The content of this leaflet was revised in accordance with Ministry of Health requirements

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

OZURDEX
Intravitreal implant in applicator

Active ingredient: Each implant contains 0.7 mg dexamethasone

Inactive ingredients and allergens in this medicine: See section 6 'Additional Information'.

Read this leaflet carefully in its entirety before using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, ask your doctor or pharmacist.

This medicine is intended for adults over 18 years old.

1. WHAT IS THE MEDICINE INTENDED FOR?

The active ingredient in Ozurdex is dexamethasone.
Dexamethasone belongs to a group of medicines called corticosteroids.
In adults, Ozurdex is used:

- To treat diabetic macular edema.
- To treat vision loss resulting from a blockage of veins in the eye. This blockage leads to a build-up of fluid causing swelling in the area of the retina called the macula (a light-sensitive layer of cells at the back of the eye). The swelling may lead to damage to the macula which affects the central vision, which is used for tasks such as reading. Ozurdex works by reducing this swelling of the macular, and in this way helps to lessen or prevent further damage to the macula.
- To treat inflammation of the back of the eye. This inflammation leads to a decline in vision and/or the presence of floaters (black dots or wispy lines that move across the field of vision). Ozurdex works to reduce this inflammation.

Therapeutic group: Corticosteroids.

2. BEFORE USING THE MEDICINE

Do not use this medicine:

- if you are sensitive (allergic) to the active ingredient dexamethasone or to any of the other ingredients that this medicine contains (see the full list of ingredients in Section 6: 'Additional information').
- if you have an infection of any kind in or around your eye (bacterial, viral

or fungal).
- if you have glaucoma or high intraocular pressure that are not responding well to the medicines you are 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 with this medicine has undergone cataract surgery and has an artificial 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 colored part of the eye (iris) and the back of the lens capsule (“the bag”) has been ruptured.

Special warnings about using this medicine

Before treatment with Ozurdex injection, tell your doctor:
- if you have had cataract surgery or iris surgery (the colored 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.
- if you are taking any medicines to thin the blood.
- if you are taking any steroids or NSAIDs (non-steroidal anti-inflammatory drugs) by mouth or applied to the eye.
- if you have had a herpes simplex infection in your eye in the past (an ulcer or sores that persist for a long time in the eye).

Occasionally 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 this as soon as possible.

Please tell your doctor immediately if you feel:
- increasing eye pain or increasing discomfort.
- worsening redness of your eye, flashing lights, sudden increase in floaters, partially blocked vision, decreased vision or increased sensitivity to light after the injection.

In some patients the eye pressure may increase and there is a possibility of developing glaucoma. This is something you may not notice so your doctor will 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 happens your ability to see will decline, 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 remain impaired as it was before you started receiving Ozurdex injections or even get worse.
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 condition continues for a long time and is left untreated, it may require tissue transplantation.
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 under 18 years old
The use has not been studied and is therefore not recommended.

Drug interactions
If you are taking, or have recently taken, any other medicines, including non-prescription medicines and dietary supplements, tell your doctor or pharmacist.

Pregnancy and breast-feeding
There is no experience using Ozurdex in pregnant women or during breast-feeding. Do not use Ozurdex during pregnancy or breast-feeding unless your doctor thinks you clearly need it. If you are pregnant or breast-feeding, think you may be pregnant or planning to become pregnant, discuss this with your doctor before Ozurdex treatment. Consult your doctor before taking any medicine.

Driving and using machines
After Ozurdex treatment you may experience some reduced vision for a short time. If this happens, do not drive or operate any tools or machines until your vision improves.

3. HOW TO USE THIS MEDICINE?

Injection of Ozurdex will be done by an appropriately qualified eye doctor. Always use this medicine according to your doctor's instructions. Only your doctor will determine your dosage and how you should take this medicine. **The recommended 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. **Do not exceed the recommended dose.**
Your doctor will give you a prescription for antibiotic eye drops. You should use them daily for 3 days before and after each injection to prevent any eye infection. These instructions must be followed strictly.
On the day of the injection, your doctor may use antibiotic eye drops to prevent development of an eye infection. Before the injection the doctor will clean your eye and eyelid. Your doctor will also give you a local anesthetic injection to reduce or prevent pain during the injection. You may hear a 'click' during the injection of Ozurdex; this is normal.
Detailed instructions for your doctor on how to carry out the Ozurdex injection are provided in the product package.

If you have further questions about this medicine or if you are not sure about your dosage or about how to use this medicine, consult your doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Ozurdex may cause side effects in some

users. Do not be alarmed by this list of side effects. You may not experience any of them.

Tell your doctor immediately if you experience:
- increasing eye pain or increasing discomfort.
- worsening redness of your eye, flashing lights, sudden increase in floaters, partially blocked vision, decreased vision or increased sensitivity to light after the injection.

The following side effects may be seen with Ozurdex:

Very common side effects (may affect more than one in ten patients): Increased pressure in the eye, clouding of the lens (cataract), bleeding on the surface of the eye*.

Common side effects (may affect 1-10 in 100 patients): High pressure in the eye, clouding at the back of the lens, bleeding into the inside of the eye*, worsening of vision*, difficulty seeing clearly, detachment of the jelly-like substance inside the eye from the light-sensitive layer at the back of the eye (vitreous detachment)*, a feeling of spots floating in front of the eye (including 'floaters')*, a feeling of looking through 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.

Uncommon side effects (may affect 1-10 in 1000 patients): 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 eyeball (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 in some cases may cause swelling of the clear part of the eye (cornea)*, incorrect placement of the Ozurdex implant in the eye*, migraine.

* These side effects may be caused as a result of the injection procedure, and not by the Ozurdex implant itself. The frequency of these symptoms increases as you undergo more injections of Ozurdex.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Medication' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link:
https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=Ad

versEffectMedic@moh.gov.il

5. HOW TO STORE THE MEDICINE?

- Prevent poisoning! To prevent poisoning, keep this, and any other medicine, in a closed place out of sight and reach of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) stated on the carton and on the inner pack. The expiry date refers to the last day of that month.
- Store this medicine below 25°C.

6. ADDITIONAL INFORMATION

In addition to the active ingredient this medicine also contains:
Ester terminated 50:50 poly D,L-lactide-co-glicolide
Acid terminated 50:50 poly D,L-lactide-co-glicolide

What the medicine looks like and what are the contents of the package:
Ozurdex is a rod-shaped implant which is stored inside the needle of an applicator. The applicator and a small packet of drying material are sealed in an aluminium foil pouch which is inside a carton. One carton contains one applicator with one implant which will be used only once.

License holder and address: Allergan Israel Ltd., 32 Shacham St., POB 6869, Petach Tikva.

Manufacturer name and address: Allergan Pharmaceuticals Ireland, Westport, Ireland.

This leaflet was reviewed and approved by the Ministry of Health in June 2015, and revised in January 2018 in accordance with Ministry of Health instructions.

Registration number of the medicine in the Ministry of Health National Drug Registry: 147-03-33284.