Injection Technique Quick-Reference Guide

Includes Ordering and Support Information

PRECISION PROGRAM

Companion booklet for the *Video Guide to Injection Technique*

Available at

OzurdexPrecisionProgram.com

Provides step-by-step directions with clinical photographs

Indications and Usage

Diabetic Macular Edema: OZURDEX® (dexamethasone intravitreal implant) is a corticosteroid indicated for the treatment of diabetic macular edema.

Retinal Vein Occlusion: OZURDEX® is a corticosteroid indicated for the treatment of macular edema following branch retinal vein occlusion (BRVO) or central retinal vein occlusion (CRVO).

Posterior Segment Uveitis: OZURDEX® is indicated for the treatment of noninfectious uveitis affecting the posterior segment of the eye.

IMPORTANT SAFETY INFORMATION

Contraindications

Ocular or Periocular Infections: OZURDEX® (dexamethasone intravitreal implant) is contraindicated in patients with active or suspected ocular or periocular infections including most viral diseases of the cornea and conjunctiva, including active epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, varicella, mycobacterial infections, and fungal diseases.

Please see additional Important Safety Information on page 3.

Ozurdex®
(dexamethasone intravitreal implant) 0.7 mg

OZURDEX® (dexamethasone intravitreal implant)

FDA-approved indications[1]

- Diabetic macular edema
- Macular edema following branch or central retinal vein occlusion
- Noninfectious posterior segment uveitis

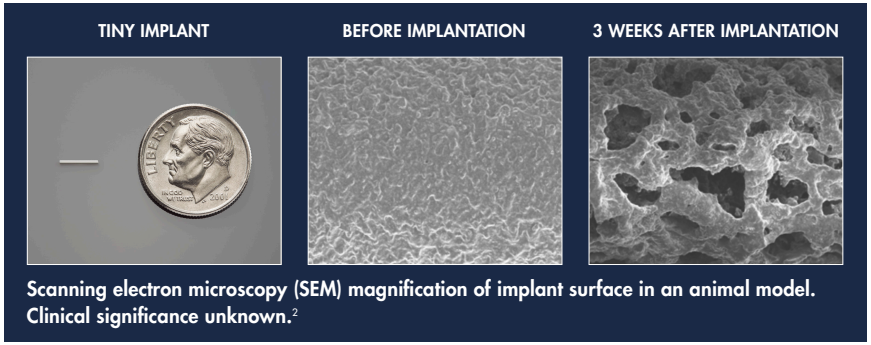
Delivers intravitreal dexamethasone via NOVADUR® technology[1]

- A sustained-release, biodegradable steroid implant[1]
  - —Solid polymer matrix contains 0.7 mg of dexamethasone, a corticosteroid[1]
  - —Biodegrades to lactic acid and glycolic acid[1]
  - —Administered by injection as an in-office procedure

Dosage and Administration
FOR OPHTHALMIC INTRAVITREAL INJECTION. The intravitreal injection procedure should be carried out under controlled aseptic conditions. Following the intravitreal injection, patients should be monitored for elevation in intraocular pressure and for endophthalmitis. Patients should be instructed to report any symptoms suggestive of endophthalmitis without delay.

An important treatment option in retinal medicine

OZURDEX® implant



Scanning electron microscopy (SEM) magnification of implant surface in an animal model. Clinical significance unknown.[2]

OZURDEX® applicator

- Sterile, single-use applicators are supplied preloaded with an implant[1]
- Includes second-generation needle
- Implants are administered using a shelved injection technique[1]

IMPORTANT SAFETY INFORMATION (continued)
Contraindications (continued)
Glaucoma: OZURDEX® (dexamethasone intravitreal implant) is contraindicated in patients with glaucoma, who have cup to disc ratios of greater than 0.8.

Torn or Ruptured Posterior Lens Capsule: OZURDEX® is contraindicated in patients whose posterior lens capsule is torn or ruptured because of the risk of migration into the anterior chamber. Laser posterior capsulotomy in pseudophakic patients is not a contraindication for OZURDEX® use.

Please see additional Important Safety Information on page 4.

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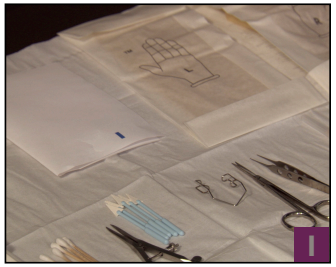
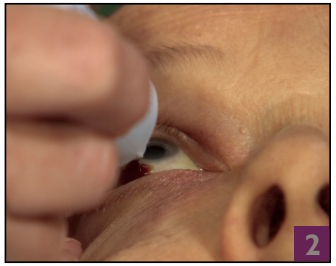
Recommendations for aseptic technique, antimicrobial prophylaxis, and anesthesia

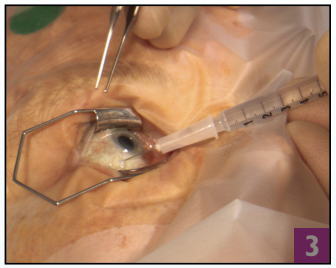
1. Both preparation and the intravitreal injection procedure should be carried out under controlled aseptic conditions, which include the use of sterile gloves, a sterile drape, and a sterile eyelid speculum (or equivalent).



