HMS- medrysone suspension
Allergan, Inc.

HMS®
(medrysone ophthalmic suspension) 1%

Sterile

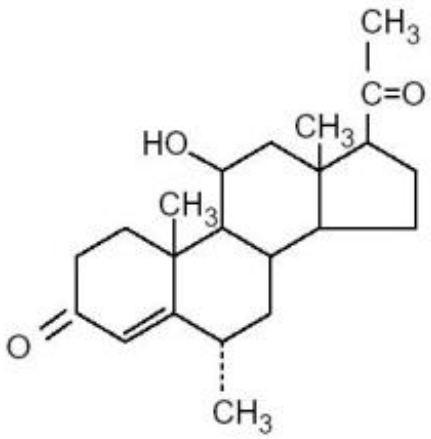
DESCRIPTION

HMS® (medrysone ophthalmic suspension) 1% is a topical anti-inflammatory agent for ophthalmic use.

Chemical Name:

11β-hydroxy-6α-methylpregn-4-ene-3,20-dione

Structural Formula:



Medrysone

Contains: Active: Medrysone 1%. **Preservative:** benzalkonium chloride 0.004%.

Inactives: edetate disodium; hypromellose; polyvinyl alcohol 1.4%; potassium chloride; purified water; sodium chloride; sodium phosphate, dibasic; sodium phosphate, monobasic; and sodium hydroxide to adjust the pH (6.2 - 7.5).

CLINICAL PHARMACOLOGY

HMS® (medrysone ophthalmic suspension) is a synthetic corticosteroid with topical anti-inflammatory activity. Glucocorticoids inhibit the edema, fibrin deposition, capillary dilation and phagocytic migration of the acute inflammatory response as well as capillary proliferation, deposition of collagen, and scar formation. HMS® (medrysone ophthalmic suspension) has less anti-inflammatory potency than 0.1% dexamethasone.

INDICATIONS AND USAGE

HMS® (medrysone ophthalmic suspension) is indicated for the treatment of allergic conjunctivitis, vernal conjunctivitis, episcleritis, and epinephrine sensitivity.

CONTRAINDICATIONS

HMS® suspension is contraindicated in most 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. HMS® suspension is also contraindicated in individuals with known or suspected hypersensitivity to any of the ingredients of this preparation and to other corticosteroids.

WARNINGS

HMS® (medrysone ophthalmic suspension) is not recommended for use in iritis and uveitis as its therapeutic effectiveness has not been demonstrated in these conditions.

Prolonged use of corticosteroids may result in glaucoma with damage to the optic nerve, defects in visual acuity and fields of vision, and in posterior subcapsular cataract formation. Prolonged use may also suppress the host immune response and thus increase the hazard of secondary ocular infections.

Various ocular diseases and long-term use of topical corticosteroids have been known to cause corneal and scleral thinning. Use of topical corticosteroids in the presence of thin corneal or scleral tissue may lead to perforation.

Acute purulent infections of the eye may be masked or activity enhanced by the presence of corticosteroid medication.

If this product is used for 10 days or longer, intraocular pressure should be routinely monitored even though it may be difficult in children and uncooperative patients.

Steroids should be used with caution in the presence of glaucoma. Intraocular pressure should be checked frequently.

The use of steroids after cataract surgery may delay healing and increase the incidence of bleb formation.

Use of ocular steroids may prolong the course and may exacerbate the severity of many viral infections of the eye (including herpes simplex). Employment of a corticosteroid medication in the treatment of patients with a history of herpes simplex requires great caution; frequent slit lamp microscopy is recommended.

Corticosteroids are not effective in mustard gas keratitis and Sjögren's keratoconjunctivitis.

PRECAUTIONS

General:

The initial prescription and renewal of the medication order beyond 20 milliliters of HMS® suspension 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. If signs and symptoms fail to improve after two days, the patient should be re-evaluated.

As fungal infections of the cornea are particularly prone to develop coincidentally with long-term local corticosteroid applications, fungal invasion should be suspected in any persistent corneal ulceration where a corticosteroid has been used or is in use. Fungal cultures should be taken when appropriate.

If this product is used for 10 days or longer, intraocular pressure should be monitored (see WARNINGS).

