

FDA-Approved
Treatment
for
Macular Edema
Following Branch
or Central Retinal
Vein Occlusion

Ozurdex[®]
(dexamethasone intravitreal
implant) 0.7 mg 

Important Safety Information

OZURDEX[®] should not be used in patients who have any infections or diseases in the eye, or surrounding eye area, including most viral diseases of the cornea and conjunctiva, including active herpes viral infection of the eye, vaccinia, varicella, mycobacterial infections, and fungal diseases.

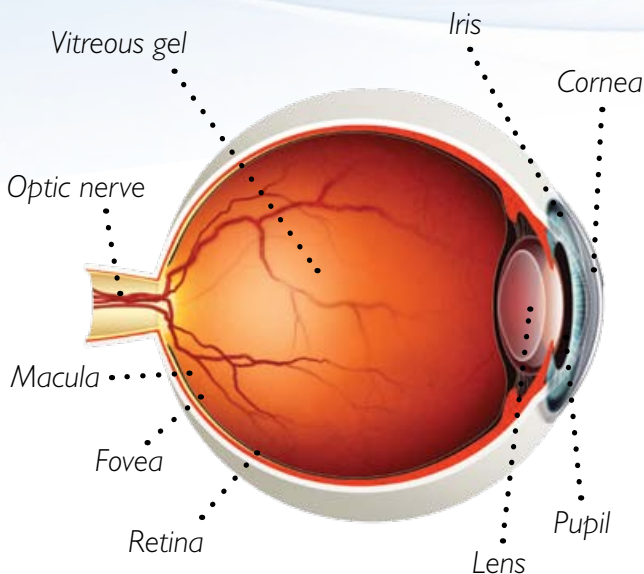
OZURDEX[®] should not be used in patients with advanced glaucoma. You should not use OZURDEX[®] if you are allergic to one of its ingredients.

*Branch or central retinal vein occlusion.

Please see additional Important Safety Information on pages 12-13.

Your eyes:

What makes up the eye?



How does the eye work?

Light enters through the cornea, passes through the opening in the iris, called the pupil, and then to the lens, which focuses light on the retina—the inner lining of the back of the eye. The retina is lined with light-sensitive cells, or photoreceptors, called rods and cones. The macula is the center of the retina, and it is responsible for sharp central vision. The fovea is a small depression in the macula that provides the sharpest vision of all. When light reaches the retina, the photoreceptors send impulses along the optic nerve to the brain, which interprets them as vision.

A Look Inside

Why is a healthy retina important?

A healthy retina is essential for normal vision. A number of diseases can damage the retina, which may lead to impaired vision or loss of vision. One of these diseases is retinal vein occlusion, which occurs more commonly as people reach middle age.

A photograph (called funduscopy) of a healthy retina.

Optic nerve

Macula

Fovea

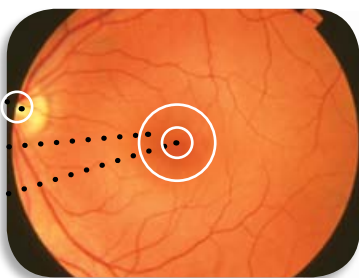


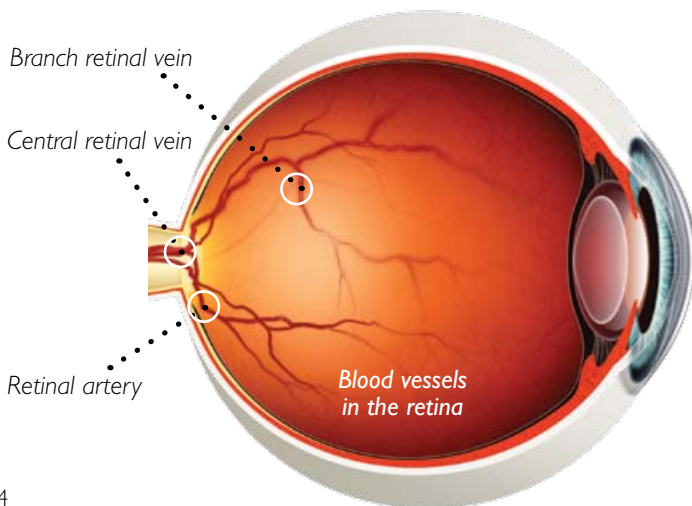
Image from the National Eye Institute online archive.

