

FLUOROMETHOLONE OPHTHALMIC SUSPENSION-
fluorometholone suspension/ drops
Amneal Pharmaceuticals NY LLC

Fluorometholone Ophthalmic Suspension USP, 0.1%

sterile

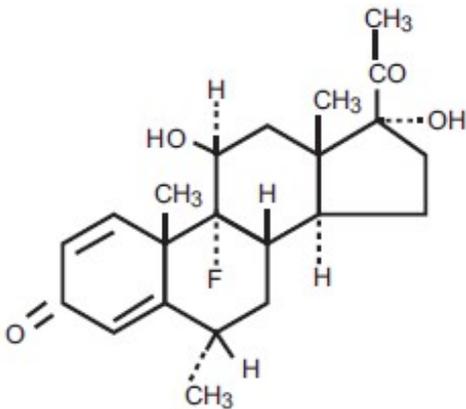
DESCRIPTION

Fluorometholone Ophthalmic Suspension USP, 0.1% is a sterile, topical anti-inflammatory agent for ophthalmic use.

Fluorometholone, USP is practically white crystalline powder. It is practically insoluble in water, slightly soluble in alcohol, very slightly soluble in chloroform and practically insoluble in ether.

Chemical name: 9-Fluoro-11 β ,17-dihydroxy-6 α -methylpregna-1,4-diene-3,20-dione.

Structural formula:



Molecular weight: 376.5 g/mol

Molecular formula: C₂₂H₂₉FO₄

Each mL of fluorometholone ophthalmic suspension USP, 0.1% contains:

Active: Fluorometholone USP, 0.1% (1 mg).

Preservative: Benzalkonium chloride, 0.004% (0.04 mg).

Inactives: Edetate disodium; polysorbate 80; polyvinyl alcohol 1.4%; water for injection; sodium chloride; sodium phosphate, dibasic, anhydrous; sodium phosphate, monobasic, monohydrate; and sodium hydroxide to adjust pH.

Fluorometholone ophthalmic suspension, USP is formulated with a pH from 6.2 to 7.5. It has an osmolality range of 290 mOsm/kg to 350 mOsm/kg.

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 A₂ 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 A₂.

Corticosteroids are capable of producing a rise in intraocular pressure. In clinical studies of documented steroid-responders, fluorometholone demonstrated a significantly longer average time to produce a rise in intraocular pressure than dexamethasone phosphate; however, in a small percentage of individuals, a significant rise in intraocular pressure occurred within one week. The ultimate magnitude of the rise was equivalent for both drugs.

INDICATIONS AND USAGE

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

CONTRAINDICATIONS

Fluorometholone ophthalmic 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.

Fluorometholone ophthalmic 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 increase intraocular pressure in susceptible individuals, resulting 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.

PRECAUTIONS

General

The initial prescription and renewal of the medication order beyond 20 milliliters of fluorometholone ophthalmic 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.

The preservative in fluorometholone ophthalmic suspension, benzalkonium chloride, may be absorbed by soft contact lenses. Patients wearing soft contact lenses should be instructed to wait at least 15 minutes after instilling fluorometholone ophthalmic suspension to insert soft contact lenses.

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

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 woman. 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 infants below the age of two 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 hypercorticism after use of topical dermatologic steroids applied to the skin.

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 fluorometholone ophthalmic suspension.

Other adverse events reported with the use of fluorometholone include: allergic reactions; foreign body sensation; erythema of eyelid; eyelid edema/eye swelling; eye discharge; eye pain; eye pruritus; lacrimation increased; rash; taste perversion; visual disturbance (blurry vision); and visual field defect.

DOSAGE AND ADMINISTRATION

Shake well before using. Instill one drop into the conjunctival sac two to four times daily. During the initial 24 to 48 hours, the dosing frequency 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 fluorometholone ophthalmic 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

Fluorometholone Ophthalmic Suspension USP, 0.1% is a sterile, white to off-white homogenous suspension essentially free from foreign particles, filled in 10 mL or 15 mL low density polyethylene white opaque bottles and low density polyethylene white opaque nozzles with high density polyethylene pink caps.

It is available as follows:

5 mL in 10 mL Containers (Filled to 1/2 Capacity): NDC 60219-1585-3

10 mL in 15 mL Containers (Filled to 2/3 Capacity): NDC 60219-1586-6

Storage: Store at 2° to 25°C (36° to 77°F). Protect from freezing. Store in an upright position.

To report SUSPECTED ADVERSE REACTIONS, contact Amneal Pharmaceuticals at 1-877-835-5472 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

This product's labeling may have been updated. For the most recent Prescribing Information, please visit www.amneal.com.

Manufactured by:

Amneal Pharmaceuticals Private Limited

Parenteral Unit

Ahmedabad 382213, INDIA

Distributed by:

