PDR®
50
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1996

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HOW SUPPLIED

	SIZE	NDC#
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ULTRAGUARD OTC
(High Potency Antoxidant)

HOW SUPPLIED

	SIZE	NDC#
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HOW SUPPLIED

	SIZE	NDC#
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HOW SUPPLIED

	SIZE	NDC#
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ABITA SPRINGS, LA 70420

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OPHTHALMIC PRODUCTS

For information on Akorn ophthalmic pharmaceutical products, consult the PDR For Ophthalmology. For literature, sample material or service items, please contact Akorn, Inc. directly. (800) 535-7155

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OPHTHALMIC PRODUCTS

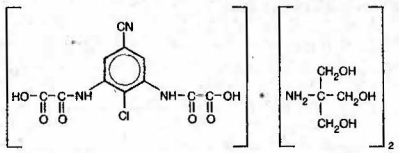
For information on Alcon ophthalmic products, consult the PDR For Ophthalmology. See a complete listing of products in the Manufacturers' Index section of this book. For information, literature, samples or service items contact Alcon Sales Services.

ALOMIDE® 0.1% ℞
(Lodoxamide Tromethamine Ophthalmic Solution)

DESCRIPTION

white, crystalline, water-soluble powder with a molecular weight of 553.91. The chemical structure is presented below:

Structural Formula:



Chemical Name:
N,N'-(2-chloro-5-cyano-m-phenylene)dioxamic acid tromethamine salt
Empirical Formula: $C_{19}H_{28}O_{12}N_5Cl$
Each mL of ALOMIDE® Ophthalmic Solution contains: Active: 1.78 mg lodoxamide tromethamine equivalent to 1 mg lodoxamide. **Preservative:** benzalkonium chloride 0.007%. **Inactive:** mannitol, hydroxypropyl methylcellulose 2910, sodium citrate, citric acid, edetate disodium, tyloxapol, hydrochloric acid and/or sodium hydroxide (adjust pH), and purified water.

CLINICAL PHARMACOLOGY
Lodoxamide tromethamine is a mast cell stabilizer that inhibits the *in vivo* Type 1 immediate hypersensitivity reaction. Lodoxamide therapy inhibits the increases in cutaneous vascular permeability that are associated with reagin or IgE and antigen-mediated reactions.
In vitro studies have demonstrated the ability of lodoxamide to stabilize rodent mast cells and prevent antigen-stimulated release of histamine. In addition, lodoxamide prevents the release of other mast cell inflammatory mediators (i.e., SRS-A, slow-reacting substances of anaphylaxis, also known as the peptidoleukotrienes) and inhibits eosinophil chemotaxis. Although lodoxamide's precise mechanism of action is unknown, the drug has been reported to prevent calcium influx into mast cells upon antigen stimulation.
Lodoxamide has no intrinsic vasoconstrictor, antihistaminic, cyclooxygenase inhibition, or other anti-inflammatory activity.
The disposition of ^{14}C-lodoxamide was studied in six healthy adult volunteers receiving a 3 mg (50 μCi) oral dose of lodoxamide. Urinary excretion was the major route of elimination. The elimination half-life of ^{14}C-lodoxamide was 8.5 hours in urine. In a study conducted in twelve healthy adult volunteers, topical administration of ALOMIDE® 0.1% (Lodoxamide Tromethamine Ophthalmic Solution), one drop in each eye four times per day for ten days, did not result in any measurable lodoxamide plasma levels at a detection limit of 2.5 ng/mL.

INDICATIONS AND USAGE
ALOMIDE® Ophthalmic Solution 0.1% is indicated in the treatment of the ocular disorders referred to by the terms vernal keratoconjunctivitis, vernal conjunctivitis, and vernal keratitis.

CONTRAINDICATIONS
Hypersensitivity to any component of this product.

WARNINGS
Not for injection. As with all ophthalmic preparations containing benzalkonium chloride, patients should be instructed not to wear soft contact lenses during treatment with ALOMIDE® Ophthalmic Solution.