Your condition:

What is retinal vein occlusion?

Blood circulating through the retina leaves the eye by draining into the retinal vein. A retinal vein occlusion is a blockage that prevents normal blood flow out of the eye. The blockage may be caused by a blood clot, by compression (squeezing) from a nearby retinal artery, or by diseases that affect the blood vessels, such as diabetes, glaucoma, high blood pressure, and atherosclerosis (hardening of the arteries).

There are 2 main types of retinal vein occlusion: branch retinal vein occlusion (BRVO) and central retinal vein occlusion (CRVO). In BRVO, the blockage occurs in one of the smaller branch vessels that connect to the central retinal vein. In CRVO, the blockage occurs in the central retinal vein, which is the main drainage line for blood leaving the retina.



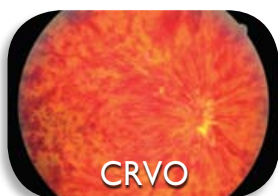
Retinal Vein Occlusion

What are the symptoms of retinal vein occlusion?

Sudden blurring or vision loss in all or part of one eye are the most common symptoms of retinal vein occlusion. For some patients, the vision loss may happen gradually over a period of days or weeks instead of suddenly. The amount of blurring or vision loss depends on how much damage to the retina has occurred.

How does retinal vein occlusion affect the eye?

The blockage of blood flow can cause retinal bleeding, damage nearby capillaries (small blood vessels), and deprive the retina of oxygen. When retinal capillaries are damaged, it can lead to swelling of the retina (known as edema). If the edema affects the central part of the retina, called the macula, it can reduce your central vision. In addition, low oxygen levels may trigger the formation of fragile new blood vessels that can also cause vision problems. Untreated retinal vein occlusion can take months to heal and lead to permanent vision impairment in the affected eye.



Images of retinal vein occlusions.

Your treatment:

Why did my doctor choose OZURDEX®?

OZURDEX® has been approved by the US Food and Drug Administration (FDA) to treat macular edema following branch or central retinal vein occlusion. OZURDEX® has been proven effective in large clinical trials. If you are to receive an OZURDEX® intravitreal implant, it means you have a retinal vein occlusion that is causing macular edema. Your doctor has chosen OZURDEX® to help treat your macular edema. He or she will discuss more specific reasons why OZURDEX® was selected as well as the benefits and risks of treatment.

How does the OZURDEX® intravitreal implant work?

OZURDEX® is a biodegradable implant containing the corticosteroid dexamethasone. Corticosteroids such as dexamethasone block chemical pathways that lead to inflammation, leakage from the retinal blood vessels, and edema. By reducing macular edema, OZURDEX® may help reverse some vision loss that may be caused by a retinal vein occlusion.

What is a biodegradable implant?

A biodegradable implant is one that doesn't need to be removed after it's done working. OZURDEX® biodegradable implants use advanced

OZURDEX[®]

(dexamethasone intravitreal implant) 0.7 mg

NOVADUR[®] drug delivery technology, in which biodegradable material is combined with the active drug dexamethasone to form a tiny rod-shaped implant. Inside the eye, the implant is slowly dissolved by the vitreous gel that fills the eye, releasing dexamethasone.

Important Safety Information

OZURDEX[®] should not be used in patients who have any infections or diseases in the eye, or surrounding eye area, including most viral diseases of the cornea and conjunctiva, including active herpes viral infection of the eye, vaccinia, varicella, mycobacterial infections, and fungal diseases.

OZURDEX[®] should not be used in patients with advanced glaucoma. You should not use OZURDEX[®] if you are allergic to one of its ingredients.

Injections into the vitreous in the eye are associated with serious eye infection (endophthalmitis), eye inflammation, increased eye pressure, and retinal detachments.

