OZURDEX®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. What OZURDEX® is used for

OZURDEX® contains the active ingredient dexamethasone which is contained in a small implant for injection into the back of the eye. OZURDEX® is used to treat swelling of the light-sensitive layer at the back of the eye known as the macular, treat vision loss caused by a blockage of veins in the eye and inflammation affecting the layer of blood vessels and connective tissue between the white of the eye and retina at the back of the eye.

For more information, see Section 1. What OZURDEX is used for? in the full CMI.

2. What should I know before I am given OZURDEX®?

Check the list of ingredients at the end of the CMI. Do not use OZURDEX® if you have ever had an allergic reaction to any of them.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I am given OZURDEX®? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with OZURDEX® and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How is OZURDEX® used?

OZURDEX® will be injected into your eye by an appropriately qualified eye doctor.

More instructions can be found in Section 4. How is OZURDEX® used? in the full CMI.

5. What should I know while using OZURDEX®?

Before Stopping Ozurdex Treatment	• If you decide not to receive a repeat OZURDEX® treatment, please go to your next appointment and

	discuss this with your doctor. Your doctor will advise you and decide how long you should be treated with OZURDEX®.
Driving or using machines	• You may experience temporarily reduced vision after being treated with OZURDEX®. • You should not drive or operate machinery until your vision has returned to normal
Looking after your medicine	• The hospital or clinic will store your medicine before use below 25°C, and protect from excessive heat.

For more information, see Section 5. What should I know while using OZURDEX®? in the full CMI.

6. Are there any side effects?

Contact your doctor immediately if you notice any of the following after OZURDEX® has been inserted: blurred or decreased vision, distorted vision, eye pain or increased discomfort, worsening eye redness, spots in front of the eye (sometimes called “floaters”), increased sensitivity to light, any unusual discharge from the eye, bleeding or

swelling on the front of the eye, seeing flashes of light, headache or migraine.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

OZURDEX (oz-er-dex)

Active ingredient(s): *[dexamethasone]* (dex-ah-meth-ah-zone)

Consumer Medicine Information (CMI)

This leaflet provides important information about using OZURDEX®. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using OZURDEX®.**

Where to find information in this leaflet:

1. What OZURDEX® is used for?
2. What should I know before I am given OZURDEX®?
3. What if I am taking other medicines?
4. How is OZURDEX® used?
5. What should I know while using OZURDEX®?
6. Are there any side effects?
7. Product details

1. What OZURDEX® is used for?

OZURDEX® contains the active ingredient dexamethasone.

Dexamethasone belongs to a group of medicines called corticosteroids. OZURDEX® works by reducing the swelling which helps to lessen or prevent more damage

to the macula. OZURDEX® is contained within a small implant injected into the back of the eye by your doctor using a specially designed applicator.

OZURDEX® is used to treat adult patients with Diabetic Macular Oedema (DME), which is a swelling of the light-sensitive layer at the back of the eye called the macula. DME is a condition that affects some people with diabetes.

OZURDEX® is used to treat vision loss caused by a blockage of veins in the eye. This blockage leads to a build up of fluid causing swelling in the area of the retina (the light-sensitive layer at the back of the eye) called the macula. The swelling may lead to damage to the macula which affects your central vision which is used for tasks like reading.

OZURDEX® is also used to treat adult patients with Uveitis, which is an inflammation affecting the choroid (the layer of blood vessels and connective tissue between the white of the eye and retina at the back of the eye). Uveitis is a chronic disease with a high risk of permanent vision loss.

2. What should I know before I am given OZURDEX®?

Warnings

Do not use OZURDEX® if:

- you have an allergy to dexamethasone or any of the ingredients listed at the end of this leaflet
- you have an infection of any kind in or around your eyes (bacterial, viral, or fungal)
- you have advanced glaucoma or high pressure inside your eye that cannot be controlled by medications alone
- the eye to be treated does not have a lens and the back of the lens capsule (“the bag”) has been ruptured
- the eye to be treated has a man-made lens, which was implanted in the front compartment of the eye (anterior chamber intraocular lens) after cataract surgery, and the back of the lens capsule (“the bag”) has been ruptured

Check with your doctor if you:

- you have had cataract surgery, iris surgery (the coloured part of the eye that controls the amount of light that enters into the eye) or surgery to remove the gel (called the vitreous) from within the eye.
- you are taking any medicines to thin the blood.

