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EPAR summary for the public

Macugen

pegaptanib

This is a summary of the European public assessment report (EPAR) for Macugen. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Macugen.

What is Macugen?

Macugen is a solution for injection into the eye that contains the active substance pegaptanib. It is available as a prefilled syringe.

What is Macugen used for?

Macugen is used to treat adults with the 'wet' form of age-related macular degeneration (AMD). This disease affects the central part of the retina called the macula at the back of the eye. The macula provides central vision that is needed to see detail for everyday tasks such as driving, reading and recognising faces.

The wet form of AMD is caused by the abnormal growth of blood vessels under the macula, which may leak fluid and blood and cause swelling. This causes the gradual loss of the central part of a person's vision.

The medicine can only be obtained with a prescription.

How is Macugen used?

Macugen should only be given by an ophthalmologist (eye specialist) who is experienced in giving intravitreal injections (injections into the vitreous humour, the jelly-like fluid in the eye). The pre-filled syringe contains more than the recommended dose, therefore when preparing the injection, the doctor must expel a certain volume and ensure the injection of the correct dose.



Macugen is given as one injection of 0.3 mg into the affected eye every six weeks. The procedure should be carried out under sterile conditions. Before each injection, a local anaesthetic will be given to reduce or prevent any pain from the injection. Antibiotic eye drops may also be given before and after the Macugen injection, to prevent eye infection. As Macugen when given by intravitreal injection can raise the pressure and cause bleeding within the eye, patients should be appropriately monitored after each injection. If, after two injections, no benefit is seen on the patient's eyesight, the treatment should be stopped or withheld.

How does Macugen work?

The active substance in Macugen, pegaptanib, is an 'aptamer'. An aptamer is a single strand of molecules called nucleotides that has been designed to attach to a specific molecule in the body. Pegaptanib has been designed to attach to and block a protein called vascular endothelial growth factor (VEGF). In the body, VEGF is involved in the growth of blood vessels and in making them more permeable. Pegaptanib injected into the eye blocks VEGF. This reduces the growth of blood vessels in the eye and controls the leakage and swelling.

How has Macugen been studied?

Macugen has been studied in two main clinical studies involving a total of 1,190 patients and lasting up to two years. The patients were given either Macugen (0.3 mg, 1 mg or 3 mg) or a 'sham' injection. This is a procedure that is similar to a Macugen injection, but with no Macugen and no needle, in which a syringe is pressed against the eye but nothing is actually injected. The main measure of effectiveness was the proportion of patients losing less than 15 letters in a standard eye test.

What benefit has Macugen shown during the studies?

After one year of treatment, about 70% of the patients treated with Macugen 0.3 and 1 mg lost less than 15 letters in the eye test compared with about 55% of those who received the sham injection. The 3 mg dose did not bring any additional benefit. This improvement lasted for two years in patients who were given Macugen.

What is the risk associated with Macugen?

The most common side effects with Macugen (seen in more than 1 patient in 10) are anterior chamber inflammation (inflammation of the front part of the eye), pain in the eye, raised intraocular pressure (increased pressure inside the eye), punctate keratitis (small marks on the eye surface) and vitreous floaters or opacities (small particles or spots in the vision). For the full list of all side effects reported with Macugen, see the package leaflet.

Sometimes, endophthalmitis (an infection inside the eye), vitreous haemorrhage (bleeding into the eye) and retinal damage can occur after Macugen treatment. It is important to treat these types of conditions as soon as possible. The symptoms of these conditions and instructions about what to do if a patient has these symptoms are explained in the package leaflet.

Macugen must not be used in people who are hypersensitive (allergic) to pegaptanib or any of the other ingredients. It must not be used in patients who have or are thought to have ocular or periocular infections (infections in or around the eyes).

Why has Macugen been approved?

The CHMP noted that in patients with wet AMD Macugen 0.3 mg had similar effects on vision loss as Macugen 1 mg, therefore the lower dose was selected for approval. The CHMP decided that Macugen's benefits are greater than its risks and recommended that it be given marketing authorisation.

What measures are being taken to ensure the safe use of Macugen?

The company that makes Macugen will provide educational material for doctors (to minimise the risks associated with the injection in the eye) and for patients (so they can recognise any serious side effects, and know when to seek urgent attention from their doctor).

Other information about Macugen

The European Commission granted a marketing authorisation valid throughout the European Union for Macugen on 31 January 2006.

The full EPAR for Macugen 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 Macugen, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 08-2012.