

Patient Information

Ozurdex implant treatment for diabetic macular oedema (DMO)

Introduction

Your doctor has found that you have leakage of blood vessels, causing swelling at the back of your eye (the macula). This occurs as a result of different conditions, including diabetes, blockage of the veins at the back of the eye, cataract surgery and inflammation. If left untreated, it may result in a permanent reduction in your vision in that eye.

In your case, the swelling at the macula is due to a diabetes-related change. Your eye doctor has already given you a patient information booklet about diabetic eye disease and its treatment. This leaflet describes a treatment available to reduce the swelling in your eye – Ozurdex implant eye injections.

What are Ozurdex implant eye injections?

The injections work by penetrating into the nerve layer at the back of the eye (the retina, see figure 1). The macula is the most important part of the retina and is responsible for your central vision. Over time, the injections close up the leaking blood vessels affecting the macula. This should reduce the swelling in the area, and hopefully improve your vision.

Depending on how your eye responds to the treatment, these injections can be repeated again after four months. If necessary, you can have up to seven injections over a three-year period.

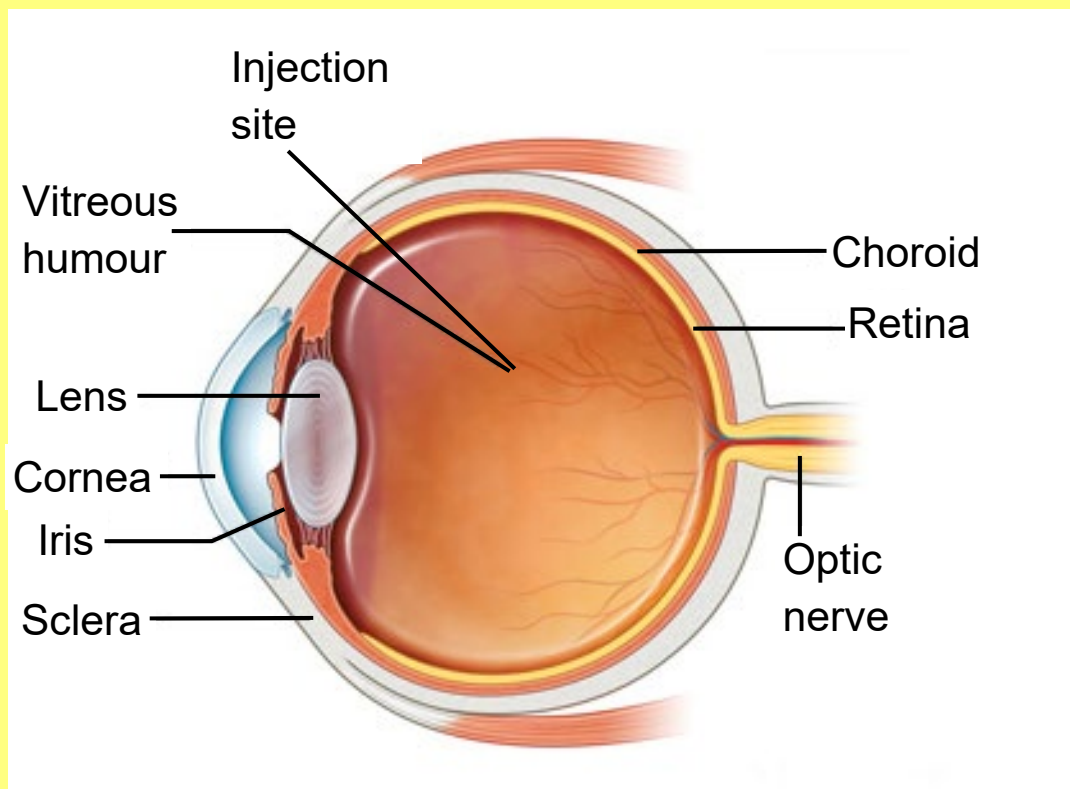


Figure 1 shows the side image of an eye (image courtesy of NHS Choices)

Studies have shown that the implant is effective. Ozurdex implants were approved by the National Institute for Health and Care Excellence (NICE) in 2015 for the treatment of diabetic central retinal swelling where a treatment called laser photocoagulation has not been adequate. The active substance in Ozurdex is dexamethasone. Dexamethasone belongs to a group of medicines called steroids.

