

Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **OZURDEX**®

Dexamethasone Intravitreal Implant

This Patient Medication Information is written for the person who will be taking **OZURDEX**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This Patient Medication Information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about **OZURDEX**, talk to a healthcare professional.

What OZURDEX is used for:

OZURDEX is used in adults to treat:

- **Macular edema:** swelling in a part of the eye called the macula that is caused by a blockage of veins in the eye.
- **Non-infectious uveitis:** inflammation of the back part of the eye that is not caused by an eye infection.
- **Diabetic macular edema (DME):** swelling of the macula in patients with diabetes who have had cataract surgery and artificial lens implantation.

These conditions all cause swelling in the back part of your eye, which leads to vision changes and vision loss.

How OZURDEX works:

OZURDEX works by reducing swelling of the macula. This helps to lessen or prevent more damage to the macula. The macula is an area in the centre of the back part of the eye. It is responsible for clear vision.

OZURDEX also works by reducing inflammation in the back part of the eye.

The ingredients in OZURDEX are:

Medicinal ingredient: dexamethasone

Non-medicinal ingredients: A polymer drug delivery system that contains PLGA biodegradable polymer matrix (NOVADUR®): Resomer® RG 502, Poly (D,L-lactide-co-glycolide), 50:50 PLGA ester terminated; and Resomer® RG 502 H, Poly (D,L-lactide-co-glycolide), 50:50 PLGA acid terminated

OZURDEX comes in the following dosage form(s):

An intravitreal implant that contains 0.7 mg dexamethasone. Intravitreal means that this implant is placed into the eye through an injection.

Do not use OZURDEX if:

- you are allergic to dexamethasone or any of the other ingredients in OZURDEX
- you are allergic to other medicines like OZURDEX, called corticosteroids
- you have an eye infection of any kind caused by bacteria, a virus or a fungus
- you have glaucoma that is at an advanced stage
- you have aphakic eyes (eyes without natural or artificial lens) along with a tear in the posterior lens capsule of your eye
- you have a condition called Anterior Chamber Intraocular Lens (ACIOL) along with a tear in the posterior lens capsule of your eye

Ask your healthcare professional if you are not sure if you have any of the conditions listed above.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take OZURDEX. Talk about any health conditions or problems you may have, including if you:

- have aphakic eyes (eyes without natural or artificial lens)
- have a tear in the posterior lens capsule of your eye
- have had a herpes simplex infection in your eye before (an ulcer on the eye that has been there a long time, or sores on the eye)
- are taking any medication to thin the blood
- are pregnant or planning to become pregnant
- are breast feeding or planning to breast feed
- had recent eye surgery, or plan to have eye surgery which may or may not cause swelling/damage of the clear part of the eye

Other warnings you should know about:

Eye problems: The following may occur or get worse after OZURDEX treatment:

- an infection inside or around the eye
- redness (inflammation) inside the eye
- glaucoma and/or increased pressure in the eye
- detachment of the layer in the back of the eye (retinal detachment)
- clouding of the lens (cataract)
- misplacement of implant that requires surgical intervention

It is important to identify and treat these conditions as soon as possible. Tell your healthcare professional immediately if you have any concerns with your eye or experience any of the following signs:

- blurred or decreased vision
- eye pain or increased discomfort
- worsening eye redness

- a feeling of spots in front of the eye (called 'floaters')
- increased sensitivity to light

In some patients the pressure in the eye may increase right after OZURDEX is implanted into the eye. This is something you may not notice, so your healthcare professional might monitor this after OZURDEX is implanted.

Driving and using machines:

After OZURDEX treatment you may experience some blurred vision for a short time. Wait until you can see clearly before driving or using machines.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with OZURDEX:

- medicines used to thin your blood called blood thinners
- sedatives and sleep-inducing medicines called barbiturates
- rifampin, which is a medicine used to treat tuberculosis
- ketoconazole, which is a medicine used to treat fungal infections
- indinavir, which is a medicine used to treat HIV infection
- medicines used to treat seizures, like phenytoin or carbamazepine
- erythromycin, which is an antibiotic

How to take OZURDEX:

- OZURDEX will be given to you by a healthcare professional, called an ophthalmologist, who has experience in giving injections into the eye.
- it will be implanted directly into your eye through an injection.
- it is not recommended that both of your eyes be injected with OZURDEX at the same time.
- after you receive the injection, your healthcare professional will check your eye.
- you may be given antibiotic eye drops to use before, during or after your injection to prevent eye infections.
- you may also be given a pain medicine on the day of your injection.
- you may hear a 'click' during the injection of OZURDEX; you should not move, as this is expected.
- follow all instructions given to you by your healthcare professional.

