Ozurdex®
(dexamethasone intravitreal implant) 0.7 mg

What patients need to know

Approved Uses

OZURDEX® (dexamethasone intravitreal implant) is a prescription medicine that is an implant injected into the eye (vitreous) and used:

- To treat adults with diabetic macular edema
- To treat adults with swelling of the macula (macular edema) following branch retinal vein occlusion (BRVO) or central retinal vein occlusion (CRVO)
- To treat adults with noninfectious inflammation of the uvea (uveitis) affecting the back segment of the eye

IMPORTANT SAFETY INFORMATION

When Not to Use OZURDEX®

OZURDEX® should not be used if you have any infections in or around the eyes, including most viral diseases of the cornea and conjunctiva, including active herpes viral infection of the eye, vaccinia, varicella, mycobacterial infections, and fungal diseases.

OZURDEX® should not be used if you have glaucoma that has progressed to a cup-to-disc ratio of greater than 0.8.

OZURDEX® should not be used if you have a posterior lens capsule that is torn or ruptured.

OZURDEX® should not be used if you are allergic to any of its ingredients.

Warnings and Precautions

Injections into the vitreous in the eye, including those with OZURDEX®, are associated with serious eye infection (endophthalmitis), eye inflammation, increased eye pressure, and retinal detachments. Your eye doctor should monitor you regularly after the injection.

Please see additional Important Safety Information on the following pages.

Key points about OZURDEX®

- The swelling in your retina can be caused by several factors
- OZURDEX® is a corticosteroid and works to help reduce the inflammation in your retina. OZURDEX® helps by improving visual acuity
- OZURDEX® is a tiny implant that slowly releases medication over time, without monthly injections. It will dissolve over months and will not need to be removed
- OZURDEX® is injected directly into the back of the eye, with minimal systemic absorption
- There is a chance of an increase in eye pressure that generally returns to where it started. If you experience this, you will be observed by your doctor to determine the need to be managed with eye drops and, rarely, with surgery
- After repeated OZURDEX® injections, a cataract may occur. If this occurs, you will need a procedure to remove the cataract and restore your vision
- In clinical studies, OZURDEX® improved vision in patients without the need for monthly injections

IMPORTANT SAFETY INFORMATION (continued)
Warnings and Precautions (continued)
Use of corticosteroids including OZURDEX® may produce posterior subcapsular cataracts, increased eye pressure, glaucoma, and may increase the establishment of secondary eye infections due to bacteria, fungi, or viruses. Let your doctor know if you have a history of ocular herpes simplex as corticosteroids are not recommended in these patients.

Please see additional Important Safety Information on the following pages.

The OZURDEX® implant

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Tiny implant

IMPORTANT SAFETY INFORMATION (continued)

Common Side Effects in Diabetic Macular Edema

The most common side effects reported in patients with diabetic macular edema include: cataract, increased eye pressure, conjunctival blood spot, reduced vision, inflammation of the conjunctiva, specks that float in the field of vision, swelling of the conjunctiva, dry eye, vitreous detachment, vitreous opacities, retinal aneurysm, foreign body sensation, corneal erosion, inflammation of the cornea, anterior chamber inflammation, retinal tear, drooping eyelid, high blood pressure, and bronchitis.

Common Side Effects in Retinal Vein Occlusion and Uveitis

The most common side effects reported in patients for retinal vein occlusion and uveitis include: increased eye pressure, conjunctival blood spot, eye pain, eye redness, ocular hypertension, cataract, vitreous detachment, and headache.

Patient Counseling Information

After repeated injections with OZURDEX®, a cataract may occur. If this occurs, your vision will decrease and you will need an operation to remove the cataract and restore your vision. You may develop increased eye pressure with OZURDEX® that will need to be managed with eye drops, and rarely, with surgery.

In the days following injection with OZURDEX®, you may be at risk for potential complications including in particular, but not limited to, the development of serious eye infection or increased eye pressure.

Please see additional Important Safety Information on the following page.

Frequently asked questions

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Q: How does OZURDEX® work?
A: OZURDEX® is an implant that slowly dissolves over time and releases a corticosteroid called dexamethasone. This medication helps to reduce inflammation in the retina. OZURDEX® helps by improving visual acuity.

Q: How will my doctor administer OZURDEX®?
A: The injection of the OZURDEX® implant will take only a few moments. The implant will be injected into the back part of your eye called the vitreous humor.

Q: How common are intravitreal injections?
A: Intravitreal injections are frequently used to treat a variety of ophthalmic diseases. Your doctor is specially trained in giving eye injections.

Q: What can I expect during the injection procedure?
A: You will be awake during the procedure. Your doctor will follow steps that clean the surface of the eye and then numb the area for your comfort.

Q: When the OZURDEX® implant is injected, will I feel anything?
A: During the injection, you may feel some pressure. You may then hear a click when the doctor presses the button that releases the OZURDEX® implant into your eye.

Q: What else should I know about OZURDEX® treatment?
A: It's possible a cataract could form if you have repeated treatments with OZURDEX®. If that happens, your vision may decrease, and you will need a procedure to remove the cataract and restore your vision. Also, you may develop increased pressure inside your eye with OZURDEX®. This will be observed by your doctor to determine the need to be managed with eye drops or, rarely, with surgery.

Q: What happens after the procedure?
A: After the procedure, your doctor will check your eye, and then you will be ready to go home. Be sure to follow the doctor's instructions.

IMPORTANT SAFETY INFORMATION (continued)
Patient Counseling Information (continued)
If your eye becomes red, sensitive to light, painful, or develops a change in vision, you should seek immediate care from your eye doctor. You may experience temporary visual blurring after receiving an injection and should not drive or use machinery until your vision has resolved.

Please see accompanying full Prescribing Information.

Allergan™

OZU104494_v2 03/17 170811

OZURDEX® HCP Indications and ISI—All Indications (8/8/18)

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.

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.

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.

Glaucoma: OZURDEX® 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.

Hypersensitivity: OZURDEX® is contraindicated in patients with known hypersensitivity to any components of this product.

Warnings and Precautions

Intravitreal Injection-related Effects: Intravitreal injections, including those with OZURDEX®, have been associated with endophthalmitis, eye inflammation, increased intraocular pressure, and retinal detachments. Patients should be monitored regularly following the injection.

Steroid-related Effects: Use of corticosteroids including OZURDEX® 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.

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%).

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).

Cataracts and Cataract Surgery: The incidence of cataract development in patients who had a phakic study eye was higher in the OZURDEX® 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.

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® 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® 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.

(Insert applicable PI Statement).