2. A broad-spectrum microbicide applied to the periocular skin, eyelid, and ocular surface is recommended to be given prior to the injection.



3. Adequate topical anesthesia should also be administered before the intravitreal injection. Topical and subconjunctival anesthesia was used in the phase 3 clinical trials of OZURDEX® (dexamethasone intravitreal implant).[3]



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IMPORTANT SAFETY INFORMATION (continued)
Contraindications (continued)
Hypersensitivity: OZURDEX® (dexamethasone intravitreal implant) is contraindicated in patients with known hypersensitivity to any components of this product.

4. Remove the foil pouch from the carton and examine it for damage. Then, in a sterile field, open the foil pouch and gently drop the applicator on a sterile tray.

Each applicator can only be used for the treatment of a single eye

- If the contralateral eye requires treatment, a new applicator must be used, and the sterile field, syringe, gloves, drapes, and eyelid speculum should be changed before OZURDEX® (dexamethasone intravitreal implant) is administered to the other eye

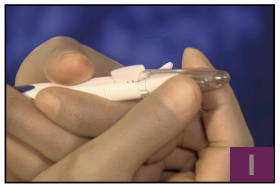
IMPORTANT SAFETY INFORMATION (continued)
Warnings and Precautions
Intravitreal Injection-related Effects: Intravitreal injections, including those with OZURDEX® (dexamethasone intravitreal implant), have been associated with endophthalmitis, eye inflammation, increased intraocular pressure, and retinal detachments. Patients should be monitored regularly following the injection.

Please see additional Important Safety Information on page 6.

Ozurdex® (dexamethasone intravitreal implant) 0.7 mg

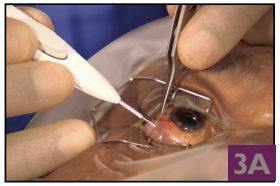
Before injecting, carefully follow the preparation procedure provided on pages 4-5 of this booklet

1. Maintaining aseptic technique, carefully remove the cap from the applicator.



2. Hold the applicator in one hand and pull the safety tab straight off the applicator. **Do not twist or flex the tab.**

3A-3B. The long axis of the applicator should be held parallel to the limbus, and the sclera should be engaged at an oblique angle with the bevel of the needle up (away from the sclera) to create a shelved scleral path. The tip of the needle is advanced within the sclera for about 1 mm (parallel to the limbus), then redirected toward the center of the eye and advanced until penetration of the sclera is completed and the vitreous cavity is entered. The needle should not be advanced past the point where the sleeve touches the conjunctiva.



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IMPORTANT SAFETY INFORMATION (continued)
Warning and Precautions (continued)
Steroid-related Effects: Use of corticosteroids including OZURDEX® (dexamethasone intravitreal implant) may produce posterior subcapsular cataracts, increased intraocular pressure, glaucoma, and may enhance the establishment of secondary ocular infections due to bacteria, fungi, or viruses.

Corticosteroids are not recommended to be used in patients with a history of ocular herpes simplex because of the potential for reactivation of the viral infection.

4. Slowly depress the actuator button until an audible click is noted.

5. Before withdrawing the applicator from the eye, make sure that the actuator button is fully depressed and has locked flush with the applicator surface.

6. Remove the needle in the same direction used to enter the vitreous.

7. Properly dispose of applicator.

IMPORTANT SAFETY INFORMATION (continued)
Adverse Reactions
Diabetic Macular Edema
Ocular adverse reactions reported by greater than or equal to 1% of patients in the two combined 3-year clinical trials following injection of OZURDEX® for diabetic macular edema include: cataract (68%), conjunctival hemorrhage (23%), visual acuity reduced (9%), conjunctivitis (6%), vitreous floaters (5%), conjunctival edema (5%), dry eye (5%), vitreous detachment (4%), vitreous opacities (3%), retinal aneurysm (3%), foreign body sensation (2%), corneal erosion (2%), keratitis (2%), anterior chamber inflammation (2%), retinal tear (2%), eyelid ptosis (2%). Non-ocular adverse reactions reported by greater than or equal to 5% of patients include: hypertension (13%) and bronchitis (5%).

Please see additional Important Safety Information on page 8.

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Recommended follow-up[1]

Patients should be monitored for elevation in intraocular pressure (IOP) and for endophthalmitis. Monitoring may consist of the following:

- Perfusion check of the optic nerve head immediately after injection
- Tonometry within 30 minutes following the injection
- Biomicroscopy between 2 and 7 days following the injection

IMPORTANT SAFETY INFORMATION (continued)
Adverse Reactions (continued)
Diabetic Macular Edema (continued)
Increased Intraocular Pressure: IOP elevation greater than or equal to 10 mm Hg from baseline at any visit was seen in 28% of OZURDEX® patients versus 4% of sham patients. 42% of the patients who received OZURDEX® were subsequently treated with IOP-lowering medications during the study versus 10% of sham patients.

