



Patient Name Surname : **BARCODE**
File Number :
Education :
Job :
State of mind :

GENERAL INFORMATION

This information is given to you to help you make an informed decision about having cataract and/or lens implant surgery. Once you have read this **Informed Consent**, you are encouraged to ask any questions you may still have about the procedure. It is impossible to list all of the possible risks and complications associated with surgery. Risks and complications that are considered to be unforeseeable, remote, or commonly known may not be specifically discussed in this consent.

INDICATIONS

Your ophthalmologist has diagnosed you with a condition that might benefit from Ozurdex™ (dexamethasone). This drug is indicated to treat a blockage in one of the blood vessels of your eye: a branch retinal vein occlusion (BRVO) or central retinal vein occlusion (CRVO). The blockage causes swelling in the eye, loss of vision, and blurry vision. Ozurdex™ (dexamethasone) is also approved by the Food and Drug Administration to treat non-infectious uveitis affecting the posterior or back of your eye. Ozurdex™ (dexamethasone) is a biodegradable steroid implant used to reduce the swelling that occurs with blockages in the eye vessels and uveitis. It may improve how well you see. It may be used to treat other causes of swelling in the eye.

POSSIBLE LIMITATION AND ADMINISTRATION

The goal of treatment is to prevent further loss of vision. 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 your disease. After the eye is numbed with anesthesia, the implant is injected into the vitreous, the jelly-like substance in the back part of your eye. Ozurdex™ (dexamethasone) is administered by an injection into your eye as needed; your ophthalmologist will tell you how often you will receive the injections.

ALTERNATIVES

You do not have to receive Ozurdex™ (dexamethasone) for your condition, although without any treatment, diseases like yours can lead to further vision loss and blindness, sometimes very quickly. Two other medications are approved by the Food and Drug Administration (FDA) to treat RVO: Lucentis™ (ranibizumab) and Eylea™ (aflibercept). Some eye surgeons use an anti-VEGF drug called Avastin™ (bevacizumab) to treat AMD and refractory macular edema; this use of Avastin™ is off-label. Eye surgeons also use triamcinolone acetonide, a long-acting cortisone-like drug (Kenalog™, Triescence™, or Trivaris™) to treat eye conditions like yours. Your doctor will discuss with you the benefits and risks associated with these other choices of treatment.

COMPLICATIONS FROM THE MEDICATION AND INJECTION

Your condition may not get any better or may become worse. Any or all of the following complications may cause decreased vision or have the possibility of causing blindness. Additional medications or procedures, including surgery, may be needed to treat these complications. During the follow up visits, you will be checked for possible side effects and the results will be discussed with you.

COMPLICATIONS OF OZURDEX™ (DEXAMETHASONE)

Possible complications and side effects of the procedure and administration of Ozurdex™ (dexamethasone) include but are not limited to infection in and around the eye (endophthalmitis), retinal detachment, cataract, glaucoma, intraocular hemorrhage, inflammation, damage to the retina or cornea, eye discharge, vitreous floaters, alterations in vision, elevated or decreased intraocular pressure, loss of vision, and/or loss of eye. You may receive eye drops with instructions on when to use them to reduce the possibility of complications. This drug may make it easier for secondary infections caused by bacteria, fungi, or viruses to occur. The implant might migrate to the front of the eye if the capsule in the back is not intact. Any of these rare complications

may lead to severe, permanent loss of vision. The most common reactions to this drug are increased intraocular pressure and conjunctival bleeding (the mucous membrane covering the outer surface of the eye).

KNOWN RISKS OF INTRAVITREAL EYE INECTIONS

Patients receiving Ozurdex™ (dexamethasone) may experience less severe side effects related to the pre-injection preparation procedure (eyelid speculum, anesthetic drops, dilating drops, antibiotic drops, povidone-iodine drops and the injection of the anesthetic). These side effects may include eye pain, subconjunctival hemorrhage (bloodshot eye), vitreous floaters, irregularity or swelling of the cornea, inflammation of the eye, and visual disturbances.

PATIENT’S ACCEPTANCE OF RISKS

Patient consent

I acknowledge that the doctor has explained;

- My medical condition and the proposed procedure, including additional treatment if the doctor finds something unexpected. I understand the risks, including the risks that are specific to me.
- The anaesthetic required for this procedure. I understand the risks, including the risks that are specific to me.
- Other relevant procedure/treatment options and their associated risks.
- My prognosis and the risks of not having the procedure.
- There is no guarantee has been made that the procedure will improve my condition even though it has been carried out with due professional care.
- The procedure may include a blood transfusion.
- Tissues and blood may be removed and could be used for diagnosis or management of my condition, stored and disposed of sensitively by the hospital.
- If immediate life-threatening events happen during the procedure, they will be treated based on my discussions with the doctor or my Acute Resuscitation Plan.
- A doctor other than the Consultant may conduct the procedure. I understand this could be a doctor undergoing further training.

DOCTOR NOTE:

I have reviewed all **three (3)** pages of this Informed Consent. The cataract and/or lens implant surgery has been explained to me in terms that I understand. I have been informed about the possible benefits, risks, and contraindications associated with the surgery. I understand that it is impossible for my doctor to inform me of every conceivable complication that may occur, and that there may be unforeseen risks. I have been given the opportunity to ask questions and have received satisfactory answers to my questions. I understand that no guarantee of a particular outcome has been given, and that my vision could become better or worse following surgery.

- I was able to ask questions and raise concerns with the doctor about my condition, the proposed procedure and its risks, and my treatment options. My questions and concerns have been discussed and answered to my satisfaction.
- I understand I have the right to change my mind at any time, including after I have signed this form but, preferably following a discussion with my doctor.
- I understand that image/s or video footage may be recorded as part of and during my procedure and that these image/s or video/s will assist the doctor to provide appropriate treatment.
- If my ophthalmologist has informed me that if I have a high degree of hyperopic (farsightedness) and/or that the axial length of my eye is short, I am at increases risk for a rare complication known as nanophthalmic choroidal effusion. This complication could result in difficulties completing the surgery and implanting a lens, or other problems.
- If my ophthalmologist has informed me that if I have a high degree of myopia (nearsightedness) and/or that the axial length of my eye is long, I am at increased risk for a retinal detachment, whether or not I have surgery. Retinal detachments can lead to vision loss or blindness. Recent studies indicate that risk doesn’t increased by the surgery, although an older study using different techniques did find an increased risk.
- I authorize the physicians and other health care personnel involved in performing my cataract surgery and pre- and post-operative care to share with one another any information relating to my health, my vision, or my surgery that they deem relevant to providing me with care. I give my permission for Dr. to use my photograph for display or promotion.