PRECAUTIONS
General: Patients may experience a transient burning or stinging upon instillation of ALOMIDE® Ophthalmic Solution. Should these symptoms persist, the patient should be advised to contact the prescribing physician.
Carcinogenesis, Mutagenesis, Impairment of Fertility:
A long-term study with lodoxamide tromethamine in rats (two-year oral administration) showed no neoplastic or tumorigenic effects at doses 100 mg/kg/day (more than 5000 times the proposed human clinical dose). No evidence of mutagenicity or genetic damage was seen in the Ames *Salmonella* Assay, Chromosomal Aberration in CHO Cells Assay, or Mouse Forward Lymphoma Assay. In the BALB/c-3T3 Cells Transformation Assay, some increase in the number of transformed foci was seen at high concentrations (greater than 4000 μg/mL). No evidence of impairment of reproductive function was shown in laboratory animal studies.
Pregnancy: Pregnancy Category B. Reproduction studies with lodoxamide tromethamine administered orally to rats and rabbits in doses of 100 mg/kg/day (more than 5000 times the proposed human clinical dose) produced no evidence of developmental toxicity. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, ALOMIDE® 0.1% (Lodoxamide Tromethamine Ophthalmic Solution) should be used during preg-

drugs are excreted in human milk, caution should be exercised when ALOMIDE® Ophthalmic Solution 0.1% is administered to nursing women.
Pediatric Use: Safety and effectiveness in pediatric patients below the age of 2 have not been established.

ADVERSE REACTIONS
During clinical studies of ALOMIDE® Ophthalmic Solution 0.1%, the most frequently reported ocular adverse experiences were transient burning, stinging, or discomfort upon instillation, which occurred in approximately 15% of the subjects. Other ocular events occurring in 1 to 5% of the subjects included ocular itching/pruritus, blurred vision, dry eye, tearing/discharge, hyperemia, crystalline deposits, and foreign body sensation. Events that occurred in less than 1% of the subjects included corneal erosion/ulcer, scales on lid/lash, eye pain, ocular edema/swelling, ocular warming sensation, ocular fatigue, chemosis, corneal abrasion, anterior chamber cells, keratopathy/keratitis, blepharitis, allergy, sticky sensation, and epitheliopathy.
Nonocular events reported were headache (1.5%) and (at less than 1%) heat sensation, dizziness, somnolence, nausea, stomach discomfort, sneezing, dry nose, and rash.

OVERDOSAGE
There have been no reports of ALOMIDE® 0.1% (Lodoxamide Tromethamine Ophthalmic Solution) overdose following topical ocular application. Accidental overdose of an oral preparation of 120 to 180 mg of lodoxamide resulted in a temporary sensation of warmth, profuse sweating, diarrhea, light-headedness, and a feeling of stomach distension; no permanent adverse effects were observed. Side effects reported following systemic oral administration of 0.1 mg to 10.0 mg of lodoxamide include a feeling of warmth or flushing, headache, dizziness, fatigue, sweating, nausea, loose stools, and urinary frequency/urgency. The physician may consider emesis in the event of accidental ingestion.

DOSAGE AND ADMINISTRATION
The dose for adults and children greater than two years of age is one to two drops in each affected eye four times daily for up to 3 months.

HOW SUPPLIED
ALOMIDE® Ophthalmic Solution 0.1% is supplied as follows: 10 mL in plastic ophthalmic DROP-TAINER® dispenser.

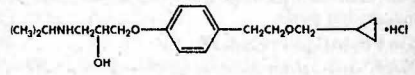
10 mL: **NDC** 0065-0345-10

STORAGE
Store at 15°C–27°C (59°F–80°F).

CAUTION
Federal (USA) law prohibits dispensing without prescription.

BETOPTIC® ℞
(betaxolol hydrochloride)
0.5% as base
Sterile Ophthalmic Solution

DESCRIPTION
BETOPTIC® Sterile Ophthalmic Solution contains betaxolol hydrochloride, a cardioselective beta-adrenergic receptor blocking agent, in a sterile isotonic solution. Betaxolol hydrochloride is a white, crystalline powder, soluble in water, with a molecular weight of 343.89. The chemical structure is presented below:



Empirical Formula:
$C_{18}H_{29}NO_3 \cdot HCl$
Chemical Name:
(±)-1-[p-[2-(Cyclopropylmethoxy)ethyl]phenoxy]-3-(isopropylamino)-2-propanol hydrochloride.
Each mL of BETOPTIC Ophthalmic Solution (0.5%) contains: Active: 5.6 mg betaxolol hydrochloride equivalent to betaxolol base 5 mg. Preservative: Benzalkonium Chloride 0.01%. Inactives: Edetate Disodium, Sodium Chloride, Hydrochloric Acid and/or Sodium Hydroxide (to adjust pH), and Purified Water.

CLINICAL PHARMACOLOGY
Betaxolol HCl, a cardioselective (beta-1-adrenergic) receptor blocking agent, does not have significant membrane-stabilizing (local anesthetic) activity and is devoid of intrinsic sympathomimetic action. Orally administered beta-adrenergic blocking agents reduce cardiac output in healthy subjects and patients with heart disease. In patients with severe impairment of myocardial function, beta-adrenergic receptor antagonists may inhibit the sympathetic stimulatory effect