

# Important Information About Diabetic Macular Edema (DME) and Treatment



For patients with DME

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

### Approved Uses

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 diabetic macular edema.

### 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.

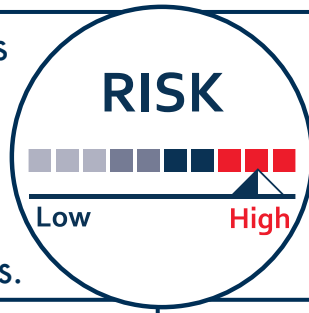
**Ozurdex**<sup>®</sup>  
(dexamethasone intravitreal  
implant) 0.7 mg

## Diabetes and vision

1.5 million Americans are diagnosed with diabetes every year.

Diabetic eye disease is the #1 cause of vision loss in working-age adults

All people with diabetes are at risk for diabetic eye disease such as diabetic retinopathy, which damages the blood vessels in the eyes.



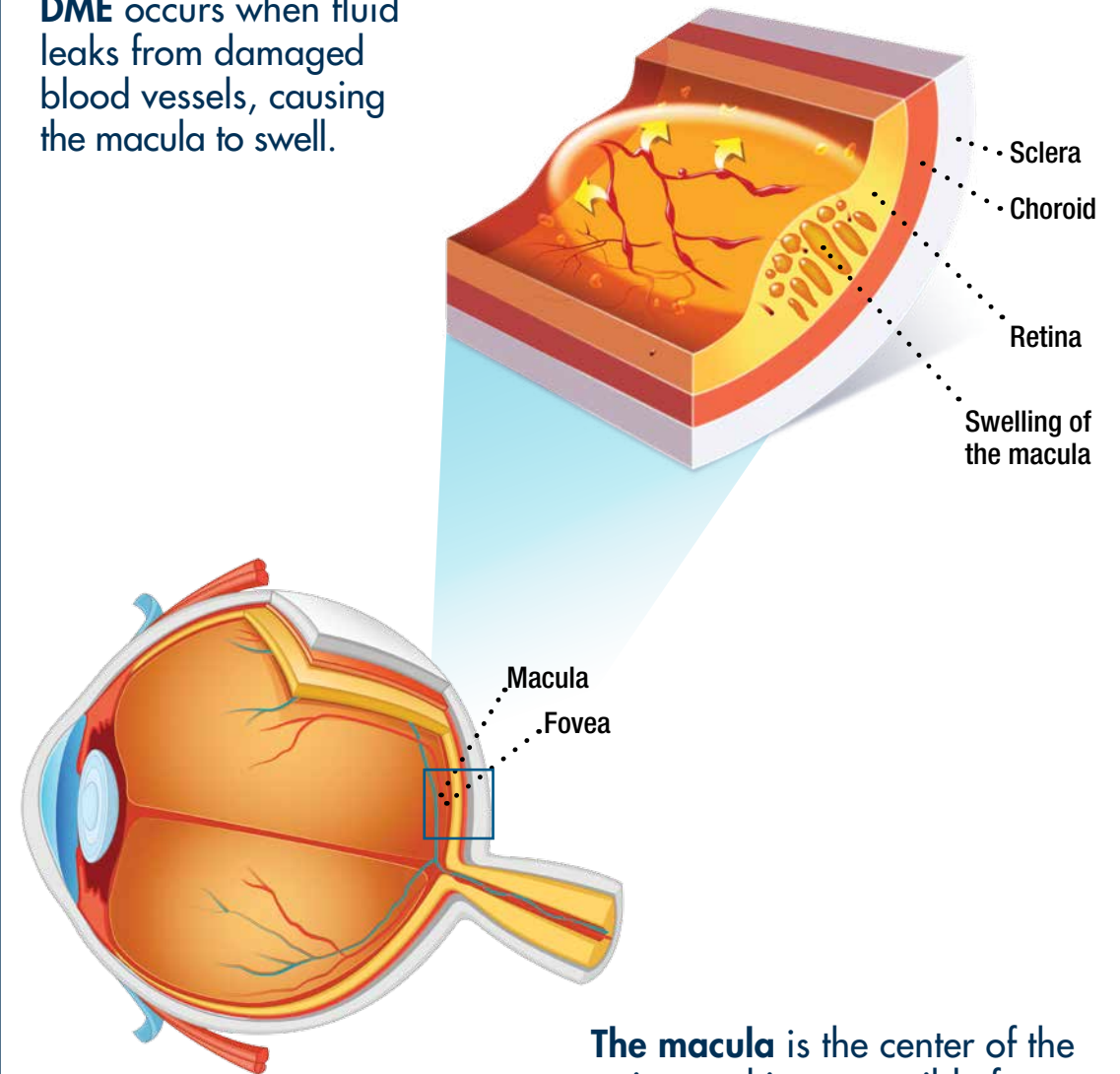
The longer a person has diabetes, the greater the risk.

DME develops in **HALF** of all people with diabetic retinopathy.



