

An Injector's Guide to OZURDEX® *(dexamethasone intravitreal implant) 0.7 mg*

This guide is intended to provide injectors with information on the recommended injection technique and the important risks related to the intravitreal injection of OZURDEX®.

A patient guide is also available. This provides information on what the patient needs to do before their treatment, what to expect during the treatment and what to look out for after the treatment. Please ensure that your patients are provided with a copy of and fully understand this guide prior to their treatment.

Before treating the patient with OZURDEX®

Prior to the day of treatment, you should;

- Explain why this treatment is recommended and what to expect during and after treatment.
- Instruct the patient to use broad spectrum antimicrobial drops daily for 3 days before treatment.

Preparing the patient for intravitreal injection with OZURDEX®

Treatment should always be administered under aseptic conditions (including preparing the patient and the intravitreal injection itself). Use sterile gloves, a sterile drape and a sterile eyelid speculum and topical antiseptic.

Prior to treating your patient, you should;

- Administer a broad-spectrum antimicrobial drop if the patient has not done so for the previous 3 days.
- Prepare the eye and periorcular skin using microbiocides; It is recommended that 2 drops of 5% povidone-iodine should be administered onto the conjunctiva prior to the injection.
- Give adequate local anaesthesia just prior to injection

Preparing the OZURDEX® delivery system

Each OZURDEX® delivery system contains 0.7 mg dexamethasone in a solid polymer implant.

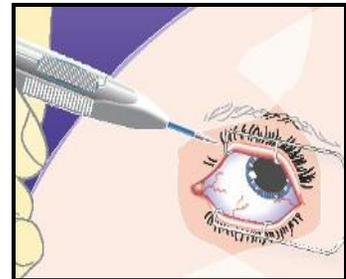
The OZURDEX® delivery system is designed to be a single use applicator. Each implant is supplied in a preloaded, single-use applicator. A separate applicator must be used for each eye treated.

To prepare the delivery system, the following steps should be followed;

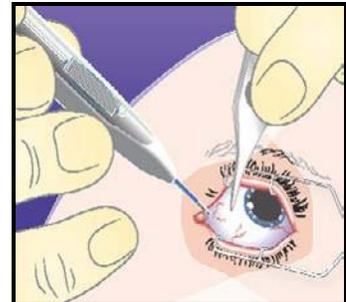
- 1) Remove the foil pouch containing the OZURDEX® applicator from the carton and check it is not damaged. Remove the applicator from the foil in a sterile environment and place on a sterile tray.
- 2) Using aseptic technique, remove the cap from the applicator carefully. The applicator should be used immediately after opening the foil pouch.
- 3) Hold the applicator in one hand and pull the safety tab straight off; do not twist or flex the tab.

Administering OZURDEX®

- 1) Hold the long axis of the applicator parallel to the limbus.



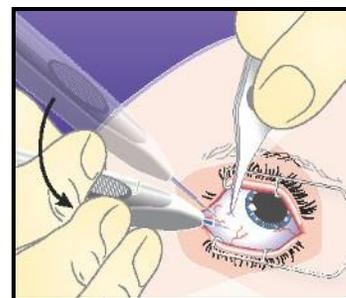
- 2) Allow the applicator to meet the sclera at an oblique angle with the bevel of the needle facing up, away from the sclera. Push the tip about 1 mm into the sclera, keeping it parallel to the limbus.



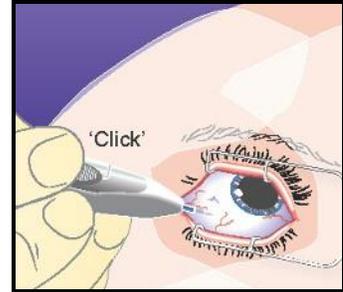
- 3) Redirect towards the centre of the eye into the vitreous cavity. This will create a shelved scleral path.

Advance the needle until you enter the vitreous cavity.

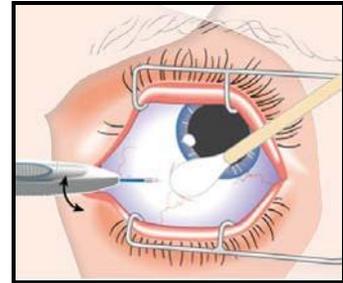
Do not advance the needle past the point where the sleeve of the applicator touches the conjunctiva.



- 4) Depress the actuator button slowly until you hear a click. Before withdrawing the applicator from the eye, make sure that the actuator button is fully depressed and has locked flush with the applicator surface.



- 5) Withdraw the applicator in the same direction that you used to enter the vitreous.



- 6) Dispose of the applicator safely immediately after treatment. The OZURDEX[®] applicator is for single use only.

Monitoring patients after OZURDEX[®] injection

Following the intravitreal injection, the patient should continue to use an antimicrobial drop for 3 days. It is important to monitor patients carefully after OZURDEX[®] injection.

