

Ozurdex® Patient Guide

(dexamethasone intravitreal implant 0.7mg)

This patient guide contains important safety information you should be aware of before and after treatment with Ozurdex®.

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Why Should I Read this Patient Guide?

Treatment with Ozurdex® may be associated with the following risks:

- Increased pressure in the eye, which can lead to glaucoma (an eye disease that causes vision loss).
- Inflammation inside the eye (usually caused by infection).

To prevent progression/minimize serious consequences, it is important for you to be aware of early signs and symptoms of these risks associated with Ozurdex®.

You should contact your doctor or nurse immediately if you experience at any time any of these signs and symptoms following Ozurdex® treatment.

- Worsening of vision after the injection.
- Pain or discomfort in or around the eye.
- An increase in floaters or spots in the vision.
- Blurred vision which lasts more than a day after the injection.
- Redness in the eye which continues to get worse.
- Discharge from the eye.

How Should I Prepare For My Treatment?

Before your treatment, your doctor will give you antibiotic eye drops. You should use these for 3 days prior to your treatment. You should continue to use the eye drops for 3 days following your treatment.

What Will My Treatment Involve?

To prepare you for your treatment, the doctor will:

- Clean your eye to minimize infection and may administer further antibiotic eye drops.
- Cover your face with a special drape.
- Numb your eye with anaesthetic so you feel no pain.
- Use a device to gently hold your eye open.

The doctor will then use a specially designed applicator to inject the medicine into your eye, through the white part of your eye. You may hear a clicking sound during this procedure as well as feeling a bit of pressure on the eye.

Your doctor will then perform routine eye examinations to confirm that the medicine has been successfully administrated.

What Will Happen After My Treatment?

After the injection:

- Your vision may be blurred for about a day.
- You may also see some floaters or spots, which is normal and should go away over time.
- If these symptoms do not go away, or worsen, please contact your doctor.
- If you normally drive or use machinery, you should not resume these activities until all blurring of your vision has stopped.

Where You Can Find More Information About Your Medicine

As with all medicines, Ozurdex® can cause side effects, but not everybody gets them. A detailed list of possible side effects can be found in the Patient Information Leaflet (PIL) that comes with Ozurdex®.

For more information about your medicine, please read the PIL, available on the EMA website at the below link (EPAR – Product Information / Section B – Package Leaflet):

https://www.ema.europa.eu/en/medicines/human/EPAR/ozurdex

If you would like additional copies of the Patient Guide, please contact AbbVie's local representative Vivian Corporation at +35622588600.

An audio version of this Patient Guide is available and has been provided in CD format along with this patient card.

Suspected Adverse Drug Reactions (side effects) or medication errors may be reported using the Medicines Authority ADR reporting form. which is available online at http:// www.medicinesauthority.gov.mt/adrportal, and sent by post or email to; P: Pharmacovigilance Section at Post-Licensing Directorate, Medicines Authority, Sir Temi Zammit Buildings, Sciences Park, San Gwann SĠN 3000 Malta Life E: postlicensing.medicinesauthority@gov.mt by contacting or AbbVie's local representative Vivian Corporation at +35622588600.