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## PATIENT INFORMATION LEAFLET

### SCHEDULING STATUS

Schedule 4

### PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

**OZURDEX, dexamethasone** 700 µg intravitreal implant

#### 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.
- OZURDEX is prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

#### 1. 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

#### 2. WHAT OZURDEX 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 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.

### **3. 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 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.

#### **Tell your doctor or healthcare professional before being given the injection 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.

#### **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.

#### **Pregnancy and breastfeeding**

There is no experience of using OZURDEX in pregnant women or during breastfeeding, so the possible risks are unknown.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before receiving OZURDEX.

#### **Driving and using machinery**

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.

#### **Using other medicines with OZURDEX**

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

### **4. 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 for the treatment of diabetic macular oedema, when used more than seven times

Your doctor will ask you to use antibiotic eye drops regularly 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.

**If you receive more OZURDEX than you should**

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

**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.

**5. POSSIBLE SIDE EFFECTS**

OZURDEX can have side effects. 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 healthcare professional 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*, migraine
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*\* 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.

## **6. STORING AND DISPOSING OF 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).

## **7. PRESENTATION OF OZURDEX**

The OZURDEX implant is 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.

## **8. IDENTIFICATION OF OZURDEX**

OZURDEX is a white to off-white rod-shaped implant.

## **9. REGISTRATION NUMBER**

44/15.2/0045

## **10. NAME AND ADDRESS OF THE REGISTRATION HOLDER**

Allergan Pharmaceuticals (Pty) Ltd  
30 New Road (entrance off Bavaria Road)  
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**11. DATE OF PUBLICATION**

Date of registration: 7 December 2012

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