FLUOR-OP- fluorometholone suspension
Novartis Ophthalmics

Fluor-Op®

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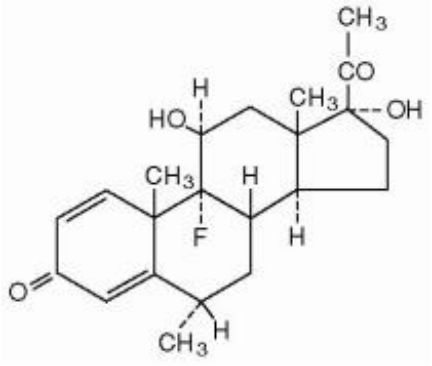
(FLUOROMETHOLONE OPHTHALMIC SUSPENSION, USP) 0.1%

DESCRIPTION

FLUOR-OP (fluorometholone ophthalmic suspension, USP) 0.1%, is a topical anti-inflammatory agent for ophthalmic use.

Chemical Name: 9-fluoro-11ß,17-dihydroxy-6α-methylpregna-1,4-diene-3,20-dione.



Contains:

Fluorometholone 0.1%

with: polyvinyl alcohol 1.4%; benzalkonium chloride 0.004%, edetate disodium; sodium chloride; sodium phosphate monobasic, monohydrate; sodium phosphate dibasic, anhydrous; polysorbate 80; sodium hydroxide to adjust the pH, and purified water.

CLINICAL PHARMACOLOGY

Corticosteroids inhibit the inflammatory response to a variety of inciting agents and probably delay or slow healing. They inhibit the 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 A_2 inhibitory proteins, collectively called lipocortins. It is postulated that these proteins control the biosynthesis of potent mediators of inflammation such as prostaglandins and leukotrienes by inhibiting the release of their common precursor, arachidonic acid. Arachidonic acid is released from membrane phospholipids by phospholipase A_2.

Corticosteroids are capable of producing a rise in intraocular pressure. In clinical studies on patients' eyes treated with both dexamethasone and fluorometholone 0.1% suspensions, fluorometholone demonstrated a lower propensity to increase intraocular pressure than did dexamethasone.

INDICATIONS AND USAGE

FLUOR-OP is indicated for the treatment of corticosteroid-responsive inflammation of the palpebral and bulbar conjunctiva, cornea and anterior segment of the globe.

CONTRAINDICATIONS

FLUOR-OP 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. FLUOR-OP suspension is also contraindicated in individuals with known or suspected hypersensitivity to any of the ingredients of this preparation and to other corticosteroids.

WARNINGS

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 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 untreated 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 FLUOR-OP 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 to the Patient

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 reach of children.

Carcinogenesis, mutagenesis, impairment of fertility

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

Pregnancy

Teratogenic effects. Pregnancy Category C

Fluorometholone has been shown to be embryocidal and teratogenic in rabbits when administered at low multiples of the human ocular dose. Fluorometholone was applied ocularly to rabbits daily on days 6-18 of gestation, and dose related fetal loss and fetal abnormalities including cleft palate, deformed rib cage, anomalous limbs and neural abnormalities such as encephalocele, craniorachischisis, and spina bifida were observed. There are no adequate and well-controlled studies of fluorometholone in pregnant women, and it is not known whether fluorometholone can cause fetal harm when administered to a pregnant women. Fluorometholone 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 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 fluorometholone, 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 children below the age of two years have not been established.

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 uveitis and perforation of the globe. Keratitis, conjunctivitis, corneal ulcers, mydriasis, conjunctival hyperemia, loss of accommodation and ptosis have occasionally been reported following 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).

DOSAGE AND ADMINISTRATION

Instill one drop into the conjunctival sac two to four times daily. During the initial 24 to 48 hours, the dosage may be increased to one application every four hours. Care should be taken not to discontinue

therapy prematurely.

If signs and symptoms fail to improve after two days, the patient should be re-evaluated (see PRECAUTIONS).

The dosing of FLUOR-OP suspension may be reduced, but care should be taken not to discontinue therapy prematurely. In chronic conditions, withdrawal of treatment should be carried out by gradually decreasing the frequency of applications.

HOW SUPPLIED

FLUOR-OP (fluorometholone ophthalmic suspension, USP) 0.1% is supplied in plastic dropper bottles in the following sizes:

5 mL……..NDC 58768-358-05

10 mL……NDC 58768-358-10

15 mL……NDC 58768-358-15

Store at controlled room temperature 15°-30°C (59°-86°F)**. Protect from freezing. Shake well before using. Keep bottle tightly closed when not in use.**

Rx only

Mfd. by OMJ Pharmaceuticals, Inc.,

San Germán, P.R., 00683 for:

Novartis Ophthalmics

Duluth, GA 30097

6069-B

FLUOR-OP

fluorometholone suspension

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:58768-358
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Fluorometholone (UNII: SV0CSG527L) (Fluorometholone - UNII:SV0CSG527L)		0.1 mL in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
benzalkonium chloride ()	0.004 mL in 100 mL
edetate disodium (UNII: 7FLD91C86K)	
polysorbate 80 ()	
polyvinyl alcohol ()	1.4 mL in 100 mL
water (UNII: 059QF0KO0R)	
sodium chloride (UNII: 451W47IQ8X)	

sodium hydroxide (UNII: 55X04QC32I)	
sodium phosphate dibasic, anhydrous ()	
sodium phosphate monobasic, monohydrate ()	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58768-358-05	5 mL in 1 BOTTLE, DROPPER		
2	NDC:58768-358-10	10 mL in 1 BOTTLE, DROPPER		
3	NDC:58768-358-15	15 mL in 1 BOTTLE, DROPPER		

Labeler - Novartis Ophthalmics

Revised: 5/2006 Novartis Ophthalmics