Use of corticosteroids may produce posterior subcapsular cataracts, increased eye pressure, glaucoma, and may increase the establishment of secondary ocular infections due to bacteria, fungi, or viruses.

Please see additional Important Safety Information on pages 12-13.

Your treatment:

How is OZURDEX® administered?

The OZURDEX® implant is so tiny that it can be injected into the eye (vitreous) through a small needle. Each implant is already inside a special applicator device that is needed to perform the insertion. The implant will be injected into the vitreous humor inside your eye. This is known as an intravitreal injection. The next section of this booklet provides more details about the intravitreal injection procedure.

Will I receive OZURDEX® more than once?

Your doctor may decide to administer OZURDEX® again if he or she believes that you may benefit from another injection.



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What results can I expect with an OZURDEX[®] intravitreal implant?

It's important to remember that each case of retinal vein occlusion is unique. In clinical studies, 20% (20 of 100) to 30% of patients (30 of 100) who received OZURDEX[®] gained 3 or more lines of vision on the eye chart in the first 2 months—compared with 7% (7 of 100) to 12% of patients (12 of 100) who received sham (simulated) injections. Once vision had improved, the improvement lasted approximately 1 to 3 months. Your own results may vary.

Is there anyone who should not be given OZURDEX[®]?

You should not receive OZURDEX[®] if you have an eye infection in or near your eye (including herpes viral infections of the eye; vaccinia; varicella; mycobacteria; and fungal diseases); if you have advanced glaucoma; or if you are allergic to corticosteroids or to any other ingredient of OZURDEX[®] intravitreal implants.

Please see additional Important Safety Information on pages 12-13.

Your intravitreal injection:

Are intravitreal injections common?

Yes. Intravitreal injections are now used to deliver medication to treat many types of eye conditions. Your Retina Specialist is specially trained in giving eye injections.

What happens during the injection procedure?

You will be awake during the procedure. Your doctor will follow steps that include ensuring the surface of the eye is clean and numbing the surface of the eye to help keep you comfortable. OZURDEX[®] is injected using a special applicator device that's about the size of a pen. The applicator is designed to help your doctor deliver OZURDEX[®] to the vitreous where the medication is needed. The injection will be complete within seconds, and the procedure is generally well tolerated by patients.

Are there any risks with intravitreal injections?

Injections into the vitreous in the eye are associated with serious eye infection (endophthalmitis, pronounced en-dof-thal-**my**-tis), eye inflammation, increased eye pressure, and retinal detachments. In the days following

Please see additional Important Safety Information on pages 12-13.

Understanding the Procedure

injection with OZURDEX[®], patients are at risk for potential complications including in particular, but not limited to, the development of serious eye infection or elevated intraocular 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 machines until this has resolved.

What do patients who've received OZURDEX[®] say about their experiences?



“There was **no real discomfort.**”

“All I felt **was a little pressure.**”



“I didn't realize he was doing the injection **until after he was done.**”



Not all patients can expect these results.
Individual results may vary.

Your safety:

Indications

OZURDEX® (dexamethasone intravitreal implant) is an implant injected into the eye (vitreous) and used:

- To treat adults with macular edema following branch retinal vein occlusion (BRVO) or central retinal vein occlusion (CRVO)
- To treat adults with noninfectious uveitis affecting the posterior segment of the eye

Important Safety Information

OZURDEX® should not be used in patients who have any infections or diseases in the eye, or surrounding eye area, including most viral diseases of the cornea and conjunctiva, including active herpes viral infection of the eye, vaccinia, varicella, mycobacterial infections, and fungal diseases.

OZURDEX® should not be used in patients with advanced glaucoma. You should not use OZURDEX® if you are allergic to one of its ingredients.

Injections into the vitreous in the eye are associated with serious eye infection (endophthalmitis), eye inflammation, increased eye pressure, and retinal detachments.

Use of corticosteroids may produce posterior subcapsular cataracts, increased eye pressure, glaucoma, and may increase the establishment of secondary ocular infections due to bacteria, fungi, or viruses.

In the days following injection with OZURDEX®, patients are at risk for potential complications including in particular, but not limited to, the development of serious eye infection or elevated

Be Aware and Follow Up

intraocular 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 machines until this has resolved.

