

# Important Information About Macular Edema Following Branch or Central Retinal Vein Occlusion (RVO) and Treatment



For patients with RVO

## What you can expect with OZURDEX<sup>®</sup>

### Approved Use

OZURDEX<sup>®</sup> (dexamethasone intravitreal implant) is a prescription medicine that is an implant injected into the eye (vitreous) and used to treat adults with swelling of the macula (macular edema) following branch retinal vein occlusion (BRVO) or central retinal vein occlusion (CRVO).

### IMPORTANT SAFETY INFORMATION

#### When Not to Use OZURDEX<sup>®</sup>

OZURDEX<sup>®</sup> 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.

**Please see additional Important Safety Information on pages 9-12.**

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

## RVO affects many patients

Affects about  
**1 out of every  
100 people**  
in a 5-year period

More likely  
in people  
**middle aged  
and older**

The **second most  
common cause  
of potential  
visual loss**  
due to retinal blood  
vessel disease

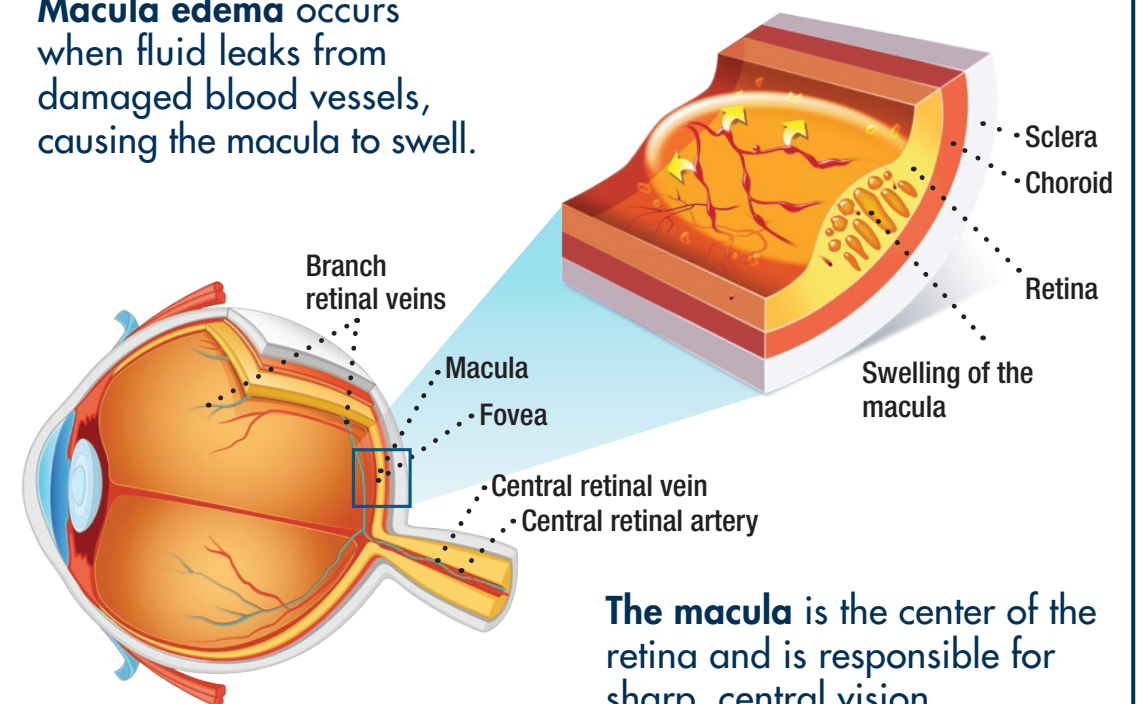


## How the eye is affected

**RVO** is a blockage of a branch (BRVO) or central (CRVO) retinal vein, preventing normal blood flow out of the eye. May be caused by:

- ⦿ A blood clot
- ⦿ Squeezing from a retinal artery
- ⦿ Diseases that affect blood vessels, such as
  - Diabetes
  - High eye pressure (glaucoma)
  - High blood pressure
  - Hardening of the arteries (arteriosclerosis)

**Macula edema** occurs when fluid leaks from damaged blood vessels, causing the macula to swell.



**The macula** is the center of the retina and is responsible for sharp, central vision.



## Symptoms of RVO

### How RVO affects vision

**Sudden blurring or vision loss in all or part of one eye are most common**

Blurry vision



Floaters



Wavy vision



Central dark spot



These images are depictions only. Actual visual symptoms vary for individuals.