Information for Patients:

If inflammation or pain persists longer than 48 hours or becomes aggravated, the patient should be advised to discontinue use of the medication and consult a physician.

This product is sterile when packaged. To prevent contamination, care should be taken to avoid touching the bottle tip to eyelids or to any other surface. The use of this bottle by more than one person may spread infection. Keep bottle tightly closed when not in use. Keep out of the reach of children.

Carcinogenesis, Mutagenesis, Impairment of Fertility:

No studies have been conducted in animals or in humans to evaluate the potential of these effects.

Pregnancy:

Teratogenic effects. Pregnancy Category C. Medrysone has been shown to be embryocidal in rabbits when given in doses 10 and 30 times the human ocular dose. Two drops of medrysone were applied to both eyes of pregnant rabbits 4 times per day on day 6 through 18 of gestation. A significant increase in early resorptions was observed in the treated rabbits. There are no adequate and well-controlled studies of medrysone in pregnant women. Medrysone should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers:

It is not known whether topical ophthalmic administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in human breast milk. Systemically administered corticosteroids appear in human milk and could suppress growth, interfere with endogenous corticosteroid production, or cause other untoward effects. Because of the potential for serious adverse reactions in nursing infants from medrysone, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use:

Safety and effectiveness in pediatric patients below the age of 3 years have not been established.

Geriatric Use:

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

ADVERSE REACTIONS

Adverse reactions include, in decreasing order of frequency, elevation of intraocular pressure (IOP) with possible development of glaucoma and infrequent optic nerve damage, posterior subcapsular cataract formation, and delayed wound healing.

Although systemic effects are extremely uncommon, there have been rare occurrences of systemic hypercorticoidism after use of topical steroids.

Corticosteroid-containing preparations have also been reported to cause acute anterior uveitis and perforation of the globe. Keratitis, conjunctivitis, corneal ulcers, mydriasis, conjunctival hyperemia, loss of accommodation and ptosis have occasionally been reported following local use of corticosteroids.

The development of secondary ocular infection (bacterial, fungal and viral) has occurred. Fungal and viral infections of the cornea are particularly prone to develop coincidentally with long-term applications of steroids. The possibility of fungal invasion should be considered in any persistent corneal ulceration where steroid treatment has been used (see WARNINGS).

Transient burning and stinging upon instillation and other minor symptoms of ocular irritation have been reported with the use of HMS® suspension. Other adverse events reported with the use of HMS® suspension include: allergic reactions, foreign body sensation, and visual disturbance (blurry vision).

OVERDOSAGE

Overdosage will not ordinarily cause acute problems. If accidentally ingested, drink fluids to dilute.

DOSAGE AND ADMINISTRATION

Shake well before using. Instill one drop into the conjunctival sac up to every four hours.

HOW SUPPLIED

HMS® (medrysone ophthalmic suspension) 1% is supplied sterile in opaque white LDPE plastic bottles with droppers with white high impact polystyrene (HIPS) caps as follows:

5 mL in 10 mL bottle - NDC 11980-074-05
10 mL in 15 mL bottle - NDC 11980-074-10

Note: Store at temperatures up to 25°C (77°F). Protect from freezing.

Rx Only

Revised August 2004

Irvine, CA 92612, U.S.A.
6089X

71741US11P

HMS
medrysone suspension

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:11980-074
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Medrysone (UNII: D2UFC189XF) (Medrysone - UNII:D2UFC189XF)		10 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
edetate disodium (UNII: 7FLD91C86K)	
hypromellose ()	
polyvinyl alcohol ()	
potassium chloride (UNII: 660YQ98I10)	
water (UNII: 059QF0KO0R)	
sodium chloride (UNII: 451W47IQ8X)	
sodium phosphate, dibasic (UNII: GR686LBA74)	
sodium phosphate, monobasic (UNII: 3980JIH2SW)	

sodium hydroxide (UNII: 55X04QC32I)	
benzalkonium chloride ()	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11980-074-05	5 mL in 1 BOTTLE		
2	NDC:11980-074-10	10 mL in 1 BOTTLE		

Labeler - Allergan, Inc.

Revised: 2/2006 Allergan, Inc.