The most common side effects reported in patients include: increased eye pressure, conjunctival bleeding, eye pain, conjunctival hyperemia, ocular hypertension, cataract, vitreous detachment, and headache.

OZURDEX® is for prescription use only. Individual results with OZURDEX® may vary.

Full prescribing information has been provided to your doctor.

What else should I know about safety and follow up?

Corticosteroids, such as OZURDEX® intravitreal implants, can cause the fluid pressure inside the eye to increase. This is not something you can feel. So, following the injection, your doctor should monitor your eye pressure. If you experience this side effect, treatment such as medicated eyedrops or surgery may be required to lower the pressure.

Some patients who receive OZURDEX® intravitreal implants may develop cataracts or their existing cataracts may worsen. It's important to remember that not treating macular edema may lead to irreversible vision loss. You should discuss this issue with your doctor.

Your “to do” list:

Before injection

Day of injection

After injection

Doctor's Instructions

You should return to the office as follows:

To help assess the effectiveness of your treatment, please note any of the following:

- Vision improvement
- Eye pain, discomfort, additional blurring of vision, or increased eye redness (please call the office immediately)

Change	Date & Time

Ozurdex[®]

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implant) 0.7 mg

FDA-approved treatment for
macular edema following branch or
central retinal vein occlusion.

To learn more:

Visit www.Ozurdex.com for information
about retinal vein occlusion and treatment
with OZURDEX[®] intravitreal implants.

**Please see Important Safety
Information on pages 12-13.**

**Full prescribing information has
been provided to your doctor.**



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HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use OZURDEX® safely and effectively. See full prescribing information for OZURDEX®.

OZURDEX® (dexamethasone intravitreal implant)

Initial U.S. Approval: 1958

RECENT MAJOR CHANGES

Indications and Usage (1) 09/2010

INDICATIONS AND USAGE

OZURDEX® is a corticosteroid indicated for the treatment of macular edema following branch retinal vein occlusion (BRVO) or central retinal vein occlusion (CRVO) (1.1) and for the treatment of non-infectious uveitis affecting the posterior segment of the eye. (1.2)

DOSAGE AND ADMINISTRATION

- For ophthalmic intravitreal injection only. (2.1)
- The intravitreal injection procedure should be carried out under controlled aseptic conditions. Following the intravitreal injection, patients should be monitored for elevation in intraocular pressure and for endophthalmitis. (2.2)

DOSAGE FORMS AND STRENGTHS

- Intravitreal implant containing dexamethasone 0.7 mg in the NOVADUR® solid polymer drug delivery system. (3)

CONTRAINDICATIONS

- Ocular or periocular infections. (4.1)
- Advanced glaucoma. (4.2)

WARNINGS AND PRECAUTIONS

- Intravitreal injections have been associated with endophthalmitis, eye inflammation, increased intraocular pressure, and retinal detachments. Patients should be monitored following the injection. (5.1)
- Use of corticosteroids may produce posterior subcapsular cataracts, increased intraocular pressure, glaucoma, and may enhance the establishment of secondary ocular infections due to bacteria, fungi, or viruses. (5.2)

ADVERSE REACTIONS

In controlled studies, the most common adverse reactions reported by ≥ 20% of patients were increased intraocular pressure and conjunctival hemorrhage. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Allergan at 1-800-433-8871 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

See 17 for PATIENT COUNSELING INFORMATION

Revised: 09/2010

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FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

1.1 Retinal Vein Occlusion

OZURDEX[®] (dexamethasone intravitreal implant) is indicated for the treatment of macular edema following branch retinal vein occlusion (BRVO) or central retinal vein occlusion (CRVO).

1.2 Posterior Segment Uveitis

OZURDEX[®] is indicated for the treatment of non-infectious uveitis affecting the posterior segment of the eye.

2 DOSAGE AND ADMINISTRATION

2.1 General Dosing Information

For ophthalmic intravitreal injection only.