Usual dose:

The usual dose is one OZURDEX implant to be given by injection into your eye. Your healthcare professional will decide if you should receive another OZURDEX injection. If you need another injection, your healthcare professional will wait 6 months to give it to you.

Overdose:

If you think you, or a person you are caring for, have taken too much OZURDEX, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

Missed dose:

If you miss your appointment to receive OZURDEX, contact your healthcare professional or hospital as soon as possible to reschedule your appointment.

Possible side effects from using OZURDEX:

These are not all the possible side effects you may have when taking OZURDEX. If you experience any side effects not listed here, tell your healthcare professional.

Serious side effects and what to do about them

Frequency/Side Effect/Symptom	Talk to your healthcare professional		[Stop taking this drug and get immediate medical help] OR [Get immediate medical help]
	Only if severe	In all cases	
Very common			
IOP increase (increased pressure in the eye): eye pain, nausea, vomiting		✓	
Glaucoma (serious eye disease where pressure in the eye is increased): blurred vision, eye redness, halos around lights, loss of vision, nausea, severe eye pain, vomiting		✓	
Cataracts (clouding of the lens of your eye): blurry vision, clouded vision, eye pain, fading or yellowing of colours, seeing halos and glare around lights, trouble seeing at night		✓	
Conjunctival haemorrhage (bleeding on the surface of the eye)	✓		
Common			
Vitreous detachment (detachment of the jelly inside the eye from the light-sensitive layer at the back of		✓	

Frequency/Side Effect/Symptom	Talk to your healthcare professional		[Stop taking this drug and get immediate medical help] OR [Get immediate medical help]
	Only if severe	In all cases	
the eye): seeing flashes of light and floaters			
Vitreous haemorrhage (bleeding into the inside of the eye): blurry or blocked vision, floaters		✓	
Abnormal sensation in eye (abnormal feeling in the eye)	✓		
Blepharitis, eyelids pruritus (inflammation and itchiness of the eyelid)	✓		
Migraine: severe headache, with or without vision changes (aura)	✓		
Conjunctival oedema (swelling on the surface of the eye)	✓		
Vitreous opacities (a feeling of looking through mist or fog)	✓		
Rare			
Retinal tear (tear in the retina or retinal detachment): seeing floaters and flashing lights; or vision loss or difficulty seeing		✓	
Anterior chamber flare (increased protein in the front of the eye due to inflammation): blurry vision	✓		
Headache		✓	
Necrotizing retinitis (severe inflammation at the back of the eye [usually due to viral infection]): eye redness, pain in your eyeball, sensitive to light, vision loss		✓	✓
Endophthalmitis (severe infection and inflammation inside the eye): eye pain, redness, vision loss		✓	
Unknown			
Device dislocation (migration of implant) with or without corneal oedema/corneal decompensation (implant migrated from the back to the front part of the eye which may or may not cause		✓	

Frequency/Side Effect/Symptom	Talk to your healthcare professional		[Stop taking this drug and get immediate medical help] OR [Get immediate medical help]
	Only if severe	In all cases	
swelling/damage of the clear part of the eye): blurry vision			
Hypotony of the eye (low eye pressure): blurry vision	✓		
Central Serous Chorioretinopathy (fluid build-up at the back of the eye): blurry vision		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting side effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (canada.ca/drug-device-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store at room temperature between 15 and 30°C. Protect from excessive heat.

Keep out of reach and sight of children.

If you want more information about OZURDEX:

Talk to your healthcare professional

- Find the full product monograph that is prepared for healthcare professionals and includes the Patient Medication Information by visiting the Health Canada Drug Product Database website ([Drug Product Database: Access the database](http://DrugProductDatabase:Access%20the%20database)); the manufacturer's website (www.abbvie.ca); or by calling 1-888-704-8271.

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