

Important Information About Noninfectious Uveitis Affecting the Back Segment of the Eye and Treatment



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 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.

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

Ozurdex[®]
(dexamethasone intravitreal
implant) 0.7 mg

Your Condition

About noninfectious uveitis affecting the back segment of the eye

Noninfectious uveitis affecting the back segment of the eye is an inflammatory disease.

Noninfectious uveitis:

Affects about
**120 out of every
100,000 people**
per year

Patients have a
**5% risk of blindness
or low vision**
over 5 years

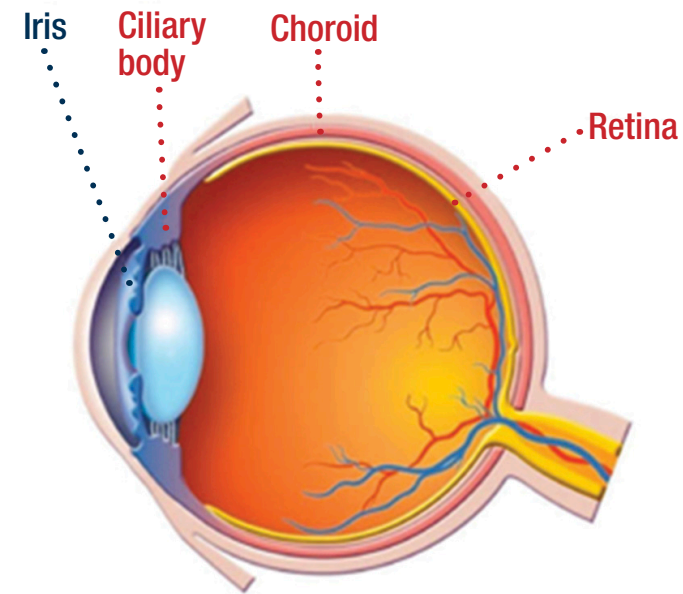
Uveitis is pronounced *you-vee-eye-tis*.



How the eye is affected

Parts of the eye become inflamed

Uveal tract



Red text = areas
of inflammation
affecting the back
segment of the eye

Back segment
of the eye

The uvea, also known as the uveal tract,
is the middle layer of the eye.

The cause of the inflammation with
noninfectious uveitis is often unknown

ⓘ No bacteria or viruses are found in the eye

How noninfectious uveitis affects vision

You may see spots (floaters)



What floaters may look like

Your vision may become cloudy

- ➊ Immune cells entering the vitreous humor, which is the clear gel that fills the back of your eye, may cause vitreous haze (cloudiness)
- ➋ The haze can block light from reaching the back of your eye

Treatment is very important

Uveitis can damage the eye, leading to significant vision loss

Range of possible visual impairment

Mild blurry vision



Moderate blurry vision

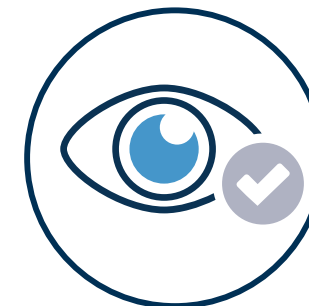


Severe blurry vision



Uveitis can recur

- ➊ New-onset uveitis occurs suddenly and duration of inflammation could be limited. However, it is possible to have recurrences over a period of months or years
- ➋ It is very important to receive medical treatment each time noninfectious uveitis affecting the back segment of the eye appears