2.2 Administration

The intravitreal injection procedure should be carried out under controlled aseptic conditions which include the use of sterile gloves, a sterile drape, and a sterile eyelid speculum (or equivalent). Adequate anesthesia and a broad-spectrum microbicide are recommended to be given prior to the injection.

Remove the foil pouch from the carton and examine for damage. Then, open the foil pouch over a sterile field and gently drop the applicator on a sterile tray. Carefully remove the cap from the applicator. Hold the applicator in one hand and pull the safety tab straight off the applicator. **Do not twist or flex the tab.** The long axis of the applicator should be held parallel to the limbus, and the sclera should be engaged at an oblique angle with the bevel of the needle up (away from the sclera) to create a shelved scleral path. The tip of the needle is advanced within the sclera for about 1 mm (parallel to the limbus), then re-directed toward the center of the eye and advanced until penetration of the sclera is completed and the vitreous cavity is entered. The needle should not be advanced past the point where the sleeve touches the conjunctiva.

Slowly depress the actuator button until an audible click is noted. Before withdrawing the applicator from the eye, make sure that the actuator button is fully depressed and has locked flush with the applicator surface. Remove the needle in the same direction as used to enter the vitreous.

Following the intravitreal injection, patients should be monitored for elevation in intraocular pressure and for endophthalmitis. Monitoring may consist of a check for perfusion of the optic nerve head immediately after the injection, tonometry within 30 minutes following the injection, and biomicroscopy between two and seven days following the injection. Patients should be instructed to report any symptoms suggestive of endophthalmitis without delay.

Each applicator can only be used for the treatment of a single eye. If the contralateral eye requires treatment, a new applicator must be used, and the sterile field, syringe, gloves, drapes, and eyelid speculum should be changed before **OZURDEX**[®] is administered to the other eye.

3 DOSAGE FORMS AND STRENGTHS

Intravitreal implant containing dexamethasone 0.7 mg in the **NOVADUR**[®] solid polymer drug delivery system.

4 CONTRAINDICATIONS

4.1 Ocular or Periocular Infections

OZURDEX[®] (dexamethasone intravitreal implant) is contraindicated in patients with active or suspected ocular or periocular infections including most viral diseases of the cornea and conjunctiva, including active epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, varicella, mycobacterial infections, and fungal diseases.

4.2 Advanced Glaucoma

OZURDEX[®] is contraindicated in patients with advanced glaucoma.

4.3 Hypersensitivity

OZURDEX[®] is contraindicated in patients with known hypersensitivity to any components of this product.

5 WARNINGS AND PRECAUTIONS

5.1 Intravitreal Injection-related Effects

Intravitreal injections have been associated with endophthalmitis, eye inflammation, increased intraocular pressure, and retinal detachments.

Patients should be monitored following the injection (see **PATIENT COUNSELING INFORMATION**, 17).

5.2 Potential Steroid-related Effects

Use of corticosteroids may produce posterior subcapsular cataracts, increased intraocular pressure, glaucoma, and may enhance the establishment of secondary ocular infections due to bacteria, fungi, or viruses.

Corticosteroids should be used cautiously in patients with a history of ocular herpes simplex.

6 ADVERSE REACTIONS

6.1 Clinical Studies Experience

Because clinical studies are conducted under widely varying conditions, adverse reaction rates observed in the clinical studies of a drug cannot be directly compared to rates in the clinical studies of another drug and may not reflect the rates observed in practice.

Adverse reactions associated with ophthalmic steroids include elevated intraocular pressure, which may be associated with optic nerve damage, visual acuity and field defects, posterior subcapsular cataract formation, secondary ocular infection from pathogens including herpes simplex, and perforation of the globe where there is thinning of the cornea or sclera.