- ⌚ For some patients, the vision loss may last for a few seconds or minutes or may be permanent
- ⌚ The amount of blurring or vision loss depends on how much damage to the retina has occurred

### Treatment is very important

**Untreated RVO can potentially lead to permanent vision impairment**

#### RVO MAY CAUSE

Retinal bleeding  
Damage to nearby capillaries  
(small blood vessels)  
Decreased oxygen to the retina

LEADING  
TO

INFLAMMATION  
OF RETINAL  
BLOOD VESSELS

CAPILLARY  
LEAKAGE

GROWTH OF NEW  
BLOOD VESSELS

Causes  
macular  
edema

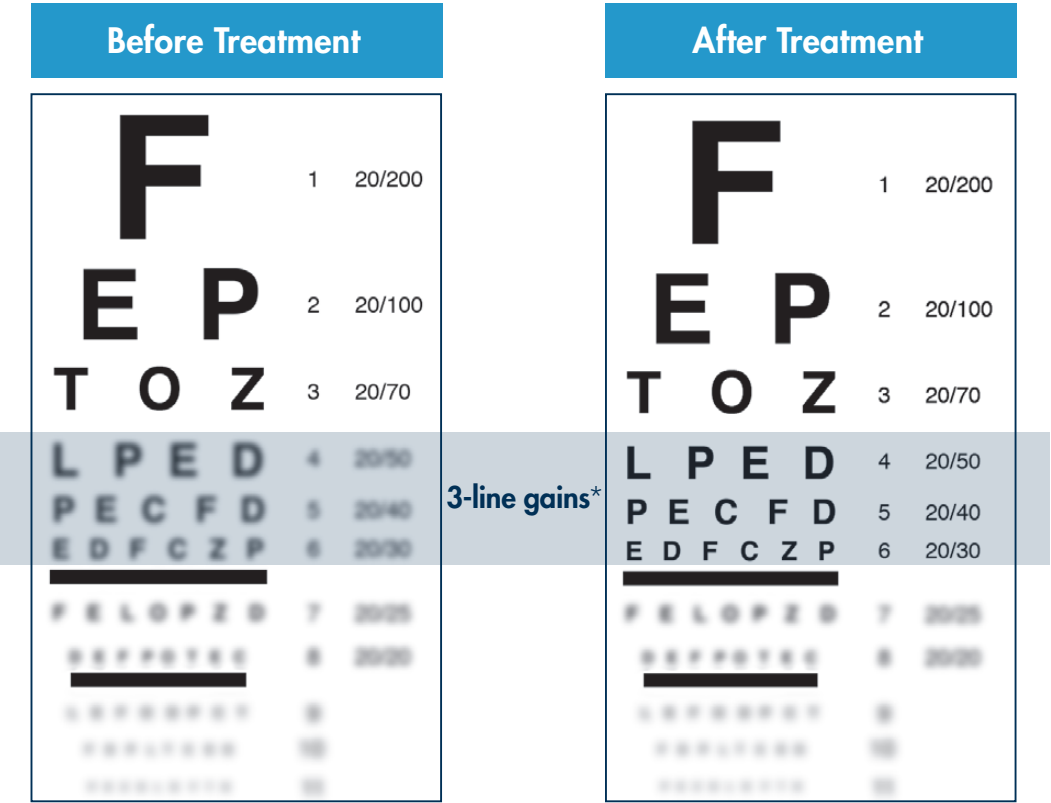
May also  
cause vision  
problems

How your visual acuity may be impacted



Visual acuity is the sharpness of vision. It is measured by the ability to read letters on an eye chart.

