



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Ximluci (*ranibizumab*)

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

What is Ximluci and what is it used for?

Ximluci 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 the macula. The macula provides the vision needed to see detail for everyday tasks such as driving, reading and recognising faces. Ximluci 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 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.

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

Ximluci contains the active substance ranibizumab.

How is Ximluci used?

Ximluci is a solution for injection which is given into the vitreous humour, the jelly-like fluid in the eye. It can only be obtained with a prescription and must be given by a qualified eye doctor who is experienced in giving injections into the eye.

Treatment 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 Ximluci into the same eye must be at least four weeks. Treatment with Ximluci should be stopped if the patient is not benefitting from it.

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

How does Ximluci work?

The active substance in Ximluci, ranibizumab, is a small piece of a monoclonal antibody. A monoclonal antibody is a type of protein that has been designed to recognise and attach to a specific target (called an antigen) that is found in certain cells 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 Ximluci have been shown in studies?

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

In addition, a main study involving 583 patients with the wet form of age-related macular degeneration found that Ximluci produced comparable improvements in the condition to those seen with Lucentis. After 8 weeks of treatment, the number of letters patients could recognise on a standard eye test improved by 4.6 letters in patients treated with Ximluci, and by 6.4 letters in patients given Lucentis. As the difference in the number of letters patients could read was lower than 3.5 (a pre-defined measure to determine whether the two medicines produced similar benefits), the two medicines are considered to have comparable effect.

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

What are the risks associated with Ximluci?

The safety of Ximluci 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 Lucentis.

The most common side effects affecting the eyes with ranibizumab (which may affect more than 1 in 10 people) are eye pain, ocular hyperaemia (increased blood supply to the eye, leading to redness of the eye), increased intraocular pressure (pressure within the eye), vitritis (inflammation in the eye), vitreous detachment (separation of the vitreous from the back of the eye), retinal haemorrhage (bleeding at the back of the eye), visual disturbance, 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 and eye pruritis (itching). Less frequent but more serious side effects include endophthalmitis (an infection inside the eye), blindness, serious damage to the retina and iatrogenic traumatic cataract (clouding of the lens caused by medication). The most common side effects not affecting the eyes are headache, nasopharyngitis (inflammation of the nose and throat) and arthralgia (joint pain).

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

Why is Ximluci authorised in the EU?

The European Medicines Agency decided that, in accordance with EU requirements for biosimilar medicines, Ximluci 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 patients with the wet form of age-related macular degeneration has shown that the safety and effectiveness of Ximluci is equivalent to that of Lucentis in this indication.

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

The company that markets Ximluci 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.

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

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

Other information about Ximluci

Ximluci received a marketing authorisation valid throughout the EU on 9 November 2022.

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

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

This overview was last updated in 11-2022.