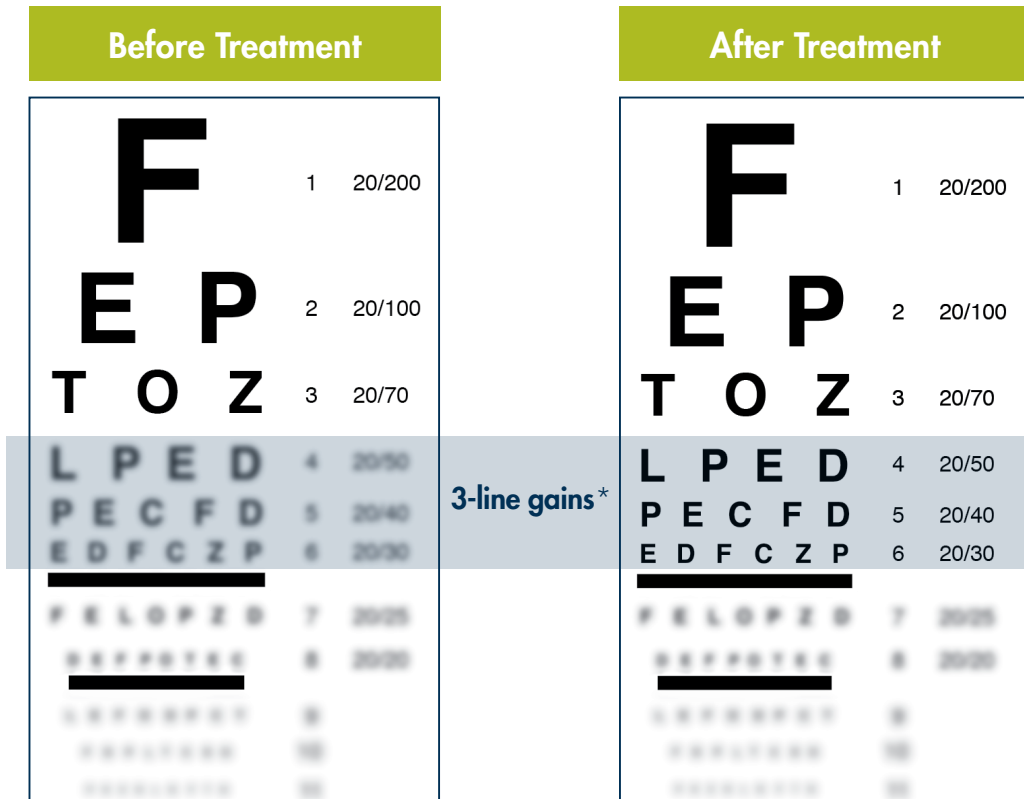


Noninfectious uveitis may affect your visual acuity



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

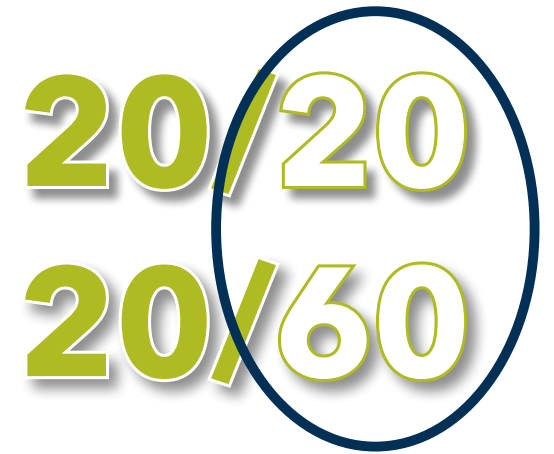
Uveitis treatments may help improve visual acuity by increasing the number of lines a patient can read on an eye chart.



*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



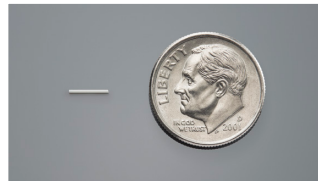
Obtain a driver license (20/40 vision is the minimum in 47 states)



Have vision to dial a telephone

OZURDEX® treatment

- ⦿ OZURDEX® is a prescription medicine approved by the U.S. Food and Drug Administration (FDA) to treat adults with noninfectious inflammation of the uvea (uveitis) affecting the back segment of the eye
- ⦿ 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 the inflammation** of uveitis to help **improve visual acuity** (sharpness of vision)



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 eye



For more education and resources, visit OZURDEX.com.



Safety Information

Approved Uses

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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

- ⊕ Cataract is a condition in which the lens of the eye becomes cloudy or opaque
- ⊕ After repeated OZURDEX[®] injections, a cataract may occur. If this occurs, 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.



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.

Common Side Effects in 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.

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.

Preparing for the procedure

Before

- ④ Speak with your doctor about any questions/concerns you may have
- ④ Arrange to have somebody take you to and from your appointment
- ④ Create a list of all the prescription and over-the-counter medications you take

During

- ④ The injection of OZURDEX® will only take a few moments
- ④ You will be awake
- ④ Your doctor will clean and numb the surface of the eye
- ④ Your doctor will inject OZURDEX® using a special applicator that's about the size of a pen
- ④ During the injection you may feel pressure
- ④ You may then hear a click when your doctor presses the button that releases the OZURDEX® implant in your eye

After

- ④ Your doctor will check your eye, and then you will be ready to go home
- ④ Over time, you should notice an improvement in your vision. Your individual results may vary
- ④ 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[®]?

153 people with noninfectious uveitis affecting the back segment of the eye participated in a 26-week clinical trial:

- 77 patients received OZURDEX[®] and 76 received sham (control) treatment

- After an OZURDEX[®] treatment, improvements in vitreous haze and vision were shown throughout the 26-week study

- At week 8:

- 46.8% (almost 5 in 10) of OZURDEX[®] treated people had a vitreous haze score of 0 (meaning no inflammation) compared to 11.8% (1 in 10) of control-treated people
- 42.9% (4 in 10) of OZURDEX[®] treated people gained greater than or equal to 15 letters (3 or more lines) of vision on an eye chart compared to 6.6% (1 in 20) of control-treated people
- OZURDEX[®] treated people gained an average of 13.5 letters of vision on an eye chart compared to 1.8 letters for control-treated people

- 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](https://www.ozurdex.com)



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



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