

AVASTIN (BEVACIZUMAB) INTRAVITREAL INJECTION

This information leaflet is designed to help you understand about Avastin

The injections are given on ward 15 at the University Hospital of North Staffordshire. This leaflet is our hospital information leaflet for patients

1. EYE CONDITIONS THAT MAY BENEFIT FROM AVASTIN INJECTION

Bleeding source (new vessels) and **Macular Oedema** (swelling around the macula) that affect vision but have not responded adequately to the usual methods.

- **Bleeding source:**

Age-related Macular Degeneration (AMD) is the leading cause of blindness in people over 50 years of age. It is caused by the breakdown of the central portion of the retina (the nerve layer part of your eye) called the macula. The macula is responsible for the fine central vision in the eye that is needed for driving a car, reading fine print, recognising faces etc. There are two types of macular degeneration: dry and wet. In the **“wet” form of AMD**, abnormal blood vessels grow in the back of the eye. Sometimes these vessels leak blood or fluid that causes blurred or distorted vision. Without treatment, vision loss may be quick and severe.

There are other similar eye conditions that cause loss of central vision due to abnormal growth of blood vessels in the back of the eye. These can occur even in young patients, and include conditions such as high myopia (nearsightedness) and eye injury. Sometimes there is no known reason for the abnormal blood vessels. Without treatment vision loss may be quick and severe.

- **Macular oedema** can occur with conditions such as retinal vein occlusion, diabetic retinopathy, uveitis (inflammation of the eyes) and others. Without effective treatment vision loss could progress and become permanent.

2. WHAT IS AVASTIN?

Avastin was not initially developed to treat your eye condition. Based upon the results of clinical trials that demonstrated its safety and effectiveness, Avastin was approved by the Food and Drug Administration (FDA) in the USA for the treatment of metastatic colorectal cancer (in large dosage, given as infusion into veins).

As a conditional approval, the manufacturer produced a “label” explaining the indications, risks and benefits. The label explains that Avastin works by blocking a substance known as vascular endothelial growth factor (VEGF). Blocking or inhibiting VEGF helps prevent further growth of abnormal blood vessels.

3. WHAT DOES “OFF LABEL” MEAN?

Once a drug is approved for any indication, Doctors may use it “off-label” for other purposes if they are well-informed about the product, base its use on firm scientific method and sound medical evidence and maintain records of its use and effects.

Ophthalmologists are using Avastin “off-label” to treat eye diseases such as diabetic retinopathy, retinal vein occlusion and wet-age related macular degeneration since research indicates that VEGF is one of the causes for the growth of the abnormal vessels and leakage in these conditions.

4. HOW DOES IT WORK IN THE EYE?

When injected into your eye Avastin works on inhibiting the growth for abnormal blood vessels in the back of the eye. This drug targets a specific type of protein thought to cause abnormal blood vessel growth. By attacking the stimulus it can stop the blood vessels leaking and growing. In most cases, it actually causes the blood vessels to regress rapidly.

5. WHAT ARE THE LIMITATION?

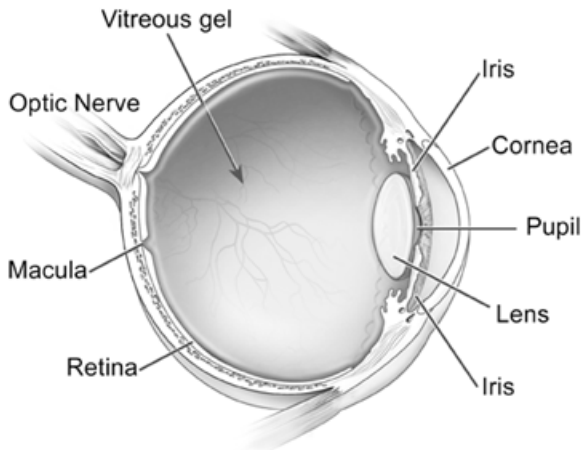
Although some patients have regained vision, the medication may not restore vision that has already been lost and may not ultimately prevent further loss of vision caused by the disease. Once a scar forms, we are unable to restore the vision but may be able to reduce the size of the original large central blind spot.

