FIRST TIME GENERIC APPROVAL

Brand Name	difluprednate
Generic Name	difluprednate
Drug Manufacturer	Cipla Limited

New Drug Approval

TYPE OF CLINICAL UPDATE

First Time Generic

FDA APPROVAL DATE

August 9, 2021

LAUNCH DATE

September 16, 2021

REVIEW DESIGNATION

Abbreviated New Drug Application (ANDA): 211776

TYPE OF REVIEW

Standard

DISPENSING RESTRICTIONS

N/A

Overview

INDICATION FOR USE

Difluprednate ophthalmic emulsion is a topical corticosteroid that is indicated for:

- The treatment of inflammation and pain associated with ocular surgery.
- The treatment of endogenous anterior uveitis.

MECHANISMS OF ACTION

Difluprednate is structurally similar to other corticosteroids. Corticosteroids inhibit the inflammatory response to a variety of inciting agents and may delay or slow healing. They inhibit edema, fibrin deposition, capillary dilation, leukocyte migration, capillary proliferation, fibroblast proliferation, deposition of collagen, and scar formation associated with inflammation. There is no generally accepted explanation for the mechanism of action of ocular corticosteroids. However, corticosteroids are thought to act by the induction of phospholipase A2 inhibitory proteins, collectively called lipocortins. It is postulated that these proteins control the biosynthesis of potent mediators of inflammation, such as prostaglandins and leukotreines by inhibiting the release of their common precursor arachidonic acid. Arachidonic acid is released from membrane phospholipids by phospholipase A2.

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DOSE FORM AND STRENGTH

Difluprednate ophthalmic emulsion contains 0.05% difluprednate, as a sterile preserved ophthalmic emulsion for topical ophthalmic use only.

DOSE & ADMINISTRATION

- For the treatment of inflammation and pain associated with ocular surgery, instill one drop into the conjunctival sac of the affected eye 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.
- For the treatment of endogenous anterior uveitis, instill one drop into the conjunctival sac of the affected eye 4 times daily for 14 days followed by tapering as clinically indicated.