19 July 2012
EMA/CHMP/271228/2012
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Ozurdex

dexamethasone

On 19 July 2012, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a variation to the terms of the marketing authorisation for the medicinal product Ozurdex. The marketing authorisation holder for this medicinal product is Allergan Pharmaceuticals Ireland. They may request a re examination of the CHMP opinion, provided that they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The CHMP adopted two new contraindications as follows:

- Aphakic eyes with rupture of the posterior lens capsule;
- Eyes with Anterior Chamber Intraocular Lens (ACIOL) and rupture of the posterior lens capsule.

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

For information, the full contraindication(s) for Ozurdex will be as follows[2]:

- Hypersensitivity to the active substance or to any of the excipients as listed in section 6.1.
- Active or suspected ocular or periocular infection including most viral diseases of the cornea and conjunctiva, including active epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, varicella, mycobacterial infections, and fungal diseases.
- Advanced glaucoma which cannot be adequately controlled by medicinal products alone.
- **Aphakic eyes with rupture of the posterior lens capsule.**

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued within 44 days (Type II variations) and 67 days (Annex II applications) from adoption of the opinion.
[2] The text in bold represents the new or the amended contraindication.

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- **Eyes with Anterior Chamber Intraocular Lens (ACIOL) and rupture of the posterior lens capsule.**