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EPAR summary for the public

Omidria

phenylephrine / ketorolac

This is a summary of the European public assessment report (EPAR) for Omidria. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Omidria.

For practical information about using Omidria, patients should read the package leaflet or contact their doctor or pharmacist.

What is Omidria and what is it used for?

Omidria is a medicine used in adults during lens replacement surgery in the eye to keep the pupil dilated (widened) and prevent its contraction, and to reduce eye pain after surgery. It contains the active substances phenylephrine and ketorolac.

How is Omidria used?

Omidria is available as a concentrate that is made up into an irrigation solution (a solution used to rinse the inside of the eye during surgery). It can only be obtained with a prescription and must be given by a qualified ophthalmological surgeon (eye surgery specialist) experienced in lens replacement. This is a type of surgery in which a new lens is implanted into the eye. The lens is the part of the eye that focuses light passing through the pupil and allows clear vision.

The recommended dose is 4 ml of Omidria diluted in 500 ml of irrigation solution, to be used during the surgery to replace the lens. The ophthalmologist may also prescribe eye drops commonly used before and after the surgery to help prevent eye infections and pain.

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How does Omidria work?

Omidria contains the active substances phenylephrine and ketorolac. Phenylephrine is a 'selective alpha-1 adrenergic receptor agonist', which attaches to and activates alpha-1 adrenergic receptors that are found on smooth muscle cells, causing these muscles to contract. When applied to the eye, phenylephrine makes the muscle of the iris contract (tighten) and allows the pupil to widen. This makes lens replacement surgery easier.

Ketorolac is a non-steroidal anti-inflammatory drug (NSAID). It works by blocking certain enzymes called cyclo-oxygenases, which produce prostaglandins, substances that are involved in pain and inflammation processes. When applied to the eye, ketorolac reduces the production of prostaglandins in the eye and thereby reduces the pain and inflammation caused by eye surgery.

Both active substances have been available in the European Union (EU) as separate preparations for a number of years.

What benefits of Omidria have been shown in studies?

Omidria has been investigated in two main studies involving a total of 821 patients undergoing lens replacement surgery, in which it was compared with placebo (a dummy treatment). In both studies, the main measures of effectiveness were the change in diameter of the pupil by the end of the surgery, and how much eye pain patients felt soon after surgery, as indicated by the patient using a standard pain scale from 1 to 100.

Both studies showed that the pupil remained dilated during surgery in patients given Omidria (+0.1 mm), while it contracted in those given placebo (-0.5 mm). Fewer than 1 in 10 of the patients given Omidria had a pupil diameter below 6 mm (which makes surgery more difficult), whereas about 4 patients in 10 experienced this after being given placebo. With respect to pain, patients treated with Omidria reported an average pain score of around 4, compared with around 9 for those given placebo. In addition, 7% (29 out of 403) of patients receiving Omidria experienced moderate-to-severe pain compared with 14% (57 out of 403) of patients given placebo, and 25% (104 out of 403) were pain-free in the early period following surgery, compared with 17% (69 out of 403) of patients receiving placebo.

What are the risks associated with Omidria?

The most common side effects with Omidria (which may affect up to 1 in 10 people) are eye pain, anterior chamber inflammation (inflammation of the fluid-filled space inside the eye between the iris and the cornea), conjunctival hyperaemia (redness of the membrane that lies over the white part of the eye), photophobia (increased sensitivity of the eyes to light), corneal oedema (swelling of the transparent layer in front of the eye that covers the pupil and iris) and inflammation. These side effects are typical following lens replacement surgery, and most were mild to moderate in severity and resolved spontaneously. The incidence of side effects with Omidria was similar to that reported in patients receiving placebo. For the full list of all side effects reported with Omidria, see the package leaflet.

Omidria must not be used in patients who have narrow-angle glaucoma, a serious condition of the eye in which the pressure inside the eye rises rapidly because fluid cannot drain out. For the full list of restrictions, see the package leaflet.

Why is Omidria approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that the benefits of Omidria are greater than its risks and recommended that it be approved for use in the EU. Omidria has been shown to be effective at maintaining pupil dilation and preventing pupil contraction during lens replacement surgery, which should help to make such surgery easier and safer. Although the effect of Omidria on pain was modest, it was considered clinically important. With regard to the safety of Omidria, the medicine was generally well tolerated.

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

A risk management plan has been developed to ensure that Omidria 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 Omidria, including the appropriate precautions to be followed by healthcare professionals and patients.

Further information can be found in the summary of the risk management plan.

Other information about Omidria

The European Commission granted a marketing authorisation valid throughout the European Union for Omidria on 28 July 2015.

The full EPAR and risk management plan summary for Omidria 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 Omidria, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 07-2015.