How long am I consenting for treatment?

You will be given an indefinite course of treatment, unless you withdraw consent or lose capacity.

Will my vision improve with the injections?

Studies have shown that people who had an Ozurdex implant had a reduction in macular swelling after three years. Compared to those having no treatment, they had improved eyesight and were able to read up to two lines more on the eye chart.

Fewer patients had decreased eyesight three years after the treatment than those who did not have treatment.

What are the benefits of the implant?

The benefits of the treatment are:

- It should reduce inflammation and swelling in the macula of your eye.
- It can also help improve vision and prevent further damage.

What are the risks?

It is important that you know about the risks of the treatment:

- About seven in every 10 people may get a cataract. However, in the UK, the implant is only used in patients who have already had cataract surgery.
- Glaucoma (about four in every 10 people may get this).
- Bleeding in the eye (about two in every 10 people may get this).
- Less than one person in every 100 may get the following:
 - Less than 0.5 per cent of patients may have an eye infection (Endophthalmitis), leading to complete loss of vision (blindness).
 - Retinal detachment.
 - Lens detachment.

Some of these complications can lead to blindness. Medications or procedures, including surgery, may be needed to treat these complications.

Other less serious side effects include floaters in your vision, damage to the retina or cornea (structures of the eye), a headache, inflammation of the eye and bleeding. Again, medications or procedures may be needed to treat these side effects.

What are the limitations?

The goal of the treatment is to prevent any further loss of vision. Although some patients have improved vision after the injections, the medication may not bring back vision that has already been lost. It may not prevent further loss of vision caused by diabetes.

What are the alternatives?

Your doctor will be happy to discuss alternative treatments. However, these may not be as effective in controlling your condition, or may have more serious side effects than the Ozurdex implant.

Alternatives include laser treatment (which you may have already had) and another type of injection called anti-vascular endothelial growth factor (anti-VEGF) therapy which currently includes Ranibizumab (Ongavia), Aflibercept (Eylea) and Faricimab (Vabysmo) intravitreal injections.

What happens before the treatment?

Please take your usual medication and eye drops on the day of your injection appointment. Before your injection, you will be given a tablet and eye drops to lower your eye pressure. If you want, you can take paracetamol tablets on the morning of the injection, if you can take them (always read the label; do not exceed the recommended dose).

What happens during the treatment?

The eye doctor will put numbing anaesthetic drops into your eye. This means you should not feel anything during the procedure. When your eye is numb, the eye doctor will deliver the Ozurdez implant through a tiny needle into the jelly (vitreous) part of your eye. While this is happening, you may feel some pressure on your eye.

The implant then slowly dissolves, releasing dexamethasone which stops inflammation, leakage from the retinal blood vessels and swelling. You will not need to stay in hospital.

What happens after the treatment?

Most patients will not have any eye drops after the injection however a small number of patients may be given antibiotic drops for five days after the treatment. Your doctor will discuss this with you. You can take a couple of paracetamol tablets (500mg) on the morning of the injection or afterwards (if not allergic) if necessary.

Please continue to take any other eye drops that you already use (such as, for glaucoma). After the injection, your eye will be covered by an eye shield to protect it. Please keep the shield on the eye until the next morning.

Is there any reason why I cannot have the implant?

- The implant cannot be given to people who have glaucoma or significant increased eye pressure.
- It will not be used if you have an infection or inflammation in or around the surrounding tissues of the eye.
- Additional support maybe needed for patients who may find local anaesthetic difficult to tolerate due to cognitive impairment. In this case, alternative solutions will be discussed with the patient and those who support them.

