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# Ranivisio (*ranibizumab*)

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

## What is Ranivisio and what is it used for?

Ranivisio 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. Ranivisio 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.

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

Ranivisio contains the active substance ranibizumab.

## How is Ranivisio used?

Ranivisio is a solution for injection of 0.5 mg 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 Ranivisio into the same eye must be at least four weeks. Treatment with Ranivisio should be stopped if the patient is not benefitting from it.

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

## How does Ranivisio work?

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

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

In addition, a study involving 477 patients with age-related macular degeneration found that Ranivisio produced comparable improvements in the condition to those seen with Lucentis. In this study, the average number of letters patients could recognise on a standard eye test improved by 5 in patients treated with Ranivisio and by 6 in patients given Lucentis after 8 weeks of treatment.

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

## What are the risks associated with Ranivisio?

The safety of Ranivisio 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 with ranibizumab (which may affect more than 1 in 10 people) are increased intraocular pressure (pressure within the eye), headache, 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, 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 pruritis (itching), arthralgia (joint pain) and nasopharyngitis (inflammation of the nose and throat). Rarely, endophthalmitis (an infection inside the eye), blindness, serious damage to the retina and cataract (clouding of the lens) can occur.

Ranivisio 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 Ranivisio, see the package leaflet.

## Why is Ranivisio authorised in the EU?

The European Medicines Agency decided that, in accordance with EU requirements for biosimilar medicines, Ranivisio has a highly similar structure, purity and biological activity to Lucentis and is distributed in the body in the same way. In addition, studies in patients with age-related macular degeneration have shown that the safety and effectiveness of Ranivisio is equivalent to that of Lucentis in this indication.

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

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

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

## Other information about Ranivisio

Ranivisio received a marketing authorisation valid throughout the EU on 25 August 2022.

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

This overview was last updated in 08-2022.