The following checks should be completed after treatment with OZURDEX[®]:

- Immediately: Check reperfusion of the optic nerve head, and use indirect ophthalmoscopy to examine the vitreous cavity for evidence of the injected implant.
- Within 30 minutes: Tonometry
- After 2-7 days: Biomicroscopy
- After 7 days: Check for elevated intraocular pressure and signs of endophthalmitis

Reassure the patient that they may experience eye pain or blurred vision just after their treatment. This should be temporary but they should not drive or use machinery until their vision has cleared. Advise patients of the possible side effects and ask them to immediately report any of these symptoms if they occur in the days after their OZURDEX[®] treatment:

- Decreased visual acuity
- Ocular pain or significant discomfort
- Ocular redness which worsens
- Impression of floaters

- Ocular discharge

Ensure the patient has received a copy of the patient guide to help early capture of symptoms which may be associated with these events.

Management of intravitreal (IVT) injection adverse events

IVT injections, including those with OZURDEX[®], can be associated with the following risks;

- Raised intraocular pressure/Glaucoma
- Endophthalmitis
- Necrotizing retinitis
- Cataract/traumatic cataract related to injection technique
- Vitreous detachment/haemorrhage
- Retinal tear/detachment
- Significant vitreous leak or hypotony
- Implant misplacement
- Device dislocation (implant migration to anterior chamber)

Further information regarding the management of possible IVT injection related adverse events is provided below:

Raised intraocular pressure/Glaucoma: If detected, immediate treatment with IOP-lowering medications is needed. In the clinical development studies, only a small number of patients required a surgical procedure to reduce intraocular pressure. Consultation with a glaucoma specialist is recommended if IOP elevation persists.

Endophthalmitis: If suspected, immediate treatment with antibiotics is usually needed if vision is to be preserved. The choice of antibiotic may be adjusted depending on which organism is found to be causing the endophthalmitis. Eyes with moderate inflammation can be treated by either topical or systemic antibiotics and steroid treatment. Eyes with severe inflammation may require pars plana vitrectomy because of dense vitreous opacity.¹ Surgery may be needed to remove infected tissue from inside the eye which may improve the chances of stopping the infection.

Necrotizing retinitis: If suspected, immediate medical intervention (e.g. anti-viral therapy) is needed. Patients with active or suspected ocular or periocular infection including most viral diseases of the cornea and conjunctiva, including active epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, varicella, mycobacterial infections, and fungal diseases should not be treated with OZURDEX[®].

Cataract/traumatic cataract related to injection technique: If observed, cataract should be managed per the standard procedure. Of note, the incidence of cataract increases with the number of injections.

Vitreous detachment: No treatment of vitreous detachment is considered necessary unless patient develops complications in which case treatment must be considered on a case by case basis.

Vitreous haemorrhage: If observed, treatment should be determined on a case by case basis. Most vitreous haemorrhage occurring after OZURDEX® treatment resolved spontaneously.

Retinal tear/detachment: Treatment should be determined on a case by case basis.

Conjunctival haemorrhage: This is a minor adverse event that usually resolves by itself in about 1 week; no formal treatment is required.²

Implant misplacement: In the case of implant misplacement the ophthalmologist must evaluate, case by case, the risk associated with its explantation based upon the location of the implant.

Device dislocation (migration of implant): To minimise the risk of device dislocation, implantation of OZURDEX® to eyes with rupture of posterior lens capsule which are aphakic or with anterior chamber intraocular lens, iris or transcleral fixated is contraindicated.

All other patients with a posterior capsule tear, such as those with a posterior lens (e.g. due to cataract surgery), and/or those who have an iris opening to the vitreous cavity (e.g. due to iridectomy) with or without a history of vitrectomy, are at risk of implant migration into the anterior chamber.

Migration of implant to anterior chamber may cause corneal oedema. Persistent severe corneal oedema could progress to the need for corneal transplantation. The ophthalmologist must evaluate on a case by case basis if usage of OZURDEX® is advisable. These patients should be closely monitored to allow early diagnosis and management. These patients should be instructed to report immediately any signs or symptoms suggestive of implant migration into the anterior chamber and/or blurred vision. If implant migration into the anterior chamber is confirmed, the ophthalmologist must evaluate on a case by case basis if an explantation is necessary.

Reporting of Adverse events

For a detailed list of possible adverse effects, please refer to the currently approved OZURDEX® SmPC.

References

All of the information in this document is taken from the Summary of Product Characteristics (SmPC) expect for the following;

1. Yamashiro K, *et al. Retina*. 2010;**30**:485-90
2. University of Maryland Medical Center Medical Reference.
<http://www.umm.edu/ency/article/001616trt.htm>. Accessed 4 June 2010.