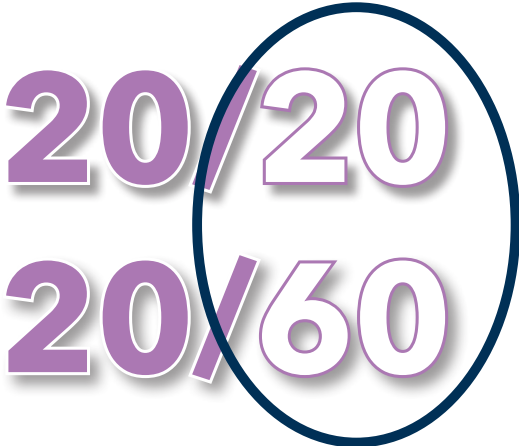
Treatment for macular edema following branch or central retinal vein occlusion may help improve visual acuity by increasing the number of lines a patient can read on an eye chart.



\*Individual results may vary.

Visual acuity by the numbers

- 20/20: A person with 20/20 vision sees the same at a distance of 20 feet that someone with ideal vision sees at 20 feet
- 20/60: A person with 20/60 vision needs to be at a distance of 20 feet to see what a person with 20/20 vision can see at 60 feet
- The second number increases as vision worsens



Decreased visual acuity may affect your ability to:

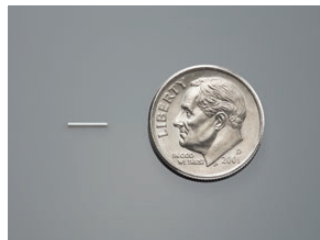
Recognize faces

Obtain a driver license (20/40 vision is the minimum in 47 states)

Have vision to dial a telephone

## Treating macular edema due to RVO with OZURDEX®

- ➊ OZURDEX® is a prescription medicine approved by the U.S. Food and Drug Administration (FDA) to treat adults with macular edema following branch or central retinal vein occlusion
- ➋ The tiny implant slowly releases medication over time, **without the need for monthly injections**. It will dissolve by itself over months and will not need to be removed
- ➌ Treatment with OZURDEX® helps **reduce inflammation** in your retina and **improve your vision**

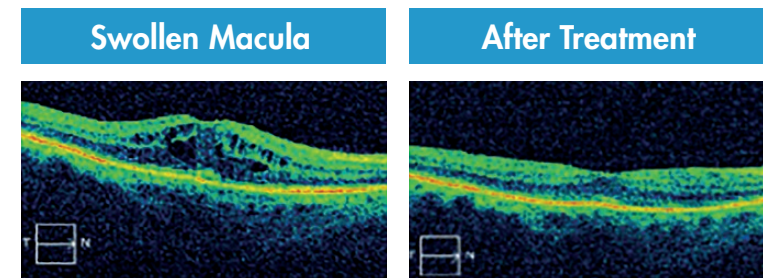


For more education and resources, visit [Ozurdex.com](http://Ozurdex.com).



## How OZURDEX® works

- ➊ OZURDEX® is injected directly into the back of the eye, with minimal systemic absorption
- ➋ Once injected, the implant dissolves slowly and releases a corticosteroid called dexamethasone
- ➌ Corticosteroids, such as dexamethasone, reduce inflammation in your retina



## Safety Information

### Approved Use

OZURDEX® (dexamethasone intravitreal implant) is a prescription medicine that is an implant injected into the eye (vitreous) and used to treat adults with swelling of the macula (macular edema) following branch retinal vein occlusion (BRVO) or central retinal vein occlusion (CRVO).

### 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.



## Possible side effects of OZURDEX<sup>®</sup>

### Increased eye pressure

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.

### Cataracts

- ⦿ Cataract is a condition in which the lens of the eye becomes cloudy or opaque
- ⦿ 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



## Safety Information (continued)

### IMPORTANT SAFETY INFORMATION (continued)

#### When Not to Use OZURDEX<sup>®</sup> (continued)

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

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

OZURDEX<sup>®</sup> 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<sup>®</sup>, 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.

Use of corticosteroids including OZURDEX<sup>®</sup> 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.

#### Common Side Effects in Retinal Vein Occlusion and Uveitis

The most common side effects reported include: increased eye pressure, conjunctival blood spot, eye pain, eye redness, ocular hypertension, cataract, vitreous detachment, and headache.

## Safety Information (continued)

### Patient Counseling Information

After repeated injections with OZURDEX<sup>®</sup>, 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<sup>®</sup> that will need to be managed with eye drops, and rarely, with surgery.

