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Rimmyrah (*ranibizumab*)

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

What is Rimmyrah and what is it used for?

Rimmyrah 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. Rimmyrah 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.

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

Rimmyrah contains the active substance ranibizumab.

How is Rimmyrah used?

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

Treatment with Rimmyrah 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 Rimmyrah should be stopped if the patient is not benefitting from it.

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

How does Rimmyrah work?

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

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

In addition, a study comparing Rimmyrah with Lucentis in 616 patients with the wet form of AMD showed that both medicines were similarly effective. After 8 weeks of treatment, the average number of letters patients could recognise on a standard eye test improved by 6 in patients treated with Rimmyrah and by 7 in patients given Lucentis.

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

What are the risks associated with Rimmyrah?

The safety of Rimmyrah 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 Rimmyrah, see the package leaflet.

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.

Why is Rimmyrah authorised in the EU?

The European Medicines Agency decided that, in accordance with EU requirements for biosimilar medicines, Rimmyrah has a highly similar structure, purity and biological activity compared to Lucentis and is distributed in the body in the same way. In addition, studies in patients with the wet form of AMD have shown that the effectiveness and safety of Rimmyrah is equivalent to that of Lucentis.

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

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

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

Other information about Rimmyrah

Rimmyrah received a marketing authorisation valid throughout the EU on 5 January 2024.

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

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