

Ozurdex[®]

(dexamethasone intravitreal implant) 0.7 mg

NONINFECTIOUS UVEITIS AFFECTING THE BACK SEGMENT OF THE EYE AND TREATMENT 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 throughout.

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

HOW CAN NONINFECTIOUS UVEITIS AFFECTING THE BACK SEGMENT OF THE EYE AFFECT MY EYES?

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

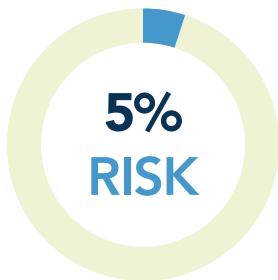
Noninfectious uveitis:

- **Affects about**



OUT OF EVERY
120 **100,000**
people per year

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



Although this disorder is considered rare, those who develop it can be at a high risk of recurrence. To help prevent this, it's important to:

- Get treatment promptly
- Continue regular eye exams and follow-ups
- Take care of your overall health

Some factors can increase your risk of developing noninfectious uveitis affecting the back segment of the eye, such as:

- Smoking
- An inflammatory disease called sarcoidosis

Uveitis

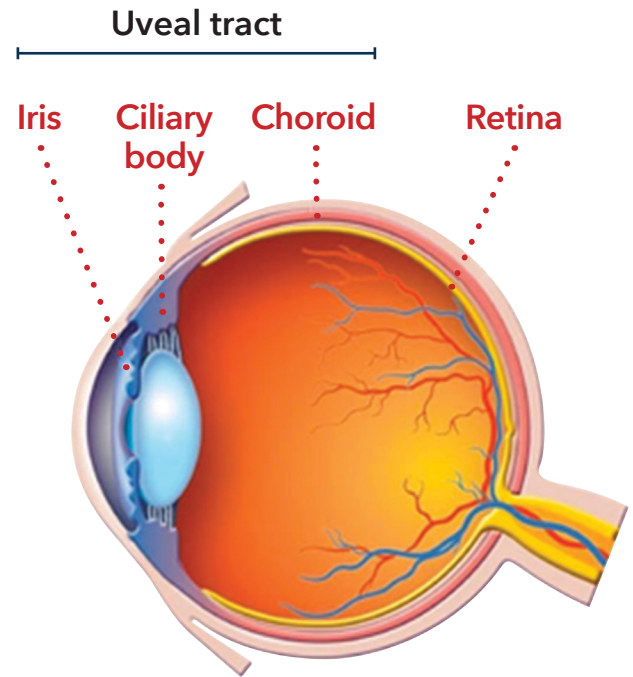
is pronounced
*you-vee-**eye**-tis.*



WHAT IS NONINFECTIOUS UVEITIS?

- Uveitis is inflammation of the uvea. The uvea, also known as the uveal tract, is the middle layer of the eye (see diagram)
- Uveitis can also affect the retina and blood vessels of the eye
- Inflammation is caused by retinal cells, your immune system's white blood cells, and the chemicals these cells release
- Noninfectious uveitis means that although the uvea is inflamed, no bacteria or viruses are found in the eye
- The cause of the inflammation with noninfectious uveitis is often unknown

UVEAL INFLAMMATION



Red text = areas of inflammation associated with uveitis

HOW CAN NONINFECTIOUS UVEITIS AFFECT MY VISION?



You may see spots (floaters)

Your vision may become cloudy

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

You may have significant vision loss

RANGE OF POSSIBLE VISUAL IMPAIRMENT



Mild
blurry vision



Moderate
blurry vision



Severe
blurry vision

Uveitis can recur

- 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
- It is very important to receive medical treatment each time noninfectious uveitis affecting the back segment of the eye appears

What can you do to prevent loss of vision due to noninfectious uveitis?



Seek treatment right away for vision problems



Regular eye exams



Appropriate follow-up

WHAT IS VISUAL ACUITY AND HOW DOES IT RELATE TO NONINFECTIOUS UVEITIS?

Visual acuity is the sharpness of your vision. It is measured by the ability to read letters on an eye chart. What you can see on the eye chart from 20 feet away is recorded as a number.

E	1	20/200
F P	2	20/100
T O Z	3	20/70
L P E D	4	20/50
P E C F D	5	20/40
E D F C Z P	6	20/30
F E L O P Z D	7	20/25
D E F P O T E C	8	20/20
L E F O D P C T	9	
F D P L T C E O	10	
F E Z O L C F T D	11	

A TYPICAL EYE CHART

You might have heard people refer to **20/20 vision** as “perfect vision.” In fact, a person with 20/20 vision can see what an average person sees on an eye chart when standing 20 feet away.

Likewise, **20/40 vision** means that, when standing 20 feet away, the person can see as well as an average person standing 40 feet away. On the eye chart to the left, this means a person with 20/40 vision can read the letters in the line labeled 20/40 and above, but not the letters below.

- As vision worsens, the second number increases
- In 46 states, you need at least 20/40 vision to obtain a driver’s license

Noninfectious uveitis can worsen your visual acuity, but treatment may help improve it.