## The eye with DME

**DME** 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.

## How DME affects vision

- ④ DME can lead to a loss of your vision (or blurry vision)
- ④ If your doctor finds DME early, you may not have any symptoms
- ④ If DME worsens, it can lead to blurry central vision  
– The blurriness can range from mild to severe

**DME can cause significant vision loss over time.**

### Range of visual impairment due to DME

Mild blurry vision



Moderate blurry vision



Severe blurry vision



### What you can do to prevent or delay loss of vision due to DME



Good management of diabetes



Regular eye exams



Appropriate follow up



## The effect of DME is measured by your visual acuity



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

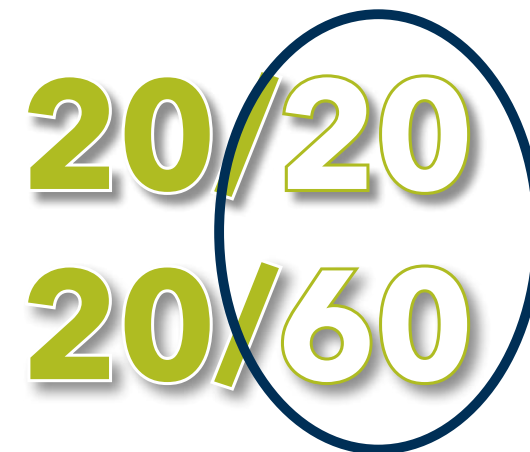
DME treatments can help improve visual acuity by increasing the number of lines a patient can read on an eye chart

Before Treatment			After Treatment		
F	1	20/200	F	1	20/200
E P	2	20/100	E P	2	20/100
T O Z	3	20/70	T O Z	3	20/70
L P E D	4	20/50	L P E D	4	20/50
P E C F D	5	20/40	P E C F D	5	20/40
E D F C Z P	6	20/30	E D F C Z P	6	20/30
F E L O P E D	7	20/25	F E L O P E D	7	20/25
S E P T E T E E	8	20/20	S E P T E T E E	8	20/20
L E G H T S E E T	9		L E G H T S E E T	9	
V A R I A T I O N S	10		V A R I A T I O N S	10	
V A R I A T I O N S	11		V A R I A T I O N S	11	

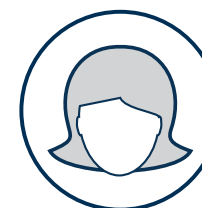
3-line gains

## 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 DME with OZURDEX®

- 1 OZURDEX® is a prescription medicine approved by the U.S. Food and Drug Administration (FDA) to treat adults with diabetic macular edema
- 2 The tiny implant slowly releases medication over time, **without the need for monthly injections**. It will dissolve naturally and will not need to be removed
- 3 OZURDEX® treatment can help **reduce inflammation** in your retina and **improve your vision**

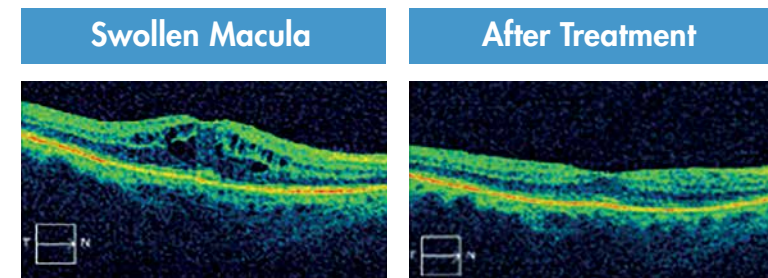


For more education and resources, visit [Ozurdex.com](http://Ozurdex.com).



## How OZURDEX® works

- 1 OZURDEX® is injected directly into the back of the eye, with minimal systemic absorption
- 2 Once injected, the implant dissolves slowly and releases a corticosteroid called dexamethasone
- 3 Corticosteroids, such as dexamethasone, reduce inflammation



## Safety Information

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## 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.



## Safety Information (continued)

### Common Side Effects in Diabetic Macular Edema

The most common side effects reported in patients 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.

### 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

- 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<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 3-year clinical trials, 328 people received OZURDEX<sup>®</sup> about every 6 months, based on their doctor's discretion, and 328 people received sham (control) treatment

- At the end of the 3-year studies, 20% (1 in 5) of OZURDEX<sup>®</sup> treated people gained  $\geq 15$  letters (3 or more lines) of vision on an eye chart compared to 11% (1 in 10) of control-treated people
- Your own individual results may vary; talk to your doctor

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

#### **Cataracts**

It's possible a cataract could form if you have repeated treatments with OZURDEX<sup>®</sup>. In clinical trials, after 1 injection, cataracts developed in about 10% (24 of 243) of OZURDEX<sup>®</sup> patients with natural lenses and 8% (18 of 230) of sham (control)-treated patients with natural lenses. After up to a maximum of 7 treatments over 3 years, cataracts occurred in 68% (166 of 243) of OZURDEX<sup>®</sup> treated patients with natural lenses and 21% (49 of 230) of sham (control)-treated patients with natural lenses. If a cataract forms, 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.





**Please see accompanying full Prescribing Information.**

### **Information Sources**

- Ali-Javadi M, Zarei-Ghanavati S. Cataracts in diabetic patients: a review article
- Boyd K. Who is at risk for diabetic retinopathy? American Ophthalmology Association website
- Diabetes and cataracts. American Academy of Ophthalmology website
- Diabetic eye disease: The number one cause of vision loss in working-age adults. National Eye Health Education Program
- Facts about diabetic eye disease. National Eye Institute website
- Facts about macular edema. National Eye Institute website
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- Segre L. What's an eye test? Eye charts and visual acuity explained. All About Vision website
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