Advice after eye injections

What should I expect after the injection?

Your eye may feel painful for up to 48 hours. Rarely, the surface of the eye can get scratched during the injection process. This can cause sharp, sudden pains for three to six hours after the injection. This is easy to treat, so please get in touch with the Urgent Referral team at the hospital if this happens:

**The Urgent Referral Clinic team at Russells Hall Hospital Eye Clinic:
01384 456111 ext. 3633 (9am to 4.30pm Monday to Friday)**

If necessary, you can take painkillers such as paracetamol or ibuprofen if you can take them (always read the label, do not exceed the recommended dose). It is best to avoid products containing aspirin. However, if you take regular soluble aspirin (75mg), you can continue to take it as advised by your GP.

If you have bruising on or around the eye, this should fade gradually over the next couple of weeks.

At times, a tiny air bubble can be introduced into the eye during the injection. This appears as a round, dark floater in the centre of your vision the day after the injection. Do not be alarmed, as this will get smaller and should disappear within 48 hours.

What do I need to do?

If you have an eye pad to prevent the cornea from being scratched or damaged, you can gently remove this the next morning. The eye pad may be slightly bloodstained, but this is nothing to worry about.

You can clean your eye the morning after your injection with cool, boiled water and a small piece of cotton wool or lint. Close your eye first, and then gently wipe from the inner corner of the eye to the outer corner of the eye, using a fresh piece of cotton wool or lint each time and for each eye.

If you were prescribed antibiotic drops, continue to use them at home for five days. If you have been prescribed glaucoma eye drops, you should use them on the morning of the injection, but not after the injection for the rest of that day. The next day you should start your glaucoma eye drops again using a new bottle.

What if I have any problems or questions after reading this leaflet?

Please contact the **Urgent Referral Clinic** team at Russells Hall Hospital Eye Clinic on 01384 456111 ext. 3633 (9am to 4.30pm, Monday to Friday).

Eye emergency, out of hours

In case of an eye emergency after the closing hours of the Eye Clinic at Russells Hall Hospital (including weekends and bank holidays), please contact:

Birmingham and Midland Eye Centre on 0121 507 4440

The doctor on call is usually based at the Eye Centre, City Hospital, Dudley Road, Birmingham. They may need to call you back, and if necessary, they will arrange for you to visit them.

Can I find out more?

You can find out more from the following weblink:

RNIB

<http://www.rnib.org.uk/eye-health-eye-conditions-z-eye-conditions/understanding-eye-conditions-related-diabetes>

Reference

Boyer DS, Yoon YH, Belfort R Jr, Bandello F, Maturi RK, Augustin AJ, Li XY, Cui H, Hashad Y, Whitcup SM and Ozurdex MEAD Study Group (2014). Three-year, randomized, sham-controlled trial of dexamethasone intravitreal implant in patients with diabetic macular edema. *Ophthalmology*. 121(10):1904-1914.

Fraser-Bell S, Lim LL, Campain A, Mehta H, Aroney C, Bryant J, Li J, Quin GJ, McAllister IL and Gillies MC (2016). Bevacizumab or Dexamethasone Implants for DME: 2-year Results (The BEVORDEX Study). *Ophthalmology*. 123(6):1399-1401.

NICE guidance (TA824 – September 14, 2022)

Ozurdex implants can be given to patients with non-responding diabetic macular oedema, who are phakic (still have their natural lens).

Note: The information in this booklet is provided for information only. The information found is **not** a substitute for professional medical advice or care by a qualified doctor or other health care professional. **Always** check with your doctor if you have any concerns about your condition or treatment.

This is only indicative and general information for the procedure. Individual experiences may vary and all the points may not apply to all patients at all times. Please discuss your individual circumstances with your eye doctor.

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<http://dgft.nhs.uk/services-and-wards/ophthalmology/>

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