The increase in mean IOP was seen with each treatment cycle, and the mean IOP generally returned to baseline between treatment cycles (at the end of the 6-month period).

Please see additional Important Safety Information on page 10.

Recommended follow-up[1] (continued)

Patients should be counseled regarding the risk of potential complications including, but not limited to, endophthalmitis, elevated IOP, or cataract

- Inform patients of the need to be vigilant for new symptoms in the days following intravitreal injection
- Stress the importance of seeking immediate care from an ophthalmologist if the eye becomes red, sensitive to light, painful, or develops a change in vision
- Advise patients that they may develop increased IOP with OZURDEX® (dexamethasone intravitreal implant) treatment, and the increased IOP will need to be managed with eye drops and, rarely, with surgery
- Advise patients that a cataract may occur after repeated treatment with OZURDEX®, which may decrease their vision and require a procedure to remove the cataract and restore their vision
- Also advise patients that they may experience temporary visual blurring after receiving an intravitreal injection
  - They should not drive or use machines until the blurring has resolved

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Ordering information

Order online or by phone

FOR ONLINE ORDERS	FOR PHONE ORDERS
AllerganDirect.com • Convenient and secure • Offers on-demand flexibility • A complete solution—from placing orders to paying bills • Online tools to help accelerate ordering OZURDEX® (dexamethasone intravitreal implant) • Options to help manage your Allergan relationship according to your schedule and specific needs	**OZURDEX® Hotline** • Just dial to order **1-866-OZURDEX (698-7339)** To order OZURDEX®: ***Press 1***

OZURDEX® is available only by direct order from Allergan

PRODUCT INFORMATION		
SIZE	**DESCRIPTION**	**NDC**
0.7-mg implant	OZURDEX® (dexamethasone intravitreal implant) preloaded in a single-use applicator	0023-3348-07

IMPORTANT SAFETY INFORMATION (continued)

Adverse Reactions (continued)

Diabetic Macular Edema (continued)

Cataracts and Cataract Surgery: The incidence of cataract development in patients who had a phakic study eye was higher in the OZURDEX® (dexamethasone intravitreal implant) group (68%) compared with Sham (21%). The median time of cataract being reported as an adverse event was approximately 15 months in the OZURDEX® group and 12 months in the Sham group. Among these patients, 61% of OZURDEX® subjects versus 8% of sham-controlled subjects underwent cataract surgery, generally between Month 18 and Month 39 (Median Month 21 for OZURDEX® group and 20 for Sham) of the studies.

Support hotline

For support services, call the OZURDEX® hotline

1-866-OZURDEX (698-7339)

REIMBURSEMENT INFORMATION AND ASSISTANCE: *Press 3*

- You will be connected with a specially trained representative from Allergan reimbursement services
- You can also access reimbursement assistance at AllerganEyeCue.com

Allergan EyeCue®

ALLERGAN MEDICAL INFORMATION DEPARTMENT: *Press 5*

- For all other questions regarding OZURDEX®

Visit Ozurdex.com for more information about OZURDEX®

IMPORTANT SAFETY INFORMATION (continued)

Adverse Reactions (continued)

Retinal Vein Occlusion and Posterior Segment Uveitis

Adverse reactions reported by greater than 2% of patients in the first 6 months following injection of OZURDEX® (dexamethasone intravitreal implant) for retinal vein occlusion and posterior segment uveitis include: intraocular pressure increased (25%), conjunctival hemorrhage (22%), eye pain (8%), conjunctival hyperemia (7%), ocular hypertension (5%), cataract (5%), vitreous detachment (2%), and headache (4%).

Increased IOP with OZURDEX® (dexamethasone intravitreal implant) peaked at approximately week 8. During the initial treatment period, 1% (3/421) of the patients who received OZURDEX® required surgical procedures for management of elevated IOP.

Please see additional Important Safety Information on back cover.

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PRECISION PROGRAM

Essential information for new injectors

Visit OzurdexPrecisionProgram.com to watch the companion video of the full injection procedure. The site also features a range of valuable office resources, including:

- OZURDEX® Ordering & Support Hotline Reference Card
- Helpful Patient Guides

Visit Ozurdex.com for more information about OZURDEX®

IMPORTANT SAFETY INFORMATION (continued)
Contraindications
Ocular or Periocular Infections: OZURDEX® (dexamethasone intravitreal implant) is contraindicated in patients with active or suspected ocular or periocular infections including most viral diseases of the cornea and conjunctiva, including active epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, varicella, mycobacterial infections, and fungal diseases.

Glaucoma: OZURDEX® is contraindicated in patients with glaucoma, who have cup to disc ratios of greater than 0.8.

Please see accompanying full Prescribing Information or visit https://www.rxabbvie.com/pdf/ozurdex_pi.pdf

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1. OZURDEX® Prescribing Information. **2.** Kuppermann BD. Dexamethasone implant for DME. *Retina Today*. 2009;May/June:52-53.
3. Data on file, ABVRRTI75618.

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