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## OZURDEX STEROID IMPLANT

### Treatment Leaflet and Patient Consent Form

Ozurdex® is licensed for treatment of patients with macular oedema (swelling of the back part of the eye) due to branch retinal vein occlusion (BRVO) or central retinal vein occlusion (CRVO) or uveitis.

BRVO and CRVO are medical conditions which occur when one of the retinal veins is blocked. The retina is the light sensitive tissue that lines the back of the eye and is responsible for the eyesight.

BRVO or CRVO usually occur when a retinal vein is either:

- "Pinched off" through the pressure of an artery lying on top of the vein; or
- Clogged with a blood clot or atherosclerotic plaque (fatty deposit in the wall of the artery); or
- Blocked due to an inflammatory condition

The macular oedema – a swelling and thickening of the macula – is a secondary condition to the retinal vein occlusion. The macula is a small area in the centre of the retina that contains a rich collection of nerve cells sensitive to light, fine detail, and colour.

The vein blocking causes the blood pressure to increase in the smallest vessels which causes them to bleed and leak fluid into the retina thus forming a macular oedema or swelling of the retina as well as loss of blood flow and inflammation. All these processes lead to painless decrease/loss of vision in the affected eye. A similar process occurs in other inflammatory eye conditions resulting in macular swelling. Ozurdex is licensed for vein occlusion and uveitis but Mr Tanner will also occasionally recommend it in other causes of macular swelling – If this is the case you should be aware that it would be an off label / unlicensed use of a licensed drug.

#### About Ozurdex®

Ozurdex® is a small biodegradable implant which is administered via a special applicator with a needle. It is applied as an ophthalmic intravitreal injection. This means that it is injected into the eye. Sufficient local anaesthetic is administered prior to the Ozurdex injection to ensure that you do not feel pain during the Ozurdex injection. The local anaesthetic is given in the form of drops or subconjunctival anaesthetic injection (under the outer covering layer on top of the white of the eye). This local anaesthetic injection is essentially painless.

Ozurdex® contains dexamethasone which is slowly released into the eye while the implant slowly dissolves into the eye (biodegrades). Dexamethasone belongs to a group of drugs called potent corticosteroids. It has been shown that it reduces inflammation, oedema, and thickening of the retina. That way, Ozurdex® can improve vision.

## **Risks associated with Ozurdex®**

All drugs can cause side effects in some people. Please read the section below in order to be aware of the most commonly reported side effects.

### **Very common side effects – might affect more than one patient in 10:**

- Increased pressure in the eye, bleeding on the surface of the eye

### **Common side effects – might affect one to 10 patients in 100:**

- High pressure in the eye
- Detachment of the jelly inside the eye (vitreous detachment)
- Clouding of the eye lens (cataract)
- Bleeding inside the eye
- Difficulties in seeing clearly, seeing the implant move within the eye
- A feeling of spots in front of the eye (including 'floaters')
- Eye pain
- Seeing flashes of light, swelling or scratching on the surface of the eye
- A feeling of looking through mist or fog
- Redness of the eye

### **Uncommon side effects – might affect one to 10 patients in 1,000:**

- Retinal tear
- Inflammation
- Migration of the implant from vitreous to front of eye
- Headache
- Decrease in eye pressure
- Loss of vision

Some of these side effects may be caused by the injection procedure and not the Ozurdex® implant itself – for example, bleeding on the surface of the eye, difficulties in seeing clearly, a feeling of spots in front of the eye (including 'floaters'), eye pain, seeing flashes of light, swelling or scratching on the surface of the eye, a feeling of looking through mist or fog, redness of the eye, decrease in eye pressure.

Please read this form carefully. If you have any further questions, please ask - we are here to help you. You have the right to change your mind at any time, even after you have signed the form.

## **Aftercare**

You can resume normal activities once you have been discharged from hospital. Please use the post-procedure antibiotic drops as advised. If you experience eye pain or loss of vision:

Please contact Mr Tanner's team on 0800 644 0700 or 0800 644 0900

Out of hours Main Hospital Switchboards are :

Princess Margaret Hospital, Windsor - 01753 743434

Spire Dunedin Hospital, Reading - 01189 587676

Circle Hospital, Reading - 0118 922 6888

Eye Casualty at Royal Berkshire Hospital, Reading - 0118 322 7162/3

**PATIENT CONSENT**

Patient details

The above explanation has been read by/to me. The nature of my eye condition has been explained to me and the proposed treatment has been described. The risks, benefits, alternatives, and limitations of the treatment have been discussed with me. All my questions have been answered.

I hereby authorise Mr Tanner to administer OZURDEX injections to my left right or both eyes at regular intervals as needed.

\_\_\_\_\_  
Patient's Signature

\_\_\_\_\_  
Date

**Confirmation of consent**

I have confirmed with the patient that he or she has no further questions and wishes the procedure to go ahead.

Mr Vaughan Tanner ..... Date .....