OZURDEX®

(dexamethasone) 700 µg intravitreal implant

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about OZURDEX®. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you receiving OZURDEX® against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet.
You may need to read it again.

What OZURDEX® is used for

OZURDEX® is contained within a small implant injected into the back of the eye by your doctor using a specially designed applicator.

OZURDEX® is used to treat adult patients with Diabetic Macular Oedema (DME), which 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.

OZURDEX® is used to treat 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. The swelling may lead to damage to the macula which affects your central vision which is used for tasks like reading.

OZURDEX® is also used to treat adult patients with Uveitis, which is an inflammation affecting the choroid (the layer of blood vessels and connective tissue between the white of the eye and retina at the back of the eye). Uveitis is a chronic disease with a high risk of permanent vision loss.

The active ingredient in OZURDEX® is dexamethasone. Dexamethasone belongs to a group of medicines called corticosteroids. OZURDEX® works by reducing the swelling which helps to lessen or prevent more damage to the macula.

Before you use OZURDEX®

When you must not use it

Do not use OZURDEX® if:

- you have an allergy to dexamethasone or any of the ingredients listed at the end of this leaflet
- you have an infection of any kind in or around your eyes (bacterial, viral, or fungal)
- you have advanced glaucoma or high pressure inside your eye that cannot be controlled by medications alone
- 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 has a man-made lens, which was implanted in the front compartment of the eye (anterior chamber intraocular lens) after cataract surgery, and the back of the lens capsule ("the bag") has been ruptured.

Before you start to use it

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).
- you are pregnant or intend to become pregnant.
  Like most medicines, OZURDEX® should not be used during pregnancy, unless clearly necessary.
- you are breast-feeding or intend to breast-feed.

Before you receive OZURDEX® treatment, your doctor should tell you to immediately report any eye pain, change in vision, red eyes or sensitivity to light that occurs post-procedure.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

How OZURDEX® is used

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

OZURDEX® is administered as a single injection into your eye under sterile conditions. Before the injection your doctor will use antibiotic eye drops and clean the surface of your eye carefully to help 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.

Afterwards your doctor may perform some additional tests to make sure there are no signs of inflammation or infection of the eye and will monitor your vision and the pressure in your eye.

If your condition is found to be worsening, your doctor may administer OZURDEX® again.

Follow all directions given to you by your doctor carefully. The directions may differ from the information contained in this leaflet.

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.

How long to use it

Your doctor will advise you and decide how long you should be treated with OZURDEX®.

If a dose is missed

If you miss an OZURDEX® appointment, you need to contact your doctor as soon as possible to arrange another appointment.

While you are using OZURDEX®

Things you must do

Tell your doctor immediately if you develop symptoms such as the following after injection of OZURDEX®:

- blurred, decreased vision or other visual disturbances
- 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 after the injection, or patients may also 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.

Before stopping OZURDEX® treatment

If you decide not to receive a repeat OZURDEX® treatment, please go to your next appointment and discuss this with your doctor. Your doctor will advise you and decide how long you should be treated with OZURDEX®.

Things you must not do

You may experience temporarily reduced vision after being treated with OZURDEX®. You should not drive or operate machinery until your vision has returned to normal.

Side effects

Tell your doctor as soon as possible if you have any problems while being treated with OZURDEX®, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

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

Tell your doctor immediately if you experience any of the following side effects associated with OZURDEX® treatment:

Common side effects:

- vision decrease caused byclouding of the lens (cataract) which may need a cataract surgery
- increased pressure in the eye (as determined by the doctor) which may need to be treated with medicines or in a rare case with a surgical procedure
- bleeding on the surface of the eye*
- vision decrease or seeing floaters due to bleeding inside of the eye*
- eye pain*
- seeing flashes of light due to detachment of the jelly inside the eye from the light-sensitive layer at the back of the eye

- perception of having something floating in the eye (floaters)*
- swelling on the surface of the eye*
- inflammation in the front part of the eye*
- redness of the eye

Uncommon side effects:

headache, tear of the light-sensitive layer at the back of the eye (retinal tear), severe inflammation at the back of the eye (usually due to viral infection), increased protein in the front of the eye due to inflammation, inflammation or infection inside the eye, glaucoma, eyelid itching, migraine, blurred vision (difficulties in seeing clearly).

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

Complications may result from insertion of the device, including implant misplacement.

Ask your doctor any questions you may have.

Product description

What OZURDEX® looks like:

OZURDEX® is a sterile rod shaped implant containing 700 µg of dexamethasone, located in the stainless steel needle of a disposable applicator.

Ingredients

Active ingredient:
Dexamethasone 700µg

Inactive ingredients:
Polyglactin, 50:50 PLGA ester
Polyglactin, 50:50 PLGA acid

Manufacturer/Supplier

AbbVie Pty Ltd
241 O'Riordan Street
Mascot NSW 2020
AUSTRALIA
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OZURDEX® can be identified by registration number:

AUST R 222392

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