In the days following injection with OZURDEX<sup>®</sup>, 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. 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.



## Preparing for the procedure

### Before

- ⦿ Speak with your doctor about any questions/concerns you may have
- ⦿ Arrange to have somebody take you to and from your appointment
- ⦿ Create a list of all the prescription and over-the-counter medications you take

### During

- ⦿ The injection of OZURDEX<sup>®</sup> will only take a few moments
- ⦿ You will be awake
- ⦿ Your doctor will clean and numb the surface of the eye
- ⦿ Your doctor will inject OZURDEX<sup>®</sup> using a special applicator that's about the size of a pen
- ⦿ During the injection you may feel pressure
- ⦿ You may then hear a click when your doctor presses the button that releases the OZURDEX<sup>®</sup> implant in your eye

### After

- ⦿ Your doctor will check your eye, and then you will be ready to go home
- ⦿ Over time, you should notice an improvement in your vision. Your individual results may vary
- ⦿ If your eye becomes red, sensitive to light, painful, or develops a change in vision, please contact your eye doctor immediately

**Be sure to follow your doctor's instructions following the procedure.**

## Frequently Asked Questions

**Q: How does OZURDEX<sup>®</sup> work?**

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>?**

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?**

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?**

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?**

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 results can I expect with OZURDEX<sup>®</sup>?**

- ⦿ In two 6-month clinical trials with BRVO and CRVO patients, 427 received OZURDEX<sup>®</sup> and 426 received sham (control) treatment
- ⦿ About 20% to 30% of those who received OZURDEX<sup>®</sup> gained 3 or more lines of vision on an eye chart within 1 to 2 months, compared to 7% to 12% of control-treated people
- ⦿ Once vision had improved, the improvement lasted approximately 1 to 3 months
- ⦿ Your own individual results may vary; talk to your doctor

**Q: What else should I know about OZURDEX<sup>®</sup> treatment?**

**Cataracts**

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.

**Increased eye pressure**

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?**

After the procedure, your doctor will check your eye, and then you will be ready to go home. Be sure to follow your doctor's instructions.



Find More Education and Support  
at Ozurdex.com



**Please see accompanying full Prescribing Information.**

### Information Sources

- Borke J. Retinal vein occlusion. *Medscape*® Reference website
- Boyd K. Branch retinal vein occlusion (BRVO) symptoms. American Academy of Ophthalmology website.
- Data on file, Allergan
- Diabetes and cataracts. American Academy of Ophthalmology website
- Facts about macular edema. National Eye Institute website
- Haller JA, Bandello F, Belfort R Jr, et al; for OZURDEX® GENEVA Study Group. Randomized, sham-controlled trial of dexamethasone intravitreal implant in patients with macular edema due to retinal vein occlusion
- Hoerauf H. Branch retinal vein occlusion. In: Jousse AM, Gardner TW, Kirchhof B, Ryan SJ, eds. *Retinal Vascular Disease*
- Jaulim A, Ahmed B, Khanam T, Chatziralli IP. Branch retinal vein occlusion: epidemiology, pathogenesis, risk factors, clinical features, diagnosis, and complications. An update of the literature
- Laouri M, Chen E, Looman M, Gallagher M. The burden of disease of retinal vein occlusion: review of the literature
- Manabe K, Osaka R, Takasago Y, et al. Metamorphopsia associated with central retinal vein occlusion.
- OZURDEX® Prescribing Information
- Ramchandran RS, Shuler RK, Fekrat S. Treatment of retinal vein occlusions. In: Holz FC, Spaide RF, eds. *Medical Retina*
- Rogers S, McIntosh RL, Cheung N, et al; International Eye Disease Consortium. The prevalence of retinal vein occlusion: pooled data from population studies from the United States, Europe, Asia, and Australia
- Segre L. What's an eye test? Eye charts and visual acuity explained. All About Vision website
- Steinkuller PG. Legal vision requirements for drivers in the United States
- Yau JW, Lee P, Wong TY, Best J, Jenkins A. Retinal vein occlusion: an approach to diagnosis, systemic risk factors and management

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



© 2018 Allergan. All rights reserved. All trademarks are the property of their respective owners.  
Ozurdex.com OZU112516 05/18 172347

## **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).**