20 May 2010
EMA/CHMP/316582/2010
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Ozurdex

dexamethasone

On 20 May 2010 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Ozurdex, 700 micrograms intravitreal implant in applicator intended for the treatment of adult patients with macular oedema following either Branch Retinal Vein Occlusion (BRVO) or Central Retinal Vein Occlusion (CRVO). The applicant for this medicinal product is Allergan Pharmaceuticals Ireland. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Ozurdex is dexamethasone, an anti-inflammatory agent (S01BA01), which has been shown to suppress inflammation by acting on and inhibiting key features of the inflammatory response such as oedema, fibrin deposition, capillary leakage and phagocytic migration.

Macular oedema involves the breakdown of the inner blood-retinal barrier at the level of the capillary endothelium, resulting in abnormal retinal vascular permeability and leakage into the adjacent retinal tissues. The macula then becomes thickened due to fluid accumulation resulting in significant disturbances in visual acuity. The reduction in vision may be reversible in the short term, but prolonged oedema can cause irreversible damage, resulting in permanent vision loss.

The benefits with Ozurdex are its effect on macular oedema following either BRVO or CRVO, its ability to overcome ocular drug delivery barriers and to prolong the duration of dexamethasone effect in the eye. The clinical safety and efficacy of Ozurdex have been assessed in two randomised, double-masked, sham-controlled studies in patients with macular oedema. The biodegradable implant delivers a 700 micrograms total dose of dexamethasone to the vitreous with gradual release over time allowing for sustained levels of dexamethasone in the target areas. The most common side effects with Ozurdex are increased intraocular pressure and conjunctival haemorrhage.

A pharmacovigilance plan for Ozurdex will be implemented as part of the marketing authorisation.

The approved indication is: “OZURDEX is indicated for the treatment of adult patients with macular oedema following either Branch Retinal Vein Occlusion (BRVO) or Central Retinal Vein Occlusion

[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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(CRVO)". It is proposed that Ozurdex is administered by a qualified ophthalmologist experienced in intravitreal injections.

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 will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit to risk balance for Ozurdex and therefore recommends the granting of the marketing authorisation.