PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

OZURDEX, 700 µg intravitreal implant

Dexamethasone

Read all of this leaflet carefully before you are given OZURDEX

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.

What is in this leaflet

1. What OZURDEX is and what it is used for
2. What you need to know before you are given OZURDEX
3. How to receive OZURDEX
4. Possible side effects
5. How to store OZURDEX
6. Contents of the pack and other information

1. What OZURDEX is and what it is used for

The active substance in OZURDEX is dexamethasone. Dexamethasone belongs to a group of medicines called corticosteroids.

OZURDEX is a small implant given by injection under local anaesthetic into the back of the eye by your eye doctor. OZURDEX is supplied in a pack with the implant already inside a specially-designed applicator which will be used once and then thrown away.

OZURDEX is used to treat adult patients with:

- Vision loss due to diabetic macular oedema (DME), if you have already had an operation for cataract, or if you have not previously responded to, or are not suitable for, other types of treatment. Diabetic macular oedema is 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.
- 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.

  Swelling of the macula may lead to damage which affects your central vision which is used for tasks like reading. OZURDEX works by reducing swelling of the macula which helps to lessen or prevent more damage to the macula.
- Inflammation of the back of the eye. This inflammation leads to a decrease of vision and/or the presence of floaters in the eye, (black dots or wispy lines that move across the field of vision). OZURDEX works by reducing this inflammation.

2. What you need to know before you are given OZURDEX

You must not be given OZURDEX:

- If you are hypersensitive (allergic) to dexamethasone or any of the other ingredients of OZURDEX;
- If you have an infection of any kind in or around your eye (bacterial, viral or fungal);
- If you have glaucoma or high pressure inside your eye which is at an advanced stage or not controlled properly with the medicines you may be using;
- If the eye to be treated does not have a lens and the back of the lens capsule (“the bag”) has been ruptured;
- If the eye to be treated has undergone cataract surgery and has a man-made lens, which was implanted in the front compartment of the eye (anterior chamber intraocular lens) or was fixed

to the white portion of the eye (sclera) or to the coloured part of the eye (iris), and the back of the lens capsule (“the bag”) has been ruptured;

- If the eye to be treated has an opening between the back (vitreous cavity) and the front (anterior chamber) of the eye.

Warnings and precautions

Before your OZURDEX injection, tell your doctor if:

- 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 in the eye).

The injection of OZURDEX may cause an infection inside the eye, pain or redness in the eye, or a detachment or tear of the retina. It is important to identify and treat these as soon as possible. Please tell your doctor immediately if you develop increased eye pain or increased discomfort, worsening redness of your eye, flashing lights and sudden increase in floaters, partially blocked vision, decreased vision or increased sensitivity to light after your injection.

In some patients the pressure in the eye may increase with the possible development of glaucoma. This is something you may not notice, so your doctor might monitor you regularly and, if necessary, provide treatment to lower the eye pressure.

In the majority of patients who have not yet had an operation for cataract, a clouding of the eye's

natural lens (a cataract) may occur after repeated treatment with OZURDEX. If this occurs your vision will decrease, and you are likely to need an operation to remove the cataract. Your doctor will help you to decide when is the most appropriate time to perform this operation, but you should be aware that until you are ready for your operation your vision may be as bad or worse than it was before you started receiving your OZURDEX injections.

The implant can move from the back to the front of the eye in patients with a tear in the back of the lens capsule and/or those who have an opening in the iris. This can lead to swelling of the clear layer in the front of the eye and cause blurred vision. If this continues for a long time and is left untreated, it may require tissue transplantation.

You may experience vision disturbance after receiving OZURDEX. Tell your doctor if you experience blurred vision or any other sight disturbances.

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.

Children and adolescents (below 18 years of age)

The use of OZURDEX in children and adolescents has not been studied and is therefore not recommended.

Other medicines and OZURDEX

Always tell your health care provider if you are taking or have recently taken any other medicine. (This includes complementary or traditional medicines and medicines obtained without prescription.)

Tell your doctor if you are using any of the following medicines:

- Medicines used to thin your blood;
- 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;
- Medicines used to treat HIV infection like indinavir, cobicistat or ritonavir;
- Medicines used to treat seizures, like phenytoin or carbamazepine;
- Antibiotics like erythromycin or clarithromycin;
- Itraconazole which is an antifungal medicine;
- Nefazodone which is used to treat depression.

