

Ozurdex[®]
(dexamethasone intravitreal
implant) 0.7 mg

DIABETIC MACULAR EDEMA (DME) AND TREATMENT WITH OZURDEX[®]



Approved Uses

OZURDEX[®] (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[®]

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 10-19.**

HOW CAN DIABETES AFFECT MY EYES?



1.5 million
Americans

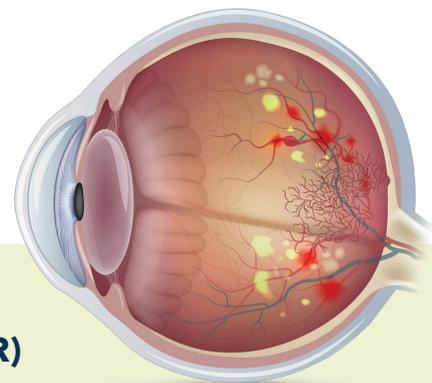
are diagnosed with
diabetes every year

- Diabetes is a lifelong condition that must be managed with insulin or other medication, depending on whether you have type 1 or type 2 diabetes



of vision loss in
working-age adults
is diabetic eye disease

- To help manage complications of diabetes, such as diabetic eye disease, it's important to see your primary care physician regularly and keep your blood sugar and blood pressure (hypertension) under control



**Diabetic
retinopathy (DR)**

- **If you have uncontrolled, high blood sugar, over time it can damage the tiny blood vessels in your eye—this is known as diabetic retinopathy (DR)**
- All people with diabetes are at risk for diabetic eye diseases like DR
 - The longer you have diabetes, the greater your risk

Please see additional Important Safety Information on pages 10-19.

WHAT IS DME?

When DR damages the blood vessels of the eye, it can lead to diabetic macular edema (DME)

- DME affects the retina, the part of the eye that sends visual images to the brain



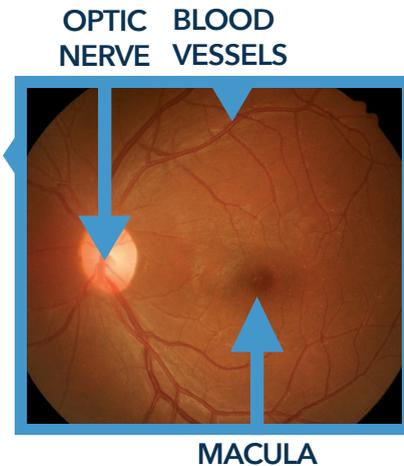
DME develops in about half of people with DR

Many factors contribute to DME, but inflammation plays a large role.

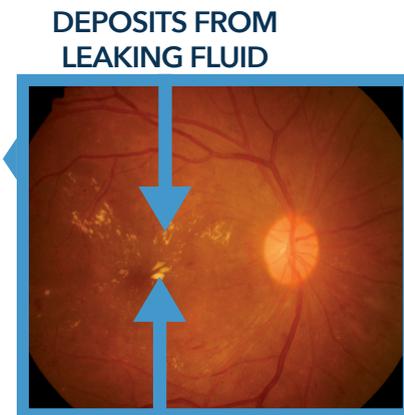
- Fluid leaks from the damaged blood vessels and causes swelling of the macula, the part of the retina responsible for sharp, central vision
- The leakage also causes deposits to form in the eye, which your doctor can see with a special type of photography (shown to the right)

Please see additional Important Safety Information on pages 10-19.

A normal eye seen with special photography



An eye with DME seen with special photography



HOW CAN DME AFFECT MY VISION?

DME can affect your visual acuity and lead to a loss of vision or blurry vision.



RANGE OF VISUAL IMPAIRMENT DUE TO DME

Mild
blurry vision



Moderate
blurry vision



Severe
blurry vision

Some symptoms of DME are:

- Blurry vision
- Faded colors
- Distorted vision

DME can cause your vision to change so slowly that you might not even notice any symptoms. If you have diabetes, it's important to get your eyes checked regularly as recommended by your doctor.

