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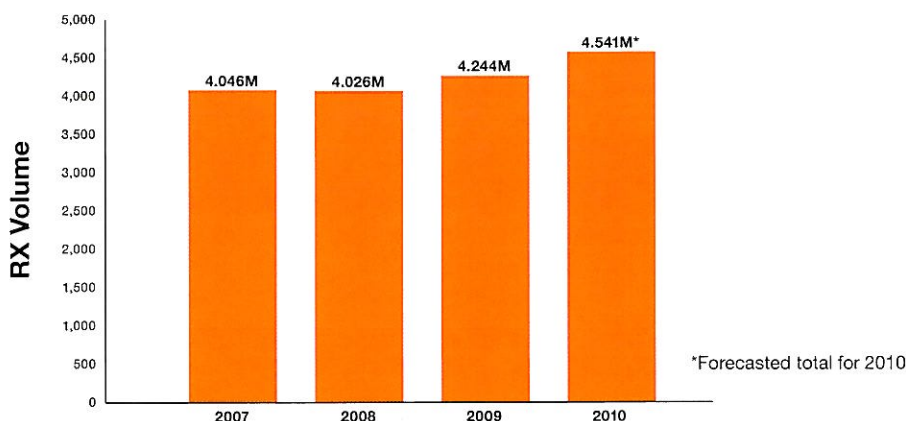
DUREZOL[®] (difluprednate ophthalmic emulsion) 0.05%

Alcon Laboratories, Inc. maintains four highly trained, specialized sales forces promoting DUREZOL[®] Emulsion to ophthalmologists (comprehensive ophthalmologist, retina, glaucoma and cornea specialists) hospitals and optometrists.

U.S. Market Information

- Approximately 5.0 million ophthalmic surgeries are performed in the U.S. annually.¹
- In 2009, 4.2 million topical ophthalmic steroids were prescribed.²

Topical Ophthalmic Steroid Growth 2007-2010



5 mL Package - NDC# 42826601-05

IMPORTANT SAFETY INFORMATION:

Dosage and Administration: Instill 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.

Contraindications: DUREZOL[®] Emulsion, as with other ophthalmic corticosteroids, is contraindicated in most active viral diseases of the cornea and conjunctiva including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, and varicella, and also in mycobacterial infection of the eye and fungal diseases of ocular structures.

Warnings and Precautions:

- **Intraocular pressure (IOP) increase** – Prolonged use of corticosteroids may result in glaucoma with damage to the optic nerve, defects in visual acuity and fields of vision. If this product is used for 10 days or longer, IOP should be monitored.
- **Cataracts** – Use of corticosteroids may result in posterior subcapsular cataract formation.
- **Delayed healing** – The use of steroids after cataract surgery may delay healing and increase the incidence of bleb formation. In those diseases causing thinning of the cornea or sclera, perforations have been known to occur with the use of topical steroids. The initial prescription and renewal of the medication

order beyond 28 days should be made by a physician only after examination of the patient with the aid of magnification such as slit lamp biomicroscopy and, where appropriate, fluorescein staining.

- **Bacterial infections** – Prolonged use of corticosteroids may suppress the host response and thus increase the hazard of secondary ocular infections. In acute purulent conditions, steroids may mask infection or enhance existing infection. If signs and symptoms fail to improve after 2 days, the patient should be re-evaluated.
- **Viral infections** – Employment of a corticosteroid medication in the treatment of patients with a history of herpes simplex requires great caution. Use of ocular steroids may prolong the course and may exacerbate the severity of many viral infections of the eye (including herpes simplex).
- **Fungal infections** – Fungal infections of the cornea are particularly prone to develop coincidentally with long-term local steroid application. Fungus invasion must be considered in any persistent corneal ulceration where a steroid has been used or is in use.

Adverse Events: Ocular adverse reactions occurring in 5-15% of subjects in clinical studies with DUREZOL[®] Emulsion included corneal edema, ciliary and conjunctival hyperemia, eye pain, photophobia, posterior capsule opacification, anterior chamber cells, anterior chamber flare, conjunctival edema, and blepharitis.

References: 1. Korenfeld M, Silverstein S, Cooke, D, et al. Difluprednate ophthalmic emulsion 0.05% for postoperative inflammation and pain. *J Cataract Refract Surg.* 2009; 35:26-34. 2. Walters Kluwer Health, Source[®], 2007-2009.

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US. Patent No. 6,114,319