Pregnancy and breastfeeding

There is no experience of using OZURDEX in pregnant women or during breastfeeding, so the possible risks are unknown. OZURDEX should not be used during pregnancy or breast-feeding unless your doctor thinks it is clearly necessary.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before receiving OZURDEX.

Driving and using machines

After OZURDEX treatment you may experience some blurred vision for a short time. If this happens, do not drive or use any tools or machines until your vision improves.

3. How to receive OZURDEX

Do not share medicines prescribed for you with any other person.

You will not be expected to give yourself OZURDEX. All OZURDEX injections will be given by your

doctor who is qualified to do so.

The usual dose is one implant to be given by injection into your eye. If the effect of this injection wears off and your doctor recommends it, another implant may then be injected into your eye. There is no experience of the efficacy or safety for the treatment of diabetic macular oedema, when used more than seven times. There is only limited information on receiving another injection less than 6 months after the previous one, when used for the treatment of vision loss caused by a blockage of veins in the eye and inflammation of the back of the eye.

Your doctor will ask you to use antibiotic eye drops daily for three days before and after each injection to prevent any eye infection. Please follow these instructions carefully.

On the day of the injection, your doctor may use antibiotic eye drops and clean the surface of your eye carefully to 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.

After the injection your doctor will monitor you for signs of infection, an increase in eye pressure or any other complication, so it can be identified and treated as soon as possible.

If you receive more OZURDEX than you should

Since a health care professional will administer this medicine, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdose.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you missed a dose of OZURDEX

If you miss your appointment to receive OZURDEX, contact your doctor or hospital as soon as possible to re-arrange your appointment.

Effects when treatment with OZURDEX is stopped

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

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

OZURDEX can have side effects, although not everybody gets them. Not all side effects reported for OZURDEX are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving OZURDEX, please consult your doctor, pharmacist or other health care provider for advice.

The following side effects may be seen with OZURDEX:

Frequent	Increased pressure in the eye, clouding of the lens (cataract), bleeding on the surface of the eye*, high pressure in the eye, clouding at the back of the lens, bleeding into the inside of the eye*, worsening of vision*, difficulties in seeing clearly, detachment of the jelly inside the eye from the light-sensitive layer at the back of the eye (vitreous detachment)*, a feeling of spots in front of the eye (including 'floaters')*, a feeling of looking through mist or fog*, inflammation of the eyelid, eye pain*, seeing flashes of light*, swelling of the layer over the white part of the eye*, redness of the eye, headache
Less frequent	A severe inflammation at the back of the eye (usually due to viral

	infection), serious infection or inflammation inside the eye*, glaucoma (an eye disease in which increased pressure in the eye is associated with damage to the optic nerve), detachment of the light-sensitive layer from the back of the eye (retinal detachment)*, tear of the light-sensitive layer at the back of the eye (retinal tear)*, a decrease in the eye pressure which is associated with leakage of the jelly (vitreous) from inside the eye*, inflammation inside the front part of the eye*, increased protein and cells in the front of the eye due to inflammation*, abnormal feeling in the eye*, itchiness of the eyelid, redness of the white of the eye*, migration of the OZURDEX implant from the back to the front of the eye causing blurred or decreased vision and which may or may not cause swelling of the clear part of the eye (cornea)*, accidental incorrect placement of the OZURDEX implant causing injury to the eye*, migraine

** Some of these side effects may be caused by the injection procedure and not the OZURDEX implant itself. The more injections you have, the more these effects can occur.*

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of OZURDEX.

You can also report side effects to AbbVie (Pty) Ltd by sending an e-mail to MEAPV@abbvie.com

5. How to store OZURDEX

- Store all medicines out of reach of children.

- Do not use OZURDEX after the expiry date which is stated on the carton and the pouch after EXP. The expiry date refers to the last day of the month.
- Store at or below 25 °C.
- OZURDEX is for single use only.
- Any unused product or waste material should be disposed of in accordance with local requirements.
- Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What OZURDEX contains

- The active substance is dexamethasone.
- Each implant contains 700 µg of dexamethasone.
- The other ingredients are: ester terminated 50:50 poly D,L-lactide-co-glycide and acid terminated 50:50 poly D,L-lactide-co-glycide

What OZURDEX looks like and contents of the pack

OZURDEX is a white to off-white rod-shaped implant, stored inside the needle of an applicator. The applicator and a packet of drying material are sealed in a foil pouch which is inside a carton. One carton contains one applicator with one implant which will be used once and thrown away.

7. Holder of Certificate of Registration

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Access to the corresponding Professional Information

For the professional information please email medicalinfo.za@abbvie.com