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®

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.

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



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

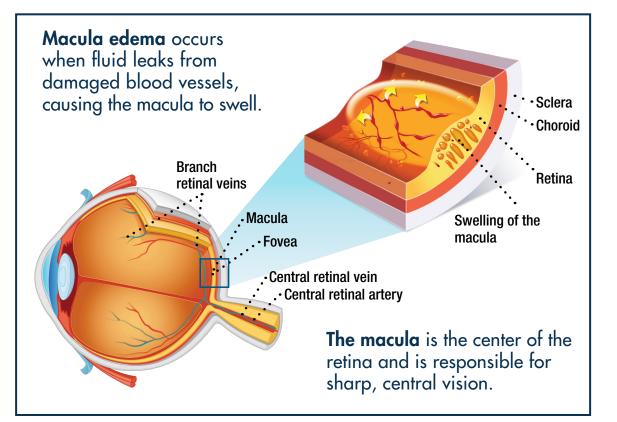
The second most common cause of potential visual loss due to retinal blood vessel disease



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:

- S 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)

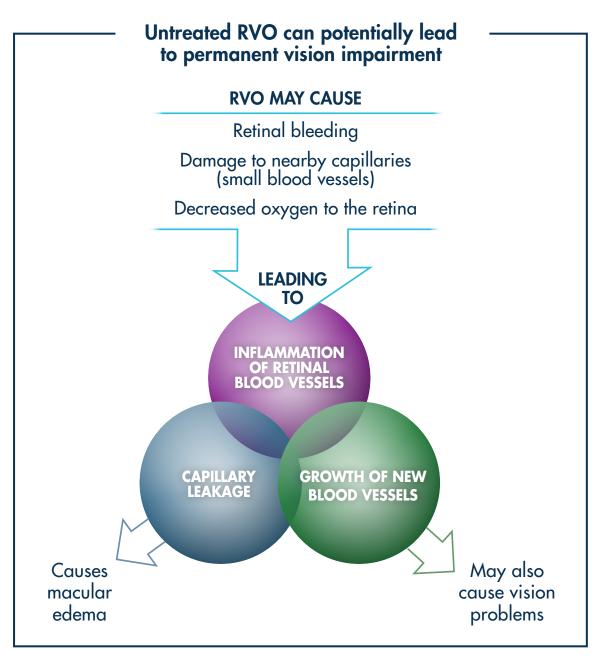


How RVO affects vision



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

Treatment is very important

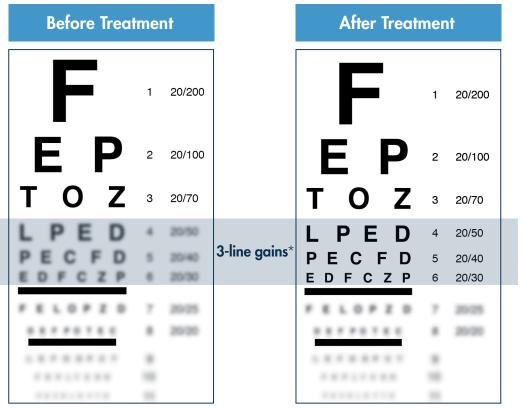


How your visual acuity may be impacted



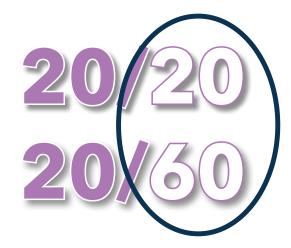
Visual acuity is the sharpness of vision. It is measured by the ability to read letters on an eye chart.

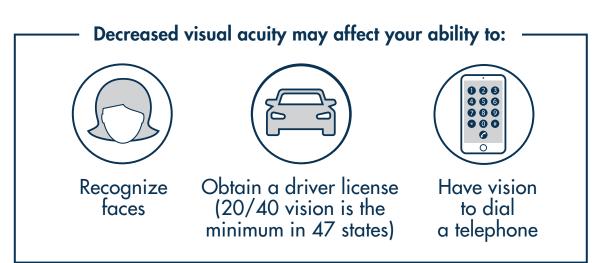
Treatment for macular edema following branch or central retinal vein occlusion may help improve visual acuity by increasing the number of lines a patient can read on an eye chart.



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





*Individual results may vary.

About OZURDEX®



Treating macular edema due to RVO with OZURDEX®

- 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
- The tiny implant slowly releases medication over time. It will dissolve by itself over months and will not need to be removed



Treatment with OZURDEX[®] helps reduce inflammation in your retina to help improve your vision

For more education and resources, visit Ozurdex.com.



How OZURDEX® works

- OZURDEX[®] is injected directly into the back of the eye, with minimal systemic absorption
- Once injected, the implant dissolves slowly and releases a corticosteroid called dexamethasone

Corticosteroids, such as dexamethasone,

reduce inflammation in your retina



 Swollen Macula
 After Treatment

 Image: Swollen Macula
 Image: Swollen Macula

Safety Information

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Possible side effects of OZURDEX®

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

- Sector 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[®]. 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[®] (continued)

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.

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.

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[®], 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. 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.



Ozurdex (dexamethasone intravitreal implant) 0.7 mg

Preparing for the procedure

Before

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

During

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

After

- S 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[®] work?

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®?

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?

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[®] 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[®] implant into your eye.

Q: What results can I expect with OZURDEX®?

- In two 6-month clinical trials with BRVO and CRVO patients, 427 received OZURDEX[®] and 426 received sham (control) treatment
- Solution 20% to 30% of those who received OZURDEX® 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

Ozurdex (dexamethasone intravitreal

implant) 0.7 mg

- 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[®] treatment? Cataracts

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.

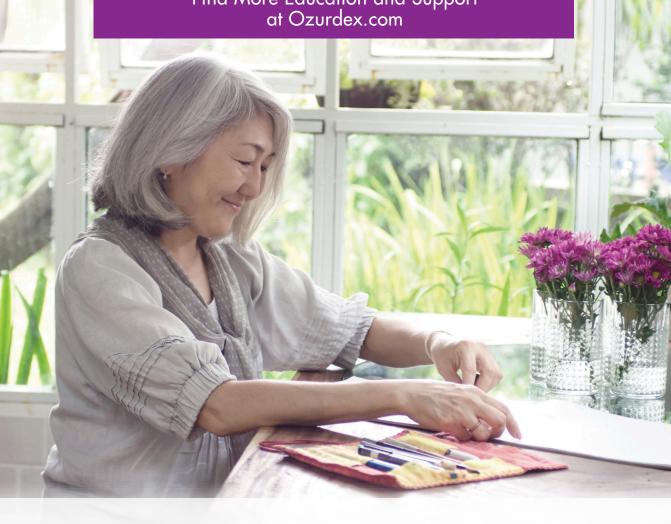
Increased eye pressure

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?

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 or visit https://www.rxabbvie.com/pdf/ozurdex_pi.pdf



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