WHAT YOU CAN DO TO PREVENT OR DELAY LOSS OF VISION DUE TO DME



Good management of diabetes, including your blood sugar and blood pressure



Regular eye exams

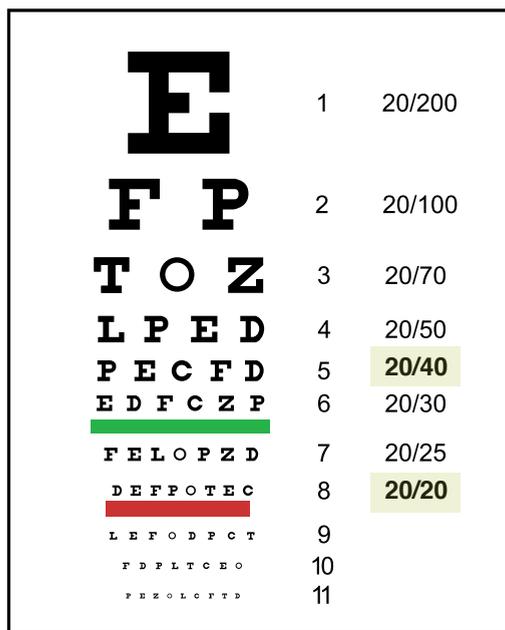


Appropriate follow-up

Please see additional Important Safety Information on pages 10-19.

WHAT IS VISUAL ACUITY AND HOW DOES IT RELATE TO DME?

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.



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

DME can worsen your visual acuity, but treatment can help improve it.



Please see additional Important Safety Information on pages 10-19.

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HOW WILL MY DME BE TREATED?



There are several treatment options for DME

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

- Laser treatment
- Injections into the eye
 - 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.

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.

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 DME. It is injected into the back of the eye, with minimal absorption into your body, and can last up to 6 months. Your doctor will decide when and if a reinjection of OZURDEX® is needed.



**OZURDEX®
IMPLANT SIZE
COMPARISON**

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

Injections into the vitreous in the eye, including those with OZURDEX® (dexamethasone intravitreal implant), 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.

Please see additional Important Safety Information on pages 12-19.

HOW WILL OZURDEX®

(dexamethasone intravitreal implant)

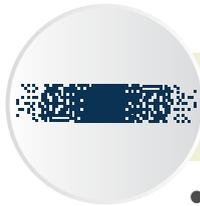
WORK INSIDE MY EYE?

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



OZURDEX® treatment

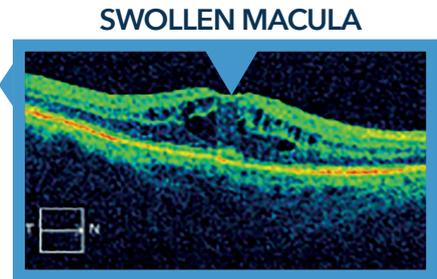
- Can help reduce inflammation in your retina and swelling in the macula



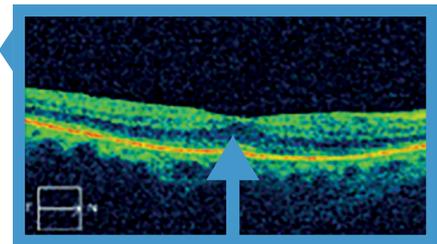
The implant dissolves

- Medication is slowly released over time as OZURDEX® dissolves
- In two 3-year clinical trials, 328 people received OZURDEX® 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® treated people gained ≥ 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

A scan of a retina with DME



After treatment with OZURDEX®



DECREASED SWELLING OF THE MACULA

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.

Please see additional Important Safety Information on pages 14-19.

WHAT CAN I EXPECT WITH THE OZURDEX® (dexamethasone intravitreal implant) 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, 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.

IMPORTANT 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.

Please see additional Important Safety Information on pages 16-19.

WHAT SIDE EFFECTS CAN HAPPEN WITH OZURDEX®

(dexamethasone intravitreal implant) ?

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 1 injection, cataracts developed in about 10% (24 of 243) of OZURDEX® 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® treated patients with natural lenses and 21% (49 of 230) of sham (control)-treated patients with natural lenses

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 very rare cases, the increase in eye pressure may require surgery. In most cases, the prescription eye drops will take care of the increased pressure

IMPORTANT SAFETY INFORMATION (continued) Patient Counseling Information

After repeated injections with OZURDEX® (dexamethasone intravitreal implant), 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.

Please see additional Important Safety Information on page 19.

WHAT PATIENT ASSISTANCE RESOURCES ARE AVAILABLE?

HOW CAN I SAVE ON OZURDEX® (dexamethasone intravitreal implant) TREATMENT?

Allergan® is committed to helping patients gain access to and afford treatments. There are cost-savings 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.

WILL MY INSURANCE COVER OZURDEX®?

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

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



**Please see Important Safety Information
throughout.**

**Please see accompanying full Prescribing
Information or visit [https://www.rxabbvie.com
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