

## CLINICAL PHARMACOLOGY REVIEW

<b>NDA / Supplement</b>	<b>22-212 / S-011</b>
<b>Drug</b>	Difluprednate Ophthalmic Emulsion 0.05%
<b>Trade Name</b>	DUREZOL <sup>®</sup>
<b>Sponsor</b>	Alcon Laboratories, Inc.
<b>Submission Type</b> <b>Submission Date</b>	Pediatric Labeling Supplement Sept. 28, 2012
<b>OCP Reviewer /Team Leader</b>	Philip M. Colangelo, Pharm.D, Ph.D
<b>OCP Division</b>	DCP4
<b>OND division</b>	Division of Transplant & Ophthalmology Products (DTOP)
<b>Indication</b>	Treatment of inflammation and pain associated with ocular surgery. Treatment of endogenous anterior uveitis

### 1. EXECUTIVE SUMMARY & BACKGROUND

Difluprednate ophthalmic emulsion 0.05% (DUREZOL<sup>®</sup>) is a topical ocular corticosteroid that was approved in 2008 for treatment of inflammation and pain associated with ocular surgery and for treatment of endogenous anterior uveitis. A Pediatric Written Request was issued by the Agency to the sponsor in February 2009 to evaluate the safety and efficacy of DUREZOL<sup>®</sup> in pediatric patients from 0 to 3 years of age for treatment of post-operative inflammation following cataract surgery. In response to this Written Request, the sponsor submitted this current labeling supplement to include information on the use of DUREZOL<sup>®</sup> in pediatric patients. Additions to the labeling are provided in Sections 6 Adverse Reactions and 8.4 Pediatric Use. The Pediatric Use Section 8.4 describes the results of a single study in 79 pediatric patients aged 0 to 3 years for treatment of inflammation following cataract surgery at the same regimen as that approved for adults (i.e., one drop 4 times daily for at least 14 days).

There was no evaluation of the systemic pharmacokinetic (PK) exposure to difluprednate in this study of pediatric patients, nor was it requested by the Agency at the time of issuance of the Pediatric Written Request. No new pharmacokinetic information or any other Clinical Pharmacology related information was added to the proposed labeling in this current submission. Thus, no Clinical Pharmacology review is needed.

## **1.1 Recommendation**

The Clinical Pharmacology reviewer recommends approval of this pediatric labeling supplement for difluprednate ophthalmic emulsion 0.05% (DUREZOL<sup>®</sup>).

## **1.2 Labeling Recommendations**

There are no Clinical Pharmacology labeling revisions.

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PHILIP M COLANGELO  
02/26/2013