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 and its quantity
Each implant contains 700 mcg dexamethasone.

Inactive ingredients and allergens in this medicine - Please read section 6 'Additional information'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.
This medicine has been prescribed to treat your illness/for you. Do not pass it on to others.
It may harm them, even if it seems to you that their illness/medical condition is similar to yours.

In addition to the leaflet, Ozurdex has a 'Patient Safety Information Card'. This card contains important safety information that you must know and adhere to before and during the treatment with Ozurdex. Read the 'Patient Safety Information Card' and the patient leaflet before starting to use the preparation. Keep the card for further reading, if necessary.

1. What is this medicine intended for?

Ozurdex is used to treat adults with:

- Diabetic macular oedema.
  This is experienced as swelling of the light-sensitive layer at the back of the eye called the macula. Diabetic macular oedema affects some people with diabetes.
- Macular oedema 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 cause damage that affects your central vision which is used for tasks like reading. Ozurdex works by reducing this swelling of the macula and in this way helps to lessen or prevent more damage to the macula.
- Inflammation in the back of the eye. This inflammation leads to a decrease of vision and/or the appearance of floaters in the eye (black dots or fine lines that move across the field of vision). Ozurdex works to reduce this inflammation.

Therapeutic group - corticosteroids.

2. BEFORE USING THIS MEDICINE

Do not use this medicine if:

- you are sensitive (allergic) to the active ingredient dexamethasone or to any of the other ingredients in this medicine (see a full list of ingredients in section 6 'Additional information').
- you have an infection of any kind in or around your eye (bacterial, viral or fungal infection).
- you have glaucoma or high pressure inside your eye which do not respond well to the medicines you are taking.

- 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 with this medicine has undergone cataract surgery and has an artificial lens, which was implanted in the space between the cornea and the iris and pupil (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.

Special warnings about using this medicine
Before treatment with Ozurdex, 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 the eye) or surgery to remove the gel (called the vitreous) from within the eye.
- you are taking medicines to thin your blood.
- you are taking steroid or non-steroidal anti-inflammatory medicines by mouth or applied to the eye.
- you have had a herpes simplex infection in your eyes in the past (an ulcer on the eye that has been there a long time, or sores on the eye)

Occasionally the injection of Ozurdex may cause an infection inside the eye, pain or redness in the eye, or detachment or tear of the retina. It is important to identify and treat these as soon as possible.
Tell your doctor immediately if you experience increasing eye pain or increasing 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 eye pressure may increase with the possible development of glaucoma. You may not notice this, 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 cataract surgery, 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 surgery to remove the cataract. Your doctor will help you to decide on the most appropriate time to perform this surgery, but you should be aware that until you are ready for your surgery your vision may be as bad or even 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 part 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.

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
The use in children and adolescents under 18 years old has not been studied and is therefore not recommended in this age group.

Interactions\Drug interactions
If you are taking or have recently taken other medicines, including non-prescription medications 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 it is clearly necessary. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, 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 use any tools or machines until your vision improves.

3. HOW TO USE THIS MEDICINE?

Ozurdex injection is given by an appropriately qualified eye doctor.
Always use this medicine according to your doctor's instructions.
Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.
Only your doctor will determine your dose and how you should take this medicine.
The recommended dosage is usually an injection of one implant 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 prescribe antibiotic eye drops. Use them daily for 3 days before and after each injection to prevent eye infection. Follow these instructions carefully.

On the day of the injection, your doctor may use antibiotic eye drops to prevent infection. Before the injection, your doctor will clean your eye and eyelid. Your doctor will also give you a local anaesthetic injection 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.

Detailed instructions for your doctor on how to carry out the Ozurdex injection are provided in the product package.

If a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.
Adhere to the treatment as recommended by your doctor.
Even if your health improves, do not stop taking this medicine without consulting your doctor.
If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. SIDE EFFECTS

Like with any medicine, using 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.
Contact your doctor immediately if:
you feel increasing eye pain or increasing 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.

Additional side effects
Very common side effects that occur in more than 1 in 10 users

- increased pressure in the eye
- clouding of the lens (cataract)

- bleeding on the surface of the eye*

Common side effects that occur in 1-10 in 100 users
- high pressure in the eye
- clouding at the back of the lens
- bleeding inside the eye*
- worsening of vision*
- difficulty seeing clearly
- detachment of the gel-like substance 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

Uncommon side effects that occur in 1-10 in 1,000 users
- 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 part of the eye* (retinal detachment)
- tear of the light-sensitive layer at the back of the eye (retinal tear)*
- decrease in the eye pressure which is associated with leakage of the vitreous (gel-like) substance 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 cause swelling of the clear part of the eye (cornea) in some cases*
- accidental incorrect placement of the Ozurdex implant*
- migraine.

** 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 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.
Reporting side effects
You can report side effects to the Ministry of Health by following the link ‘Reporting Side Effects of Drug Treatment' 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://sideeffects.health.gov.il

5. HOW TO STORE THE MEDICINE?

Prevent poisoning! To prevent poisoning, keep this and all other medicines in a closed place, out of the reach and sight 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) which is stated on the carton and on the inner package. The expiry date refers to the last day of that month.
Storage conditions: Store below 25°C.
Use immediately after opening.
Do not throw the medicine away via wastewater or household waste. Ask the pharmacist how to dispose of this medicine (medicines you no longer use). This will help protect the environment.

6. ADDITIONAL INFORMATION

In addition to the active ingredient, this medicine also contains:
acid terminated 50:50 poly D,L-lactide-co-glycolide
ester terminated 50:50 poly D,L-lactide-co-glycolide

What the medicine looks like and contents of the pack:
Ozurdex is a rod-shaped implant which is stored inside the needle of the applicator. The applicator and drying material are in a sealed inner foil pouch which inside a carton. One carton contains one applicator with one implant for single use.

Registration holder's name and address: AbbVie Biopharmaceuticals Ltd.,
4 Haharash St., Hod Hasharon, Israel.

Manufacturer's name and address: Allergan Pharmaceuticals Ireland, Castlebar Road, Westport, County Mayo, Ireland.

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