.

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

Studies carried out with Vislyfa are described in more detail in the medicine's assessment report.

What are the side effects and restrictions associated with Vislyfa?

The safety of Vislyfa has been evaluated and, based on all the studies carried out, the side effects of the medicine are considered to be comparable to those of Lucentis.

For the full list of side effects and restrictions of Vislyfa, see the package leaflet.

The most common side effects with Vislyfa (which may affect more than 1 in 10 people) include increased intraocular pressure (pressure within the eye), headache, vitritis (inflammation in the eye), vitreous detachment (separation of the vitreous humour from the back of the eye), retinal haemorrhage (bleeding at the back of the eye), visual disturbance, eye pain, vitreous floaters (spots in the vision), conjunctival haemorrhage (bleeding at the front of the eye), eye irritation, sensation of a foreign body in the eye, increased lacrimation (watery eyes), blepharitis (inflammation of the eyelids), dry eye, ocular hyperaemia (increased blood supply to the eye, leading to redness of the eye), eye pruritus (itching), arthralgia (joint pain) and nasopharyngitis (inflammation of the nose and throat).

Less commonly, some side effects can be serious. These include endophthalmitis (an infection inside the eye), blindness, serious damage to the retina and cataract (clouding of the lens).

Vislyfa must not be used in patients who may have an infection of the eye or of the area around the eye, or who have severe inflammation within the eye.

Why is Vislyfa authorised in the EU?

The European Medicines Agency decided that, in accordance with EU requirements for biosimilar medicines, Vislyfa has a highly similar structure, purity and biological activity to Lucentis and is distributed in the body in the same way.

In addition, a study in the wet form of AMD has shown that Vislyfa and Lucentis are equivalent in terms of safety and effectiveness.

All these data were considered sufficient to conclude that Vislyfa will have the same effects as Lucentis in its authorised uses.

Therefore, the Agency's view was that, as for Lucentis, the benefits of Vislyfa 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 Vislyfa?

The company that markets Vislyfa will provide an information pack to patients to help them prepare for treatment, recognise serious side effects and know when to seek urgent medical attention.

These materials may be made available by national competent authorities on their websites. A list of national repositories is available on the EMA website.

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

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

Other information about Vislyfa

Vislyfa received a marketing authorisation valid throughout the EU on 15 July 2026.

Further information on Vislyfa, including the package leaflet and assessment report, can be found on the Agency's website: ema.europa.eu/en/medicines/human/EPAR/vislyfa.

For information about the availability of this medicine in your country, contact your national competent authority.