21 May 2015
EMA/CHMP/289526/2015
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Omidria

phenylephrine / ketorolac

On 21 May 2015, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Omidria, intended for maintenance of intraoperative mydriasis, prevention of intraoperative miosis and reduction of acute postoperative ocular pain in intraocular lens replacement surgery. The applicant for this medicinal product is Omeros London Limited.

Omidria will be available as a concentrate for solution for intraocular irrigation (12.37 mg/ml + 4.24 mg/ml). The active substances of Omidria are phenylephrine (ATC code: not yet assigned) and ketorolac (ATC code: not yet assigned). Phenylephrine is a α1-adrenergic receptor agonist and acts by contracting the radial muscle of the iris, dilating the pupil and preventing miosis during surgery. Ketorolac is a non-steroidal anti-inflammatory drug (NSAID) that inhibits the enzymes cyclooxygenase COX1 and COX2 and so reduces production of prostaglandins, substances that are involved in inflammation and pain.

The benefits with Omidria are its ability to maintain mydriasis during lens replacement eye surgery and reduce postoperative pain. The most common side effects are eye pain and anterior chamber inflammation.

The full indication is: "Omidria is indicated in adults for maintenance of intraoperative mydriasis, prevention of intraoperative miosis and reduction of acute postoperative ocular pain in intraocular lens replacement surgery. “

It is proposed that Omidria is administered in a controlled surgical setting by a qualified ophthalmological surgeon experienced in intraocular lens replacement surgery.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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