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Ranluspec (*ranibizumab*)

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

What is Ranluspec and what is it used for?

Ranluspec 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. In adults, Ranluspec 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.

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

How is Ranluspec used?

Ranluspec is available as an injection in prefilled syringes or vials, for single use. It is given by intravitreal injection (injection 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 intravitreal injections.

The recommended dose for Ranluspec is 0.5 mg given as a single injection. The interval between two injections of Ranluspec into the same eye must be at least four weeks.

Treatment with Ranluspec 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. Treatment with Ranluspec should be stopped if the patient is not benefiting from it.

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

How does Ranluspec work?

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

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

In addition, a study involving 600 people with the wet form of age-related macular degeneration found that Ranluspec produced improvements in the condition comparable to those seen with Lucentis. In this study, the average number of letters patients could recognise on a standard eye test improved by around 11 in both patients treated with Ranluspec and those given Lucentis after 12 months of treatment.

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

What are the risks associated with Ranluspec?

The safety of Ranluspec 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.

For the complete list of side effects and restrictions of Ranluspec, see the package leaflet.

The most common side effects with ranibizumab (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 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). Rarely, endophthalmitis (an infection inside the eye), blindness, serious damage to the retina and cataract (clouding of the lens) can occur.

Ranluspec 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 Ranluspec authorised in the EU?

The European Medicines Agency decided that, in accordance with EU requirements for biosimilar medicines, Ranluspec 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 age-related macular degeneration has shown that Ranluspec and Lucentis are equivalent in terms of safety and effectiveness in this use.

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

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

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

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

Other information about Ranluspec

Ranluspec received a marketing authorisation valid throughout the EU on 10 February 2026.

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

This overview was last updated in 02-2026.