HOW WILL MY NONINFECTIOUS UVEITIS BE TREATED?

There are several treatment options for noninfectious uveitis



Your doctor will determine which is most appropriate for you and your noninfectious uveitis. These options include:

- Oral medications (steroids)
- Injections under the skin (biologics)
- Eye drops (steroids)
- Injections into the eye (steroids)
 - One type is an anti-inflammatory injection, like OZURDEX® (dexamethasone intravitreal implant)

IMPORTANT SAFETY INFORMATION (continued) When Not to Use OZURDEX® (dexamethasone intravitreal implant) (continued)

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

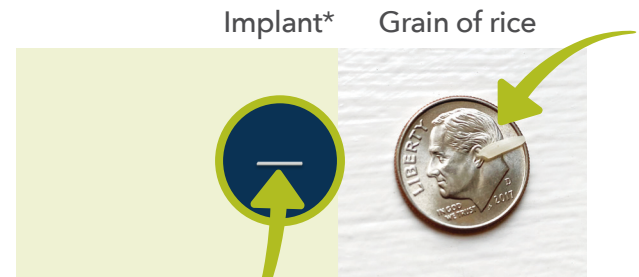
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What is OZURDEX®?

OZURDEX® is a tiny implant that releases an anti-inflammatory agent (a corticosteroid) called dexamethasone and is 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. It is injected into the back of the eye, with minimal absorption into your body. Your doctor will decide when and if a reinjection of OZURDEX® is needed.

OZURDEX® IMPLANT SIZE COMPARISON



*Actual size

HOW WILL OZURDEX® WORK INSIDE MY EYE?

OZURDEX® will be injected into the vitreous cavity in the back of your eye.

OZURDEX® treatment



- Can help improve visual acuity (sharpness of vision)

The implant dissolves



- Medication is slowly released over time as OZURDEX® dissolves

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:
 - 47% (almost 5 in 10) of OZURDEX® treated people had a vitreous haze score of 0 (meaning no inflammation) compared to 12% (1 in 8) of control-treated people
 - 43% (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 7% (1 in 14) 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



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WHAT CAN I EXPECT WITH THE OZURDEX® 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® 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® using a special applicator that's about the size of a pen
- During the injection, you may feel pressure on the eye
- You may then hear a click when your doctor presses the button that releases the OZURDEX® implant into your eye

After

- Your doctor will check your eye, and then you will be ready to go home
- Over time, check for 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
- You may experience temporary visual blurring after receiving an intravitreal injection. Do not drive or use machines until this has been resolved

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

IMPORTANT SAFETY INFORMATION (continued) When Not to Use OZURDEX® (dexamethasone intravitreal implant) (continued)

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

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WHAT SIDE EFFECTS CAN HAPPEN WITH OZURDEX®?

OZURDEX® can cause cloudiness of the lens that can lead to a cataract.

- A cataract could form if you have multiple treatments with OZURDEX®
- If that happens, your vision may decrease, and you will need a procedure to remove the cataract and restore your vision
 - Ask your doctor about cataract surgery. About 3.8 million surgeries are performed in the United States every year
- In clinical trials, after 26 weeks, cataracts developed in about 15% out of 62 OZURDEX® patients with natural lenses and 7% out of 55 sham (control)-treated patients with natural lenses

IMPORTANT SAFETY INFORMATION (continued) When Not to Use OZURDEX® (dexamethasone intravitreal implant) (continued)

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

OZURDEX® can also cause your eye pressure to increase.

- Your doctor will monitor your eye pressure
- If there is an increase in eye pressure, then your doctor may prescribe you an eye drop that will need to be used daily
- In most cases, the prescription eye drops will take care of the increased pressure
- In rare cases, the increase in eye pressure may require surgery

IMPORTANT SAFETY INFORMATION (continued) 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.

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WHAT PATIENT ASSISTANCE RESOURCES ARE AVAILABLE?

How can I save on OZURDEX® treatment?

AbbVie is committed to helping patients gain access to and afford treatments. There are cost-saving opportunities available for OZURDEX®.

If you have commercial insurance and meet other eligibility requirements, you can pay as little as \$0 for OZURDEX®.

Ask your doctor if you qualify. If you are eligible, your doctor will enroll you.

IMPORTANT SAFETY INFORMATION (continued) Warnings and Precautions (continued)

Use of corticosteroids including OZURDEX® (dexamethasone intravitreal implant) 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.

Will my insurance cover OZURDEX®?

Ask your doctor's office to verify coverage through your specific insurance carrier.

IMPORTANT SAFETY INFORMATION (continued) 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.

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**LEARN MORE ABOUT OZURDEX[®]
AND NONINFECTIOUS UVEITIS
AT OZURDEX.COM**



**IMPORTANT SAFETY INFORMATION (continued)
Patient Counseling Information (continued)**

In the days following injection with OZURDEX[®] (dexamethasone intravitreal implant), 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.

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

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