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EPAR summary for the public

Lucentis

ranibizumab

This is a summary of the European public assessment report (EPAR) for Lucentis. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Lucentis.

For practical information about using Lucentis, patients should read the package leaflet or contact their doctor or pharmacist.

What is Lucentis and what is it used for?

Lucentis is a medicine used to treat adults with certain conditions that impair their sight by damaging 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. The conditions Lucentis is used to treat are:

- the '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);
- other sight problems associated with choroidal neovascularisation;
- macular oedema (swelling of the macula) caused by diabetes;
- macular oedema caused by occlusion (blockage) of the veins behind the retina.

How is Lucentis used?

Lucentis is available as a solution for 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 Lucentis is 0.5 mg given as a single intravitreal injection. The procedure should be carried out under sterile conditions. The prefilled syringe contains more than the recommended dose, therefore when preparing the injection, the doctor must expel the excess volume and ensure the injection of the correct dose.

Treatment with Lucentis is started with one injection every month, with regular checks of the patient's vision and the appearance of the back of the eye, until maximum vision is achieved and/or there are no signs of disease activity; the monitoring and treatment intervals should then be determined by the treating doctor. Treatment with Lucentis should be stopped if the patient is not benefitting from it.

For wet AMD and macular oedema, three or more consecutive monthly injections may be needed initially. For choroidal neovascularisation, treatment depends on the patient's condition: some patients may only need one or two injections during the first year of treatment, while some may need more frequent treatment.

The interval between two injections of Lucentis into the same eye must be at least four weeks. Before each injection, a local anaesthetic is given to reduce or prevent any pain from the injection, and the eye, eyelid and skin around the eye are disinfected. For more information, see the package leaflet.

How does Lucentis work?

The active substance in Lucentis, ranibizumab, is a small piece of a monoclonal antibody. A monoclonal antibody is an antibody (a type of protein) that has been designed to recognise and attach to a specific structure (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. These effects worsen the damage to the macula. By blocking this factor, ranibizumab reduces the growth of the blood vessels and controls the leakage and swelling.

What benefits of Lucentis have been shown in studies?

AMD

Three main studies of Lucentis involved 1,323 patients with the wet form of AMD. All of the patients were over 50 years of age and had not been treated for wet AMD before. Two of the studies compared Lucentis with a sham injection. This is a procedure that is similar to a Lucentis injection, but with no Lucentis and no needle, in which the syringe is pressed against the surface of the eye but no actual injection is carried out. The patients cannot tell whether they received Lucentis or the sham procedure. The third study compared Lucentis with verteporfin photodynamic therapy (PDT, another treatment for AMD). The main measure of effectiveness was the change in vision in the affected eye after a year of treatment, using a standard eye test with a letter chart. Patients were classified as having experienced no significant worsening of vision if the number of letters that they could see increased, stayed the same, or fell by less than 15.

Lucentis was more effective at preventing a worsening of vision than the comparison treatment. After one year, between 94 and 96% of the AMD patients receiving Lucentis every month experienced no significant worsening of their vision, compared with 62% of those receiving sham injections and 64% of those treated with verteporfin PDT. The vision of patients receiving Lucentis also remained better than the vision of those receiving sham injections in a study in which injections were given less frequently, with injections every month for the first three months and then every three months.

Choroidal neovascularisation

For choroidal neovascularisation other than that associated with wet AMD, Lucentis has been studied in 2 main studies each lasting a year. The main measure of effectiveness in both was the change in vision using a standard eye test with a letter chart. One study compared Lucentis with verteporfin PDT in 277 patients with choroidal neovascularisation associated with pathologic myopia (a severe type of short sightedness). On average over the first 3 months of treatment, patients given Lucentis could see around 8 to 9 letters more than those receiving verteporfin PDT.

A second study involved 178 patients with choroidal neovascularisation associated with other conditions, and compared Lucentis with a sham injection. After 2 months of treatment, patients given Lucentis could see around 10 letters more on average than those given sham treatment.

In both studies, the improvement in vision was maintained over the course of the study.

Diabetic macular oedema

For diabetic macular oedema, Lucentis was studied in two main studies involving a total of 454 patients. The first study compared Lucentis with a sham injection. The second study compared Lucentis, given on its own or as an add-on to laser photocoagulation (a treatment for diabetic macular oedema using a laser), with laser photocoagulation on its own.

Lucentis was more effective at improving vision than its comparison treatments. In the first study, over one year, patients receiving Lucentis could see about 6 letters more than those receiving sham injections. In the second study, patients receiving Lucentis on its own or as an add-on to laser photocoagulation could see over one year an average of 5 letters more than patients receiving laser photocoagulation on its own.

Macular oedema due to occlusion of retinal veins

For macular oedema due to retinal vein occlusion, Lucentis was looked at in two main studies involving a total of 789 patients, where Lucentis was compared with a sham injection. In both studies, the main measure of effectiveness was the change in vision in the affected eye, measured by comparing the number of letters that the patient could see at the end of the treatment period with the number before starting treatment.

Lucentis was more effective than a sham injection: patients receiving Lucentis at the 0.5 mg dose for six months could see around 11 letters more than patients receiving a sham injection in one study and 14 letters more in the other study.

What are the risks associated with Lucentis?

The most common side effects with Lucentis (seen in more than 1 in 10 patients) 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 (tear production), blepharitis (inflammation of the eyelids), dry eye, ocular hyperaemia (red 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. For the full list of all side effects reported with Lucentis, see the package leaflet.

Lucentis must not be used in patients who may have an infection of the eye or the area around the eye, or who have severe inflammation within the eye. For the full list of restrictions, see the package leaflet.

Why is Lucentis approved?

The CHMP decided that Lucentis's benefits are greater than its risks and recommended that it be given marketing authorisation.

What measures are being taken to ensure the safe and effective use of Lucentis?

The company that makes Lucentis will provide information packs to all clinics where Lucentis is expected to be used, including information for doctors on the measures needed to minimise the risk of infection associated with injections into the eye, and packs for patients to help them prepare for Lucentis 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 Lucentis have also been included in the summary of product characteristics and the package leaflet.

Other information about Lucentis

The European Commission granted a marketing authorisation valid throughout the European Union for Lucentis on 22 January 2007.

The full EPAR for Lucentis can be found on the Agency's website ema.europa.eu/Find_medicine/Human_medicines/European_Public_Assessment_Reports. For more information about treatment with Lucentis, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 10-2016.