



North Shore Eye Centre

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LUCENTIS

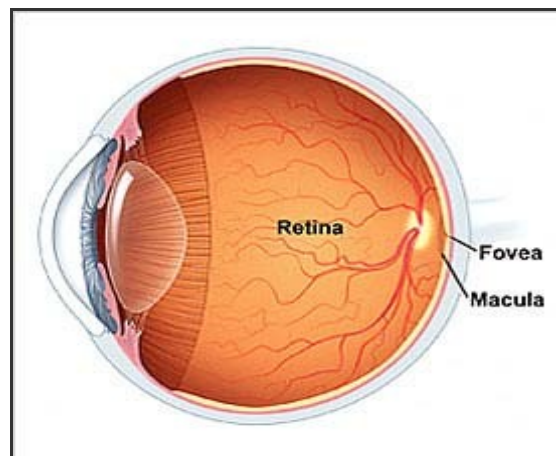


About Macular Degeneration

Macular degeneration is the degeneration of the central part of the retina (macula), which is responsible for central vision and can cause loss of vision. There are 2 types of macular degeneration: the 'dry' type and the 'wet' type. The dry type is generally caused by aging and thinning of the macular layers and results in a gradual loss of vision.

The wet type involves growth of abnormal blood vessels in the retina. These blood vessels are fragile and can leak fluid and blood, causing scar tissue to form behind the eye, and can lead to damage of the macula. This affects central vision, which is required for daily activities, causing distorted and blurred vision. The degeneration may result in rapid vision loss.

Treatment of macular degeneration (AMD) does not cure the disease but aims to stabilise the disease process and maintain the best vision for as long as possible.





New Treatment

Lucentis is a new form of treatment that is available for the treatment of macular degeneration. Until recently, treatments for macular degeneration could slow the progression of the disease and stabilise or reduce the rate of vision loss. Recently, a new treatment has become available that can result in actual improvement of vision.

What is Lucentis?

Lucentis (also known as Ranibizumab) is a form of medical treatment that has been developed to specifically treat the wet type of macular degeneration. Lucentis is made from a human antibody fragment and was developed by Genetec and Novartis. It is still in the process of being approved by regulatory authorities, and therefore is not yet available by prescription in Australia. However, it is available under the Authorised Prescriber Scheme or for use in accordance with the principles of the Special Access Scheme. The drug was approved by the US Food and Drugs authorities in June 2006 and is undergoing evaluation by the Therapeutic Goods Administration in Canberra as part of a program of obtaining approval throughout the world.

How Does Lucentis Work?

Vascular endothelial growth factor (VEGF) is a naturally occurring molecule that triggers the growth of new blood vessels and leakage of fluids and molecules from blood vessels. VEGF is responsible for the development of new abnormal blood vessels under the retina. Anti-VEGF therapy blocks the effect of new blood vessel growth and leakage. Lucentis is an anti-VEGF. It works by blocking a molecule (known as VEGF-A) that is thought to be the main form of vascular endothelial growth factor (VEGF) involved in the formation of abnormal new blood vessels as well as leakage from these blood vessels. Consequently Lucentis blocks blood vessel growth and leakage, which if left untreated would lead to progression of macular degeneration and vision loss.

How is Lucentis used?

An anaesthetic is used to numb the eye prior to the treatment. A small device may be used to keep the eyelids open. Lucentis is injected into the eye once every month. However, close monitoring is required for the detection of any signs of disease activity that would determine the need for re-injection. Following the injection of Lucentis, your eyes will be monitored to ensure that it is improving the eye condition and is not causing any harmful effects.



What are the risks?

Lucentis has been studied through clinical trials on patients with macular degeneration. Treatment with Lucentis has been linked to a number of side effects.

Serious side effects related to the injection are found to be rare. Serious side effects, which can result in loss of vision include:

- Inflammation inside the eye. Serious eye infection (endophthalmitis)
- Blockage of a major vein behind the eye (central retinal vein occlusion)
- Increased pressure inside the eye
- Cataract
- Detachment of the jelly-like substance in the eye (vitreous), detachment of the retina
- Bleeding behind the eye or bleeding into the vitreous

Other less serious side effects include:

- Watery eyes, blurred vision
- Itching sensation, foreign body feeling in the eye following the injection
- Bleeding of a small blood vessel at the front of the eye beneath the transparent surface layer (conjunctiva), causing the eye to appear bright red in colour. This will resolve in about a week.
- Inflammation of the conjunctiva (conjunctivitis)
- Small specks in the vision
- Decreased vision. During the period of treatment, there is a chance that vision may deteriorate. This may be related to the actual injection or may be due to the progression of the disease process of macular degeneration.

It is important to contact your eye doctor if you notice any unusual changes such as eye pain, redness, reduced vision, discharge from your eye, swelling around your eye, flashes of lights in your vision. Also, it is important to seek emergency medical help if you experience an allergic reaction such as skin rash, difficulty breathing and swelling of the face.

Tests have indicated that following the injection of Lucentis into the eye, small amounts can enter the blood stream. Although the degree of significance of this is not well understood, patients are carefully monitored for signs of side effects. In the clinical trials, non-ocular serious side effects were also infrequent. Possible effects on the body, which are found to be rare, include hypertension, myocardial infarction and cerebrovascular events.

Lucentis should be avoided in patients with hypersensitivity and infections associated with the eyes. Other side effects that have not been mentioned may also occur. It is important to contact your doctor about any side effects that seem unusual to you.



Results of Lucentis Treatment

There is no guarantee that this treatment will be beneficial. Results from controlled clinical trials support the use of Lucentis to treat AMD. The results have indicated that treatment with Lucentis in the form of monthly injections resulted in stabilised vision or improvement of vision. Approximately 95% of the participants that received a monthly injection of Lucentis maintained their vision, losing less than 15 letters compared to about 60% of patients who were given the control treatment. Also, up to 40% of participants demonstrated an actual improvement in their vision of at least 15 letters (3 lines) on the eye chart.

Trials for treatment of AMD have showed a positive outcome with a significant number of patients having a very good chance of stabilising or gaining vision, combined with reassuring safety results.

For further information regarding studies investigating treatment with Lucentis, refer to the document titled "Clinical Trials of Ranibizumab (Lucentis)"



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