

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 because it contains important information for you.

- 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. See section 4.

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 OZURDEX is used
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 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 a 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 this swelling of the macular 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 allergic to dexamethasone or any of the other ingredients of this medicine (listed in section 6)
- 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

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 on 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 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 eye pressure may increase with the possible development of 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 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.

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.

Other medicines and OZURDEX

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 breast-feeding, think you may be pregnant or are planning to have a baby, 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 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.

Your doctor will ask you to use antibiotic eye drops daily for 3 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 to prevent infection. Before the injection, your doctor will clean your eye and eyelid. 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.

Detailed instructions for your doctor on how to carry out the OZURDEX injection are provided in the medicine carton.

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

4. Possible side effects

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

The following side effects may be seen with OZURDEX:

Very common (may affect more than 1 in 10 people):

Increased pressure in the eye, clouding of the lens (cataract), bleeding on the surface of the eye*

Common (may affect up to 1 in 10 people):

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

Uncommon (may affect up to 1 in 100 people):

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

**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.*

Reporting of side effects

If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via

United Kingdom

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard

Ireland

HPRA Pharmacovigilance

Earlsfort Terrace

IRL - Dublin 2

Tel: +353 1 6764971

Fax: +353 1 6762517

Website: www.hpra.ie

e-mail: medsafety@hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store OZURDEX

Keep this medicine out of the sight and 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 that month.

This medicine does not require any special storage conditions.

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. Contents of the pack and other 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

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For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

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

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