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EPAR summary for the public

Ozurdex

dexamethasone

This document is a summary of the European public assessment report (EPAR) for Ozurdex. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for Ozurdex.

What is Ozurdex?

Ozurdex is an implant that is injected into the eye. Each implant is provided in an applicator and contains 700 micrograms of the active substance, dexamethasone.

What is Ozurdex used for?

Ozurdex 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 in whom the lens of the affected eye has been surgically replaced, or who previously did not respond to or are unsuitable for other types of treatment.

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.

The medicine can only be obtained with a prescription.

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How is Ozurdex used?

Ozurdex must be given by a qualified ophthalmologist (eye specialist) who has experience in giving intravitreal injections (injections into the vitreous humour, the jelly-like fluid in the eye). The procedure should be carried out under sterile conditions.

Patients receive one Ozurdex implant at a time, injected directly into the vitreous humour. Further treatments can be given if the patient's condition initially responds to treatment but later 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.

The patient's eye should be disinfected and numbed with an anaesthetic before the implant is injected. Patients should also receive antibiotic eye drops before and after injection and they should be monitored after the injection to check for infection or raised eye pressure. For further information, see the summary of product characteristics (also part of the EPAR).

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 and swelling.

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 swelling in macular oedema and uveitis occurs. The implant is made of a material that dissolves over several months while gradually releasing the dexamethasone.

How has Ozurdex been studied?

Because dexamethasone has been used as an anti-inflammatory for a number of years, the company presented information from the published literature.

Ozurdex has been studied in two main studies involving a total of 1,267 adults with macular oedema related to blockage of the veins of the retina. The patients were given an Ozurdex implant or they received a 'sham' treatment where an applicator was pressed against their eye but nothing was actually injected. The main measure of effectiveness was the number of patients whose 'best corrected visual acuity' (BCVA) had improved enough after 90 or 180 days so that they could read at least 15 more letters in a standard eye test. BCVA is how well a person can see after they have been given appropriate corrective lenses.

Two further main studies involving 1,048 patients compared the effects of a 700 microgram or a 350 microgram implant of Ozurdex with a sham treatment in macular oedema related to diabetes. Patients were studied for 3 years, and could be given repeat treatment if considered appropriate. The main measure of effectiveness was the change in BCVA over the period of the study.

Ozurdex has also been studied in one main study involving 229 adults with uveitis. Patients were given either a 700 microgram or a 350 microgram implant of Ozurdex or they received a sham treatment. The main measure of effectiveness was the number of patients whose 'vitreous haze score' decreased to zero after eight weeks. The vitreous haze score gives an indication of inflammation with zero indicating no inflammation.

What benefit has Ozurdex shown during the studies?

Ozurdex was more effective than the sham treatment at improving the eyesight of patients with macular oedema related to blockage of veins. In the first study, around 23% of the patients receiving Ozurdex had an increase in 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.

In patients with macular oedema related to diabetes and who already had their lens 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 with macular oedema related to diabetes, who had not previously responded to, or were unsuitable for, other types of treatment, 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

Ozurdex was more effective than the sham treatment at reducing inflammation in patients with uveitis. Eight 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 is the risk associated with Ozurdex?

The most common side effects with Ozurdex (seen in more than 1 patient in 10) are increased intraocular pressure (the pressure inside the eye), conjunctival haemorrhage (bleeding from the membrane that lines the front of the eye) and cataract (clouding of the lens – in uveitis patients and those with diabetes). The bleeding is thought to be caused by the injection procedure and not by the medicine itself. For the full list of all side effects reported with 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 (a disease in which the pressure inside the eye rises because fluid cannot drain out of the eye) that is not adequately controlled with medicines alone. It must also not be used in certain cases where the back part of the membrane that surrounds the lens (the lens capsule) has been ruptured. For the full list of restrictions with Ozurdex, see the package leaflet.

Why has Ozurdex been approved?

The CHMP noted that 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. Based on the results of the studies, the Committee decided that Ozurdex's benefits are greater than its risks in patients with uveitis or macular oedema related to blocked veins, and recommended that it be given marketing authorisation.

In the overall group of patients with macular oedema related to diabetes the CHMP 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?

A risk management plan has been developed to ensure that Ozurdex is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Ozurdex, including the appropriate precautions to be followed by healthcare professionals and patients.

In addition, the company that makes Ozurdex will ensure that doctors who are expected to use Ozurdex will be provided with an information pack that will include diagrams showing how the injections are given and how to recognise serious side effects. There will also be an information pack for patients, including a booklet and an audio CD.

Other information about Ozurdex:

The European Commission granted a marketing authorisation valid throughout the European Union for Ozurdex on 27 July 2010.

The full EPAR for Ozurdex can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports. For more information about treatment with Ozurdex, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 08-2014.