The following information is based on the combined clinical trial results from 3 initial, randomized, 6-month, sham-controlled studies (2 for retinal vein occlusion and 1 for posterior segment uveitis):

Adverse Reactions Reported by Greater than 2% of Patients in the First Six Months

MedDRA Term	OZURDEX® N=497 (%)	Sham N=498 (%)
Intraocular pressure increased	125 (25%)	10 (2%)
Conjunctival hemorrhage	108 (22%)	79 (16%)
Eye pain	40 (8%)	26 (5%)
Conjunctival hyperemia	33 (7%)	27 (5%)
Ocular hypertension	23 (5%)	3 (1%)
Cataract	24 (5%)	10 (2%)
Vitreous detachment	12 (2%)	8 (2%)
Headache	19 (4%)	12 (2%)

Increased IOP with **OZURDEX®** peaked at approximately week 8. During the initial treatment period, 1% (3/421) of the patients who received **OZURDEX®** required surgical procedures for management of elevated IOP.

Following a second injection of **OZURDEX®** in cases where a second injection was indicated, the overall incidence of cataracts was higher after 1 year.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Teratogenic Effects: Pregnancy Category C

Topical dexamethasone has been shown to be teratogenic in mice producing fetal resorptions and cleft palate. In the rabbit, dexamethasone produced fetal resorptions and multiple abnormalities involving the head, ears, limbs, palate, etc. Pregnant rhesus monkeys treated with dexamethasone sodium phosphate intramuscularly at 1 mg/kg/day every other day for 28 days or at 10 mg/kg/day once or every other day at 3 or 5 days between gestation days 23 and 49 had fetuses with minor cranial abnormalities. A 1 mg/kg/dose in pregnant rhesus monkeys would be approximately 85 times higher than an **OZURDEX®** injection in humans (assuming 60 kg body weight).

There are no adequate and well-controlled studies in pregnant women. **OZURDEX®** (dexamethasone intravitreal implant) should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

8.3 Nursing Mothers

It is not known whether ocular administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in human milk. Systemically administered corticosteroids appear in human milk and could suppress growth, interfere with endogenous corticosteroid production, or cause other untoward effects. Caution should be exercised when corticosteroids are administered to a nursing woman.

8.4 Pediatric Use

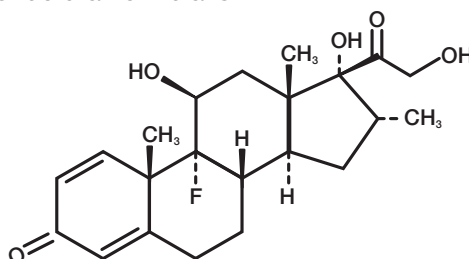
Safety and effectiveness of **OZURDEX®** in pediatric patients have not been established.

8.5 Geriatric Use

No overall differences in safety or effectiveness have been observed between elderly and younger patients.

11 DESCRIPTION

OZURDEX® is an intravitreal implant containing 0.7 mg (700 µg) dexamethasone in the **NOVADUR®** solid polymer drug delivery system. **OZURDEX®** is preloaded into a single-use, specially designed **DDS®** applicator to facilitate injection of the rod-shaped implant directly into the vitreous. The **NOVADUR®** system contains poly (D,L-lactide-co-glycolide) PLGA intravitreal polymer matrix without a preservative. The chemical name for dexamethasone is Pregna-1,4-diene-3,20-dione, 9-fluoro-11,17,21-trihydroxy-16-methyl-, (11β,16α)-. Its structural formula is:



MW 392.47; molecular formula: C₂₂H₂₉FO₅.

Dexamethasone occurs as a white to cream-colored crystalline powder having not more than a slight odor, and is practically insoluble in water and very soluble in alcohol.

The PLGA matrix slowly degrades to lactic acid and glycolic acid.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Dexamethasone, a potent corticosteroid, has been shown to suppress inflammation by inhibiting multiple inflammatory cytokines resulting in decreased edema, fibrin deposition, capillary leakage and migration of inflammatory cells.

12.3 Pharmacokinetics

Plasma concentrations were obtained from 21 patients in two 6 month studies prior to dosing and on Days 7, 30, 60, and 90 following the intravitreal implant containing 0.35 mg or 0.7 mg dexamethasone. In both studies, the majority of plasma dexamethasone concentrations were below the lower limit of quantitation (LLOQ = 50 pg/mL). Plasma dexamethasone concentrations from 10 of 73 samples in the 0.7 mg dose group and from 2 of 42 samples in the 0.35 mg dose group were above the LLOQ, ranging from 52 pg/mL to 94 pg/mL. The highest plasma concentration value of 94 pg/mL was observed in one subject from the 0.7 mg group. Plasma dexamethasone concentration did not appear to be related to age, body weight, or sex of patients.

