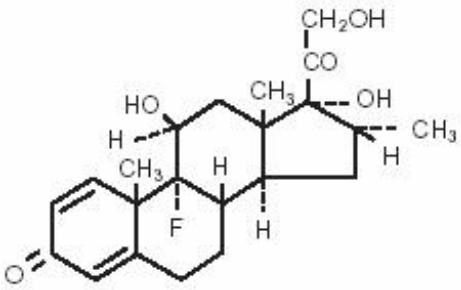
MAXIDEX- dexamethasone suspension/ drops
ALCON LABORATORIES, INC.

Maxidex® 0.1%
(dexamethasone ophthalmic suspension)
Sterile

DESCRIPTION

MAXIDEX® 0.1% (dexamethasone ophthalmic suspension) is an adrenocortical steroid prepared as a sterile topical ophthalmic suspension. The active ingredient is represented by the chemical structure:



Chemical name:
Pregna-1,4-diene-3,
20-dione,9-fluoro-11,17,
21-trihydroxy-16-
methyl-,(11β,16α)-.

Each mL contains

Active: dexamethasone 0.1%. **Preservative:** benzalkonium chloride 0.01%. **Vehicle:** hypromellose 0.5%. **Inactives:** sodium chloride, dibasic sodium phosphate, polysorbate 80, edetate disodium, citric acid and/or sodium hydroxide (to adjust pH), purified water.

CLINICAL PHARMACOLOGY

Dexamethasone suppresses the inflammatory response to a variety of agents and it probably delays or slows healing.

INDICATIONS AND USAGE

Steroid responsive inflammatory conditions of the palpebral and bulbar conjunctiva, cornea, and anterior segment of the globe such as allergic conjunctivitis, acne rosacea, superficial punctuate keratitis, herpes zoster keratitis, iritis, cyclitis, selected infective conjunctivitides when the inherent hazard of steroid use is accepted to obtain an advisable diminution in edema and inflammation; corneal injury from chemical, radiation, or thermal burns, or penetration of foreign bodies.

CONTRAINDICATIONS

Contraindicated in epithelial herpes simplex (dendritic keratitis), vaccinia, varicella, and most other viral diseases of the cornea and conjunctiva; tuberculosis of the eye; fungal disease of ocular structures; and in those persons who have shown hypersensitivity to any component of this preparation.

WARNINGS

Prolonged use may result in ocular hypertension and/or glaucoma, with damage to the optic nerve, defects in visual acuity and fields of vision, and posterior subcapsular cataract formation. Prolonged use may suppress the host response and thus increase the hazard of secondary ocular infections. In those diseases causing thinning of the cornea or sclera, perforations have been known to occur with the use of topical corticosteroids. In acute purulent conditions of the eye, corticosteroids may mask

infection or enhance existing infection. If these products are used for 10 days or longer, intraocular pressure should be routinely monitored even though it may be difficult in children and uncooperative patients.

Employment of corticosteroid medication in the treatment of herpes simplex other than epithelial herpes simplex keratitis, in which it is contraindicated, requires great caution; periodic slit-lamp microscopy is essential.

PRECAUTIONS

General

FOR TOPICAL OPHTHALMIC USE ONLY. The possibility of persistent fungal infections of the cornea should be considered after prolonged corticosteroid dosing.

Information for Patients

Do not touch dropper tip to any surface, as this may contaminate the contents. The preservative in MAXIDEX® (dexamethasone ophthalmic suspension), benzalkonium chloride, may be absorbed by soft contact lenses. MAXIDEX® (dexamethasone ophthalmic suspension) should not be administered while wearing soft contact lenses.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term animal studies have not been performed to evaluate the carcinogenic potential or the effect on fertility of MAXIDEX® dexamethasone ophthalmic suspension).

Pregnancy

Pregnancy Category C

Dexamethasone has been shown to be teratogenic in mice and rabbits following topical ophthalmic application in multiples of the therapeutic dose.

In the mouse, corticosteroids produce fetal resorptions and a specific abnormality, cleft palate. In the rabbit, corticosteroids have produced fetal resorptions and multiple abnormalities involving the head, ears, limbs, palate, etc.

There are no adequate or well-controlled studies in pregnant women. MAXIDEX® (dexamethasone ophthalmic suspension) should be used during pregnancy only if the potential benefit to the mother justifies the potential risk to the embryo or fetus. Infants born of mothers who have received substantial doses of corticosteroids during pregnancy should be observed carefully for signs of hypoadrenalism.

Nursing Mothers

Systemically administered corticosteroids appear in human milk and could suppress growth, interfere with endogenous corticosteroid production, or cause other untoward effects. It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in human milk. Because many drugs are excreted in human milk, caution should be exercised when MAXIDEX® (dexamethasone ophthalmic suspension) is administered to a nursing woman.

Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

Geriatric Use

No overall differences in safety or effectiveness have been observed between elderly and younger

patients.

ADVERSE REACTIONS

Glaucoma with optic nerve damage, visual acuity and field defects; cataract formation; secondary ocular infection following suppression of host response; and perforation of the globe may occur.

DOSAGE AND ADMINISTRATION

SHAKE WELL BEFORE USING. One or two drops topically in the conjunctival sac(s). In severe disease, drops may be used hourly, being tapered to discontinuation as the inflammation subsides. In mild disease, drops may be used up to four to six times daily.

HOW SUPPLIED

MAXIDEX® (dexamethasone ophthalmic suspension) in plastic DROP-TAINER® dispensers:

5 mL **NDC** 0998-0615-05

15 mL **NDC** 0998-0615-15

STORAGE

Store upright at 8°-27°C (46°-80°F).

Rx Only

ALCON LABORATORIES, INC.
Fort Worth, Texas 76134 USA
Printed in USA

340907-0803

MAXIDEX

dexamethasone suspension/ drops

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0998-0615
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
dexamethasone (UNII: 7S5I7G3JQL) (dexamethasone - UNII:7S5I7G3JQL)		1 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
benzalkonium chloride ()	0.1 mg in 1 mL
hypromellose ()	5 mg in 1 mL

sodium chloride (UNII: 451W47IQ8X)	
dibasic sodium phosphate (UNII: GR686LBA74)	
polysorbate 80 ()	
edetate disodium (UNII: 7FLD91C86K)	
citric acid and/or sodium hydroxide ()	
water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0998-0615-04	5 mL in 1 BOTTLE, PLASTIC		
2	NDC:0998-0615-05	5 mL in 1 BOTTLE, PLASTIC		
3	NDC:0998-0615-15	15 mL in 1 BOTTLE, PLASTIC		
4	NDC:0998-0615-06	5 mL in 1 BOTTLE, PLASTIC		

Labeler - ALCON LABORATORIES, INC.

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