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Ozurdex *(dexamethasone)*

An overview of Ozurdex and why it is authorised in the EU

What is Ozurdex and what is it used for?

Ozurdex is an implant that is injected into the eye.

It is used to treat adults with impaired vision due to macular oedema associated with:

- blockage of the veins carrying blood from the back of the eye;
- damage to blood vessels caused by diabetes in patients who have an artificial lens in their eye or in whom other treatment did not work or was unsuitable.

Macular oedema is swelling in the macula, the central part of the retina (the light-sensing layer at the back of the eye), which can reduce the central part of a person's vision and affect tasks such as reading and driving.

Ozurdex is also used to treat adults with non-infectious uveitis at the back of the eye. Uveitis is inflammation of the uvea, the middle layer of the eye.

How is Ozurdex used?

Ozurdex can only be obtained with a prescription and must be given by an ophthalmologist (eye specialist) who has experience in giving intravitreal injections (injections into the vitreous humour, the jelly-like fluid in the eye).

Each implant is in an applicator and contains 700 micrograms of the active substance, dexamethasone.

Patients receive one Ozurdex implant at a time, injected directly into the vitreous humour. Further treatments can be given if the patient's condition improves but then gets worse and if the doctor believes that the patient will benefit from further treatment. Patients whose vision gets better and stays better should not receive any more implants. Patients whose vision is getting worse and is not improved by Ozurdex should also not receive any more implants.

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For more information about using Ozurdex, see the package leaflet or contact your doctor or pharmacist.

How does Ozurdex work?

The active substance in Ozurdex, dexamethasone, belongs to a group of anti-inflammatory medicines known as corticosteroids. It works by entering cells and blocking the production of vascular endothelial growth factor (VEGF) and prostaglandins, substances that are involved in inflammation.

Ozurdex implants are injected directly into the vitreous humour of the eye. This ensures that adequate amounts of dexamethasone reach the area inside the eye where the inflammation in macular oedema and uveitis occurs. The implant is made of a material that dissolves over several months while gradually releasing the dexamethasone.

What benefits of Ozurdex have been shown in studies?

Because dexamethasone is a well-known anti-inflammatory medicine, the company presented studies from the published literature where Ozurdex was compared with a 'sham' treatment (where an applicator was pressed against their eye but nothing was actually injected).

Macular oedema related to blocked veins of the retina

In two main studies involving a total of 1,267 adults Ozurdex was more effective than the sham treatment at improving patients' eyesight. Eyesight was measured using the 'best corrected visual acuity' (BCVA) indicating how well a person can see (after they have been given corrective lenses). In the first study, around 23% of the patients receiving Ozurdex had increased BCVA of at least 15 letters after 180 days compared with 17% of the patients receiving the sham treatment. In the second study, the figures were around 22% for Ozurdex after 90 days and 12% for the sham treatment.

Macular oedema related to diabetes

Two main studies involving 1,048 patients compared the effects of a 700 microgram or a 350 microgram implant of Ozurdex. Patients were followed up for 3 years and could be given repeat treatment if appropriate. In patients whose lens had already been surgically replaced, there was an average improvement in BCVA over both studies of 6.5 letters after Ozurdex 700 micrograms, compared with 1.7 letters after sham treatment. In patients in whom other types of treatment had not worked or were unsuitable, there was an average improvement in BCVA over both studies of 3.2 letters after Ozurdex 700 micrograms, compared with 1.5 letters after sham treatment.

Uveitis

Ozurdex was more effective than sham treatment at reducing inflammation in patients with uveitis measured by an improvement in patients' vitreous haze score which gives an indication of inflammation, with zero indicating no inflammation. In one main study involving 229 adults with uveitis, 8 weeks after injection, around 47% of patients treated with 700 micrograms of Ozurdex achieved a vitreous haze score of zero, compared with 36% of patients treated with 350 micrograms of Ozurdex and 12% of patients who received the sham treatment.

What are the risks associated with Ozurdex?

The most common side effects with Ozurdex (which may affect more than 1 in 10 people) are increased intraocular pressure (the pressure inside the eye), conjunctival haemorrhage (bleeding from

the membrane over the white of the eye) and cataract (clouding of the lens – in patients with uveitis and with diabetes). The bleeding is thought to be caused by the injection procedure and not by the medicine itself. For the full list of side effects of Ozurdex, see the package leaflet.

Ozurdex must not be used in patients who have or are thought to have ocular or periocular infections (infections in or around the eyes) and in patients with advanced glaucoma (damage to the nerve of the eye usually caused by high pressure inside the eye) that is not adequately controlled with medicines alone. It must also not be used in certain cases where the back of the membrane that surrounds the lens (the lens capsule) is torn. For the full list of restrictions with Ozurdex, see the package leaflet.

Why is Ozurdex authorised in the EU?

The European Medicines Agency decided that Ozurdex's benefits are greater than its risks in patients with uveitis or macular oedema related to blocked veins, and it can be authorised for use in the EU. Ozurdex injection causes only minor trauma to the eyeball and the increase in intraocular pressure is considered to be manageable. In addition, injections do not need to be given frequently because the implant stays in the eye for several months.

In the overall group of patients with macular oedema related to diabetes the Agency noted that the benefit was modest and was outweighed by the risks, including the development of cataracts. However, in those with an artificial lens in the affected eye or who previously have not responded to or are unsuitable for other non-corticosteroid treatments, the benefits of Ozurdex were considered to outweigh the risks. Therefore the use of Ozurdex in patients with macular oedema related to diabetes was restricted to these two groups.

What measures are being taken to ensure the safe and effective use of Ozurdex?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Ozurdex have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Ozurdex are continuously monitored. Side effects reported with Ozurdex are carefully evaluated and any necessary action taken to protect patients.

In addition, the company that makes Ozurdex will ensure that patients are provided an information pack, including a booklet and an audio CD.

Other information about Ozurdex

Ozurdex received a marketing authorisation valid throughout the European Union on 27 July 2010.

Further information on Ozurdex can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/ozurdex.

This overview was last updated in 10-2019.