In an in vitro metabolism study, following the incubation of [¹⁴C]-dexamethasone with human cornea, iris-ciliary body, choroid, retina, vitreous humor, and sclera tissues for 18 hours, no metabolites were observed.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

No adequate studies in animals have been conducted to determine whether **OZURDEX**[®] (dexamethasone intravitreal implant) has the potential for carcinogenesis.

Although no adequate studies have been conducted to determine the mutagenic potential of **OZURDEX**[®], dexamethasone has been shown to have no mutagenic effects in bacterial and mammalian cells in vitro or in the in vivo mouse micronucleus test.

14 CLINICAL STUDIES

Retinal Vein Occlusion

The efficacy of **OZURDEX**[®] for the treatment of macular edema following branch retinal vein occlusion (BRVO) or central retinal vein occlusion (CRVO) was assessed in two, multicenter, double-masked, randomized, parallel studies.

Following a single injection, **OZURDEX**[®] demonstrated the following clinical results for the percent of patients with ≥ 15 letters of improvement from baseline in best-corrected visual acuity (BCVA):

Number (Percent) of Patients with ≥ 15 Letters Improvement from Baseline in BCVA

Study Day	Study 1			Study 2		
	DEX 700 N=201	Sham N=202	p-value*	DEX 700 N=226	Sham N=224	p-value*
Day 30	40 (20%)	15 (7%)	< 0.01	51 (23%)	17 (8%)	< 0.01
Day 60	58 (29%)	21 (10%)	< 0.01	67 (30%)	27 (12%)	< 0.01
Day 90	45 (22%)	25 (12%)	< 0.01	48 (21%)	31 (14%)	0.039
Day 180	39 (19%)	37 (18%)	0.780	53 (24%)	38 (17%)	0.087

*P-values were based on the Pearson's Chi-square test.

In each individual study and in a pooled analysis, time to achieve ≥ 15 letters (3-line) improvement in BCVA cumulative response rate curves were significantly faster with **OZURDEX**[®] compared to sham ($p < 0.01$), with **OZURDEX**[®]-treated patients achieving a 3-line improvement in BCVA earlier than sham-treated patients.

The onset of a ≥ 15 letter (3-line) improvement in BCVA with **OZURDEX**[®] occurs within the first two months after implantation in approximately 20-30% of subjects. The duration of effect persists approximately one to three months after onset of this effect.

Posterior Segment Uveitis

The efficacy of **OZURDEX**[®] was assessed in a single, multicenter, masked, randomized study of 153 patients with non-infectious uveitis affecting the posterior segment of the eye.

After a single injection, the percent of patients reaching a vitreous haze score of 0 (where a score of 0 represents no inflammation) was statistically significantly greater for patients receiving **OZURDEX**[®] versus sham at week 8 (primary time point) (47% vs. 12%). The percent of patients achieving a 3-line improvement from baseline BCVA was 43% for patients receiving **OZURDEX**[®] vs. 7% for sham at week 8.

16 HOW SUPPLIED/STORAGE AND HANDLING

OZURDEX[®] (dexamethasone intravitreal implant) 0.7 mg is supplied in a foil pouch with 1 single-use plastic applicator, NDC 0023-3348-07.

Storage: Store at 15°-30°C (59°-86°F).

17 PATIENT COUNSELING INFORMATION

In the days following intravitreal injection of **OZURDEX**[®], patients are at risk for potential complications including in particular, but not limited to, the development of endophthalmitis or elevated intraocular pressure. If the eye becomes red, sensitive to light, painful, or develops a change in vision, the patients should seek immediate care from an ophthalmologist.

Patients may experience temporary visual blurring after receiving an intravitreal injection. They should not drive or use machines until this has resolved.

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U.S. Patents 6,726,918; 6,899,717; 7,033,605; and 7,767,223

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