

## Ozurdex for Uveitic Macular Edema

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**Purpose:** **Methods:** We performed a 26 week, multicenter, double-masked, randomized clinical trial comparing a 700 mcg DEX-DDS® (N=77) and 350 mcg DEX-DDS® (N=76) to sham (N=76) in patients with non-infectious posterior and intermediate uveitis. The primary endpoint was a vitreous haze score of 0 at week 8. Secondary endpoints included ETDRS best-corrected visual acuity (BCVA) and safety throughout the 26 week study.

**Results:** The proportion of patients with a vitreous haze score of 0 at week 8 was significantly higher in patients receiving DEX-DDS® 700 mcg (46.8%) and DEX-DDS® 350mcg (35.5%) than in sham-treated patients (11.8%) (p<.001). This treatment benefit persisted through the final 26 week visit. Patients with at least a 15 letter improvement from baseline BCVA was also significantly greater in patients receiving DEX-DDS® compared to sham at all study visits: 42.9% for DEX-DDS® 700 mcg, 39.5% for DEX-DDS® 350 mcg, and 6.6% for sham at the primary timepoint (p<.001). Overall the DEX-DDS® 700 mcg demonstrated greater efficacy than the DEX-DDS® 350 mcg dose. The percent of patients with an IOP ≥ 25 mm Hg peaked at 7.1% for DEX-DDS® 700, 8.7% DEX-DDS® 350, and 4.2% Sham, with no statistically significant difference between groups at any study visit. Cataracts and subcapsular cataracts were reported as adverse events in 11/76 DEX-DDS® 700 mcg patients, 10/74 DEX-DDS® 350 mcg patients, and 8/75 sham patients (p=.769).

**Conclusion:** DEX-DDS® appears to be both safe and effective for treating non-infectious intermediate and posterior uveitis with efficacy improvements in intraocular inflammation and visual acuity persisting through 6 months following a single administration. Overall the DEX-DDS® 700 mcg dose demonstrated greater efficacy with similar side effects to the DEX-DDS® 350 mcg dose.

**Background Statement:** Corticosteroids remain the mainstay of therapy for uveitis but adverse effects have limited their use. Ozurdex™ is an intravitreal sustained-release drug delivery system (DEX-DDS®) that releases dexamethasone for approximately 6 months with pharmacokinetic properties designed to optimize efficacy and limit side effects.

**Precis:** DEX-DDS® is safe and effective in treating intraocular inflammation and improving vision in patients with non-infectious intermediate and posterior uveitis.