



Preferred Drug List

NEW DRUG REVIEW

Proprietary Name: Durezol™

Common Name: Difluprednate

PDL Category: Ophthalmic Anti-Inflammatory / Steroid Ophthalmic

<u>Comparable Products</u>	<u>Preferred Drug List/ Recommended Drug List Status</u>
Lotemax®	Preferred
Vexol®	Non-Preferred

Summary

Indications and Usage: Treatment of postoperative ocular inflammation and pain.¹

Mechanism of Action: Inhibits the inflammatory response to inciting agents that may delay or slow healing.¹

Dosage Forms: Emulsion, ophthalmic: 0.05%

Recommended Dosage: One drop into the conjunctival sac of the affected eye(s) 4 times daily beginning 24 hours after surgery and continuing throughout the first 2 weeks of the postoperative period, followed by 2 times daily for a week and then a taper based on the response.¹

Common Adverse Drug Reactions: Raised intraocular pressure, corneal edema, ciliary and conjunctival hyperemia, eye pain, photophobia, posterior capsule opacification, anterior chamber cells, anterior chamber flare, conjunctival edema, blepharitis.¹

Contraindications: Patients with active viral diseases of the cornea and conjunctiva including epithelial herpes simplex keratitis, vaccinia, varicella, and also mycobacterial infections of the eye and fungal disease of ocular structures.¹

Manufacturer: Sirion Therapeutics, Inc.

Analysis: Durezol™ is an ophthalmic corticosteroid emulsion indicated for the treatment of postoperative ocular inflammation and pain. In the two studies used to gain FDA approval, Durezol™ was only compared to placebo and the endpoint measurement of reduced pain was not clearly defined. A common side effect associated with ophthalmic corticosteroids is a rise in intraocular pressure (IOP). Trials with Durezol™ report 3% of patients experienced a rise in IOP¹, similar to that of Lotemax reported at 2%. Preferred alternatives appear on the Preferred Drug List which are more cost effective. Therefore, it is recommended that Durezol™ be added to the Preferred Drug List as a non-preferred drug.

IME Recommendation:

<input type="checkbox"/> Preferred Drug	<input type="checkbox"/> Recommended Drug
<input checked="" type="checkbox"/> Non-Preferred Drug	<input type="checkbox"/> Non-Recommended Drug
<input type="checkbox"/> Preferred Drug with Conditions	

1. Durezol™ [package insert]. Sirion Pharmaceuticals, Inc.; 2008.