ALLERGAN

PACKAGE LEAFLET:
INFORMATION FOR THE USER

Ozurdex™

700 micrograms intravitreal implant in applicator
Dexamethasone

Read all of this leaflet carefully before you are given this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

In this leaflet:

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 used to treat vision loss in adults 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 works by reducing this swelling of the macula which helps to lessen or prevent more damage to the macula.

2. BEFORE YOU ARE GIVEN OZURDEX

You must not be given OZURDEX

- if you are allergic (hypersensitive) to dexamethasone or any of the other ingredients of OZURDEX (for a full list of ingredients, see section 6 "FURTHER INFORMATION"),
- 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.

Take special care with OZURDEX

- Before your OZURDEX injection tell your doctor if: You have had cataract surgery
- You are taking any medicines to thin the blood
- 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).

Please tell your doctor immediately if you develop symptoms such as the following after injection with OZURDEX:
- blurred or decreased vision,
- 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 straight after the injection, or you may 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.

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 adolescent (below 18 years of age)
The use of OZURDEX in children and adolescents has not been studied and is therefore not recommended.

Using other medicines
Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding
There is no experience of using OZURDEX in pregnant women or during breast-feeding. OZURDEX should not be used during pregnancy or breast-feeding unless your doctor thinks it is clearly necessary. If you are pregnant or planning to become pregnant, or if you are breast-feeding, please discuss this with your doctor before OZURDEX treatment. Ask your doctor for advice 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 OZURDEX IS USED

All OZURDEX injections will be given by an appropriately qualified eye doctor. 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.

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 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.

There are detailed instructions for your doctor on how to carry out the OZURDEX injection at the end of this leaflet.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, OZURDEX can cause side effects, although not everybody gets them.

The frequency of possible side effects listed below is defined using the following convention:

Very common	affects more than 1 user in 10
Common	affects 1 to 10 users in 100
Uncommon	affects 1 to 10 users in 1,000
rare	affects 1 to 10 users in 10,000
very rare	affects less than 1 user in 10,000
not known	frequency cannot be estimated from the available data

The following side effects may be seen with OZURDEX:

Very common: Increased pressure in the eye, bleeding on the surface of the eye*

Common: High pressure in the eye, detachment of the jelly inside the eye from the light-sensitive layer at the back of the eye (vitreous detachment), clouding of the lens (cataract), bleeding into the inside of the eye*, difficulties in seeing clearly, a feeling of spots in front of the eye (including 'floaters')*, eye pain*, seeing flashes of light*, swelling on the surface of the eye*, a feeling of looking through mist or fog*, redness of the eye*

Uncommon: Tear of the light-sensitive layer at the back of the eye (retinal tear)*, increased protein in the front of the eye due to inflammation*, headache

**Some of these side effects may be caused by the injection procedure and not the OZURDEX implant itself.*

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

5. HOW TO STORE OZURDEX

Keep out of the reach and sight 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 that month.

Do not store above 25ºC.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What OZURDEX contains

- The active substance is dexamethasone.
- Each implant contains 700 micrograms of dexamethasone.
- The other ingredients are: Ester terminated 50:50 poly D,L-lactide-co-glycolide and Acid terminated 50:50 poly D,L-lactide-co-glycolide.

What OZURDEX looks like and contents of the pack

OZURDEX is a rod-shaped implant which 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.

Marketing Authorisation Holder and Manufacturer

Allergan Pharmaceuticals Ireland
Castlebar Road
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This leaflet was last approved in July 2010

Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu/.

(THIS IS A MEDICAMENT)

- Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.

Keep medicament out of reach of children

Council of Arab Health Ministers
Union of Arab Pharmacists

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