



# 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 to help improve visual acuity (sharpness of vision)
- OZURDEX® is a tiny implant that slowly releases medication over time. 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 for several months

## 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

**Ozurdex®**  
(dexamethasone intravitreal  
implant) 0.7 mg



## 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

**Ozurdex**<sup>®</sup>  
(dexamethasone intravitreal  
implant) 0.7 mg

- Q:** How does **OZURDEX**<sup>®</sup> work?  
**A:** **OZURDEX**<sup>®</sup> is an implant that slowly dissolves over time and releases a corticosteroid called dexamethasone. This medication helps to reduce inflammation in the retina. **OZURDEX**<sup>®</sup> helps by improving visual acuity.
- Q:** How will my doctor administer **OZURDEX**<sup>®</sup>?  
**A:** The injection of the **OZURDEX**<sup>®</sup> 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**<sup>®</sup> 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**<sup>®</sup> implant into your eye.
- Q:** What else should I know about **OZURDEX**<sup>®</sup> treatment?  
**A:** It's possible a cataract could form if you have repeated treatments with **OZURDEX**<sup>®</sup>. 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**<sup>®</sup>. 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 or visit [https://www.rxabbvie.com/pdf/ozurdex\\_pi.pdf](https://www.rxabbvie.com/pdf/ozurdex_pi.pdf)