- you are taking any steroid or non-steroidal anti-inflammatory medicines by mouth or applied to the eye
- you have had a herpes simplex infection in your eye in the past (an ulcer on the eye that has been there a long time, or sores on the eye)
- Before you receive OZURDEX® treatment, your doctor should tell you to immediately report any eye pain, change in vision, red eyes or sensitivity to light that occurs post-procedure

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Like most medicines OZURDEX® should not be used during pregnancy, unless clearly necessary

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Your doctor may prescribe antibiotics for you following surgery. These are OK to use with OZURDEX®.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect OZURDEX®.

4. How is OZURDEX® used?

How much to use

- All OZURDEX® injections will be administered by an appropriately qualified eye doctor.
- OZURDEX® is administered as a single injection into your eye under sterile conditions. Before the injection your doctor will use antibiotic eye drops and clean the surface of your eye carefully to help prevent infection. Your doctor will also give you a local anaesthetic to reduce or prevent any pain you might have with the injection. You may hear a “click” during the injection of OZURDEX®; this is normal.
- Afterwards your doctor may perform some additional tests to make sure there are no signs of inflammation or infection of the eye and will monitor your vision and the pressure in your eye.
- If your condition is found to be worsening, your doctor may administer OZURDEX® again.
- Follow all directions given to you by your doctor carefully. The directions may differ from the information contained in this leaflet.

- The injection of OZURDEX® into both eyes at the same time has not been studied and is not recommended. Your doctor should not inject OZURDEX® into both eyes at the same time.
- Follow the instructions provided and use OZURDEX® until your doctor tells you to stop.

How to long to use OZURDEX®

- Your doctor will advise you and decide how long you should be treated with OZURDEX®.

If a dose is missed

If you miss an OZURDEX® appointment, you need to contact your doctor as soon as possible to arrange another appointment.

If you have been given too much OZURDEX®

If you think that you have been given too much OZURDEX®, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using OZURDEX®?

Things you should do

Tell your doctor immediately if you develop symptoms such as the following after injection of OZURDEX®

- blurred, decreased vision or other visual disturbances
- eye pain or increased discomfort
- worsening eye redness
- a feeling of spots in front of the eye (sometimes called “floaters”)
- increased sensitivity to light
- any discharge from the eye

In some patients the pressure in the eye may increase for a short period after the injection, or patients may also develop an eye infection.

Increase in pressure in the eye can also occur at any time following injection, this is something you may not notice so your doctor will monitor you regularly after treatment.

Remind any doctor, dentist or pharmacist you visit that you are using OZURDEX.

Before stopping OZURDEX® treatment

- If you decide not to receive a repeat OZURDEX® treatment, please go to your next appointment and discuss this with your doctor. Your doctor will advise

you and decide how long you should be treated with OZURDEX®.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how OZURDEX® affects you.

You may experience temporarily reduced vision after being treated with OZURDEX®.

You should not drive or operate machinery until your vision has returned to normal.

Looking after your medicine

The hospital or clinic will store your medicine before use below 25°C, and protect from excessive heat.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
• **Eye-related:** • eyelid itching • redness of the eye	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
• **Eye-related:** • decreased vision • blurred vision • distorted vision • eye pain or increased discomfort • worsening eye redness • a feeling of spots in front of the eye or seeing floaters • increased sensitivity to light • any unusual discharge from the eye • bleeding or swelling on the front of the eye	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Serious side effects	What to do
• seeing flashes of light **Other:** • headache or migraine	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people. This includes complications from device insertion, including from implant misplacement.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription and will be injected by an appropriately qualified eye doctor.

What OZURDEX® contains

Active ingredient **(main ingredient)**	dexamethasone
Other ingredients **(inactive ingredients)**	polyglactin [poly (D,L-lactide-coglycolide)] PLGA biodegradable polymer matrix

Do not take this medicine if you are allergic to any of these ingredients.

What OZURDEX® looks like

OZURDEX® is a rod-shaped implant supplied in the needle part of a disposable application device. The implant and device are sterile. (Aust R 222392).

Who distributes OZURDEX®

OZURDEX® is distributed in Australia by:

AbbVie Pty Ltd

Mascot NSW 2020

Australia

Toll-free: 1800 252 224

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