6. ARE THERE ALTERNATIVES?

You do not have to receive treatment for your condition, although without treatment, these diseases can lead to further vision loss and blindness, sometimes very quickly.

7. HOW IS THE TREATMENT GIVEN?

Avastin is given by an intravitreal injection. The drug is injected by retinal specialist into the vitreous gel, which is the jelly-like substance in the back chamber of your eye.



- This is a sterile procedure that takes place in our special sterile out-patient room.
- Local anaesthetic drops and injection are used to numb the eye before the procedure and antibiotic drops have to be instilled 4 days after your treatment.
- You should experience minimal or no pain after the procedure.
- This injection may have to be repeated at regular intervals (about every 4 to 6 weeks), our retinal specialist will tell you how often you will receive the injection and for how long by repeating tests and examining your eye.

8. WHAT ARE THE RISKS AND POSSIBLE COMPLICATIONS?

When Avastin is given to patients with metastatic colorectal cancer, some patients experience serious and sometimes life-threatening complications such as, gastrointestinal perforations or wound healing complications, haemorrhage, arterial thromboembolic events (such as stroke or heart attack), hypertension, proteinuria (protein in your urine) and congestive heart failure. Patients who experience these complications not only had metastatic colon cancer but were also given 400 times the dose you will be given, at more frequent intervals and in a way (through an intravenous infusion) that spreads the drug throughout their bodies.

9. WHAT ARE THE RISKS WHEN IT IS GIVEN TO ME IN MY EYE?

Ophthalmologists believe that the risk of these complications mentioned above is very low. Patients receiving Avastin for eye conditions are healthier than the cancer patients and receive a significantly smaller dose (0.05ml), delivered only to the cavity of their eye. While there are no FDA-approved studies about the use of Avastin in the eye that prove it is safe and effective, there are ongoing studies receiving Avastin off-label. Another similar drug (anti VEGF) Lucentis in the multicentre trials in the treatment of Age Related Macular Degeneration is found to be safe and effective.

One study of patients who received Avastin through an intravenous infusion reported only a mild elevation in blood pressure. Another study of patients treated like you with intravitreal Avastin (that is Avastin injected in to the eye) did not have these elevations or the other serious problems seen in the patients with cancer.

However, the risks of intravitreal Avastin for eye condition are not fully known. In addition, whenever a medication is used in a large number of patients, a small coincidental life-threatening problems may occur that have no relationship to the treatment. For example, patients with Diabetes are already at increased risk for heart attacks and strokes. If one of these patients being treated with Avastin suffers a heart attack or stroke, it may be caused by Diabetes and not the Avastin treatment.

10. RISKS OF ANY INTRAVITREAL EYE INJECTIONS

Serious complications are rare but may lead to severe, permanent loss of vision:

- The possibility of an eye infection, 1:1000 risk.
- You will receive eye drops with instructions on when to use them to reduce the possibility of this occurring.
- You should report to us immediately if you have developed a lot of eye pain, blood shot eye and blurred vision (with or without discharge).
- Contact the **Macular Assessment Clinic 01782 555141**

Other complications of less serious outcome:

- Glaucoma (increased pressure in the eye) – common with steroid injection only.

- Cataract formation (blurred vision due to clouding of the lens of the eye).
- Retinal detachment (floaters, shadow, reduce vision) is a rare risk.

Additional procedures may be needed to treat these complications, often with good outcome.

11. **POST INJECTION ADVICE**

- The eye in which you received an injection should have minimal or no discomfort. It may however be slightly bloodshot from the local anaesthetic given to you.
- You are advised to use the antibiotic eye drops 4 times a day to the injected eye for 4 days.
- You will be reviewed in 3 to 5 weeks time in clinic.
- You are advised to report to us as soon as possible if you experience any of the adverse events described above on **01782 555141**, Macular Assessment Clinic, Royal Infirmary, University Hospital of North Staffordshire.