

FDA-Approved
Treatment
for
Noninfectious Uveitis
Affecting the Posterior
Segment of the Eye

Ozurdex[®]
(dexamethasone intravitreal
implant) 0.7 mg

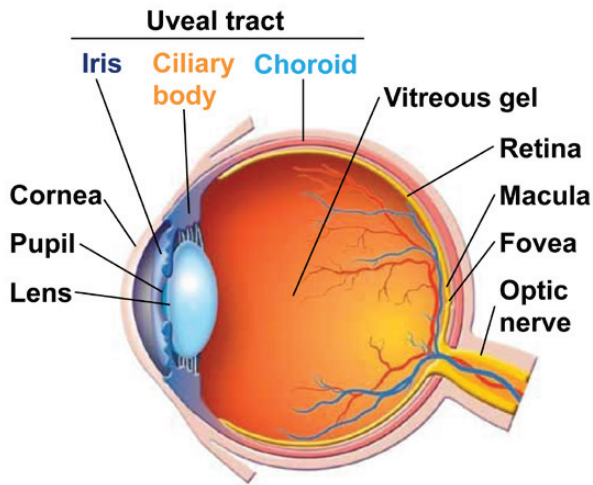
Important Safety Information

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.

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

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.

What role does the uvea play in the eye?

The uvea, or uveal tract, is the middle layer of the eye. The 3 parts of the uvea—the iris, ciliary body, and choroid—have important functions.

The iris, which is the colored part of the eye, contracts and dilates to control how much light enters the eye. By adjusting, it allows you to see under a variety of lighting conditions.

The ciliary body releases aqueous humor, which nourishes the front part of the eye. It also contains the ciliary muscle, which changes the shape of the lens to help you focus.

Located between the sclera (white of the eye) and the retina, the choroid is a layer of connective tissue and blood vessels. The choroid nourishes the inner parts of the eye.

Why is a healthy uvea important?

A healthy uvea is essential for normal vision. When a disease such as uveitis occurs, it may lead to impaired vision or loss of vision. In the next section of this booklet, you will learn more about uveitis.

Your condition:

Noninfectious Uveitis Affecting the Posterior Segment of the Eye

What is noninfectious posterior segment uveitis?

Uveitis (pronounced you-vee-eye-tis) is inflammation of the uvea. Inflammation is caused by your immune system's white blood cells and by the chemicals these cells release.

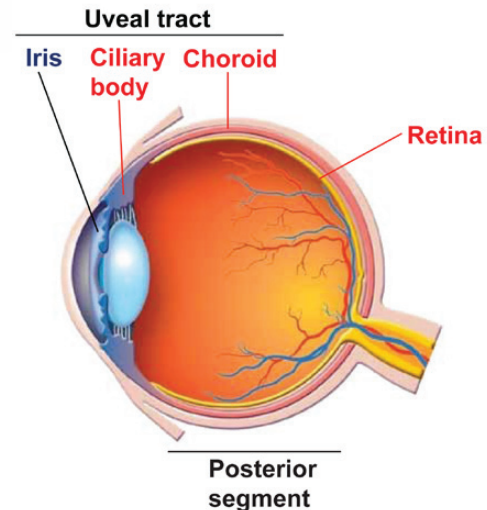
Noninfectious uveitis means that although the uvea is inflamed, no bacteria or viruses are found in the eye. The inflammation may be caused indirectly by a disease affecting one of your body's other systems, but often no cause can be found. When that is the case, you may be having an autoimmune reaction, which means that, for an unknown reason, the body is reacting to some of its own cells as if they were foreign, creating vitreous haze.

Posterior segment uveitis may include the middle section of the uvea around the ciliary body (reaching the edge of the retina) and/or it may affect the choroid and other parts of the back of the eye, including the entire retina and the blood vessels of the retina.

What are the symptoms?

Posterior segment uveitis is usually painless. Your vision may be decreased and you may see irregular floating black spots (floaters). More severe posterior uveitis affecting the retina can lead to significant loss of vision.

Uveal inflammation affecting the posterior segment of the eye (highlighted in red)



How can this condition affect the eye?

The inflammation associated with posterior segment uveitis can cause immune cells to enter the vitreous gel that fills the back of your eye, creating what is known as vitreous haze. The haze can contribute to decreased vision.

Uveitis can damage the eye and cause long-term complications that reduce vision. While many people have only a single episode of uveitis, others may have recurrences over months to years. It is very important to receive medical treatment for the inflammation of posterior segment uveitis.

Your treatment:

OZURDEX[®]
(dexamethasone intravitreal implant) 0.7mg

Why did my doctor choose OZURDEX[®]?

OZURDEX[®] has been approved by the US Food and Drug Administration (FDA) to treat noninfectious uveitis affecting the posterior segment of the eye. OZURDEX[®] intravitreal implant has been proven effective in a large clinical trial. Your doctor has chosen OZURDEX[®] to help treat the inflammation causing vitreous haze that is affecting your vision. 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 (swelling) of the retina. OZURDEX[®] may help reverse some vision loss that may be caused by uveitis.

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 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. OZURDEX[®] is an implant injected into the eye (vitreous) 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.

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

Your treatment:

OZURDEX[®]
(dexamethasone intravitreal implant) 0.7mg

How is OZURDEX[®] administered?

The OZURDEX[®] implant is so tiny that it can be injected into the eye (vitreous) with a procedure in your doctor's office. 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.

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

In a clinical study, 46.8% of OZURDEX[®] patients (about 47 of 100) achieved a vitreous haze score of zero, that is, no detectable haze, at week 8—compared with 11.8% of patients (about 12 of 100) who received sham (simulated) injections. Also, at week 8, 42.9% of OZURDEX[®] patients (about 43 of 100) gained 3 or more lines of vision on the eye chart, compared with 6.6% of sham-treated patients (about 7 of 100).

It's important to remember that each case of uveitis is unique. 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:

Understanding the Procedure

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), eye inflammation, increased eye pressure, and retinal detachments. 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 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.

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



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 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 uveitis may lead to irreversible vision loss. You should discuss this issue with your doctor.

Your "to do" list:

Doctor's Instructions

Before injection

Day of injection

After injection

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[®]

(dexamethasone
intravitreal implant) 0.7mg

FDA-approved treatment for
noninfectious uveitis affecting
the posterior segment of the eye.

To learn more:

Visit www.Ozurdex.com for
information about uveitis 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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OZURDEX®

(dexamethasone intravitreal implant) 0.7 mg

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

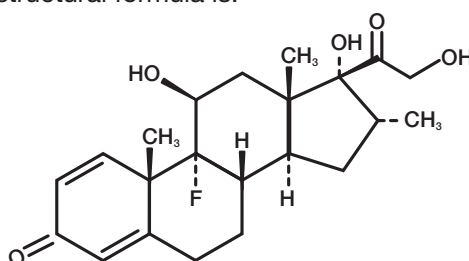
Safety and effectiveness of **OZURDEX®** in pediatric patients have not been established.

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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