Amneal Pharmaceuticals LLC

Bridgewater, NJ 08807

Rev. 01-2024

Version-01

PRINCIPAL DISPLAY PANEL

NDC 60219-1585-3

Fluorometholone Ophthalmic Suspension USP, 0.1%

Rx only

5 mL Container Label

Amneal Pharmaceuticals LLC

The image shows a rectangular label for a 5 mL container of Fluorometholone Ophthalmic Suspension USP, 0.1%. The label is divided into several sections. On the left, a vertical dashed line indicates an unvarnished area for a 6 x 18 mm label. The main body of the label has a pink background. At the top left, it displays 'NDC 60219-1585-3' and 'Rx only'. The product name 'Fluorometholone Ophthalmic Suspension, USP' is prominently displayed in the center, with '0.1%' in a white oval below it. Underneath, it says 'Sterile' and '5 mL' in a grey curved area at the bottom left. To the right of this, the text 'EACH ML CONTAINS:' is followed by 'Active: Fluorometholone USP, 0.1% (1 mg)'. Below that, 'Preservative: Benzalkonium chloride, 0.004% (0.04 mg)'. The 'USUAL DOSAGE' section states 'Shake well before using. Instill one drop two to four times daily. Care should be taken not to discontinue therapy prematurely. Refer to package insert.' The 'Storage' section says 'Store at 2° to 25°C (36° to 77°F). Protect from freezing. Store in an upright position.' A 'Note' indicates 'Bottle filled to 1/2 capacity.' Further right, it lists 'Mfg. Lic. No. G/28/1539', 'Distributed by: Amneal Pharmaceuticals LLC', 'Rev. 11-2023-01', and 'Made in INDIA.' A barcode is located to the right of the text, with the number '(01) 0 0360219 15853 5' printed below it. On the far right, another vertical dashed line indicates an unvarnished area for a 10 x 18 mm label.

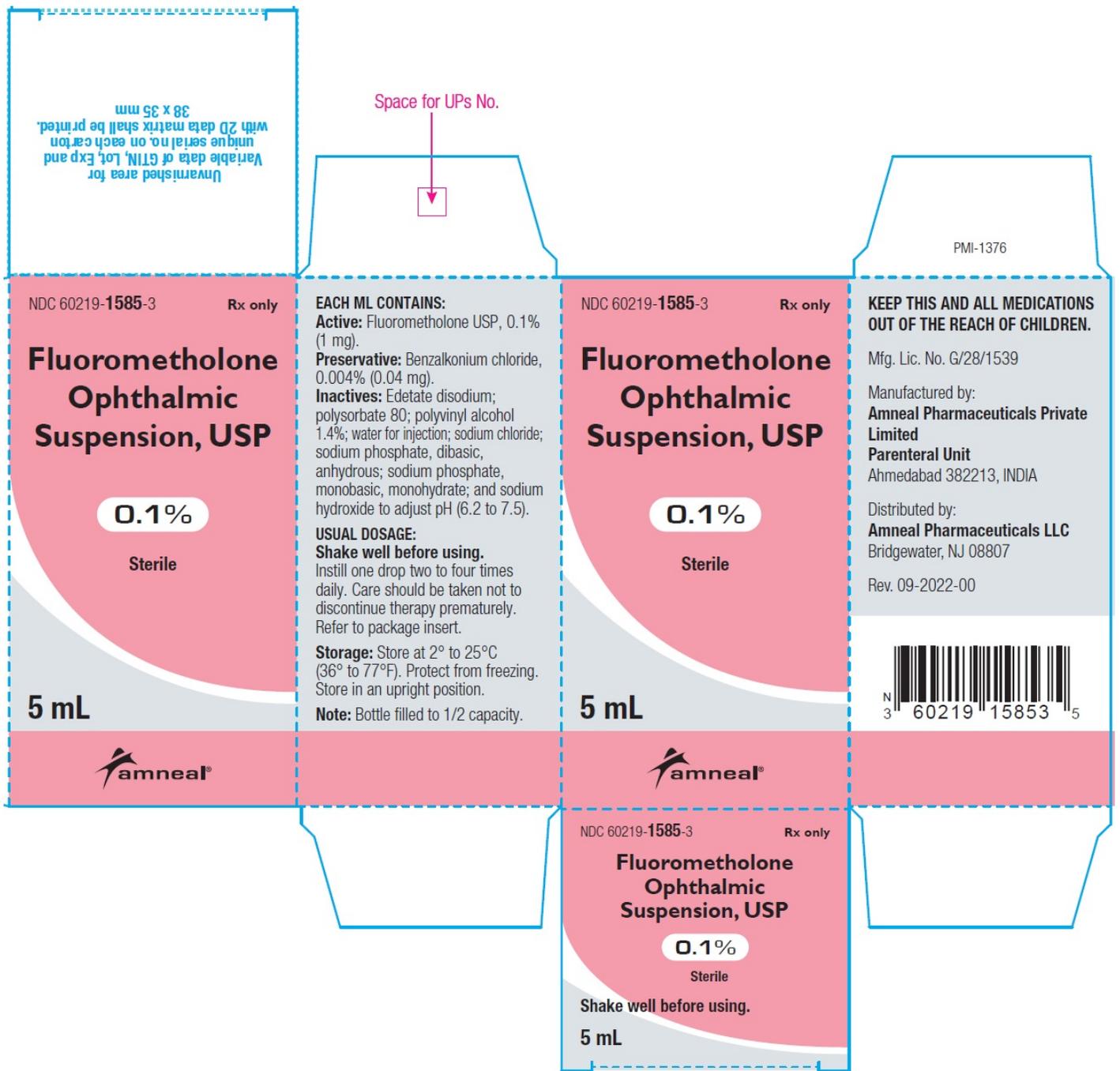
NDC 60219-1585-3

Fluorometholone Ophthalmic Suspension USP, 0.1%

Rx only

5 mL Carton Label

Amneal Pharmaceuticals LLC



NDC 60219-1586-6
Fluorometholone Ophthalmic Suspension USP, 0.1%
Rx only
10 mL Container Label
Amneal Pharmaceuticals LLC

Unvarnished Area for,
(6 x 28 mm)

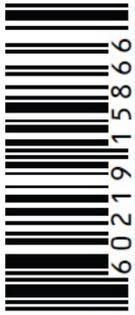
NDC 60219-1586-6 Rx only

**Fluorometholone
Ophthalmic
Suspension, USP**

0.1%
Sterile

10 mL

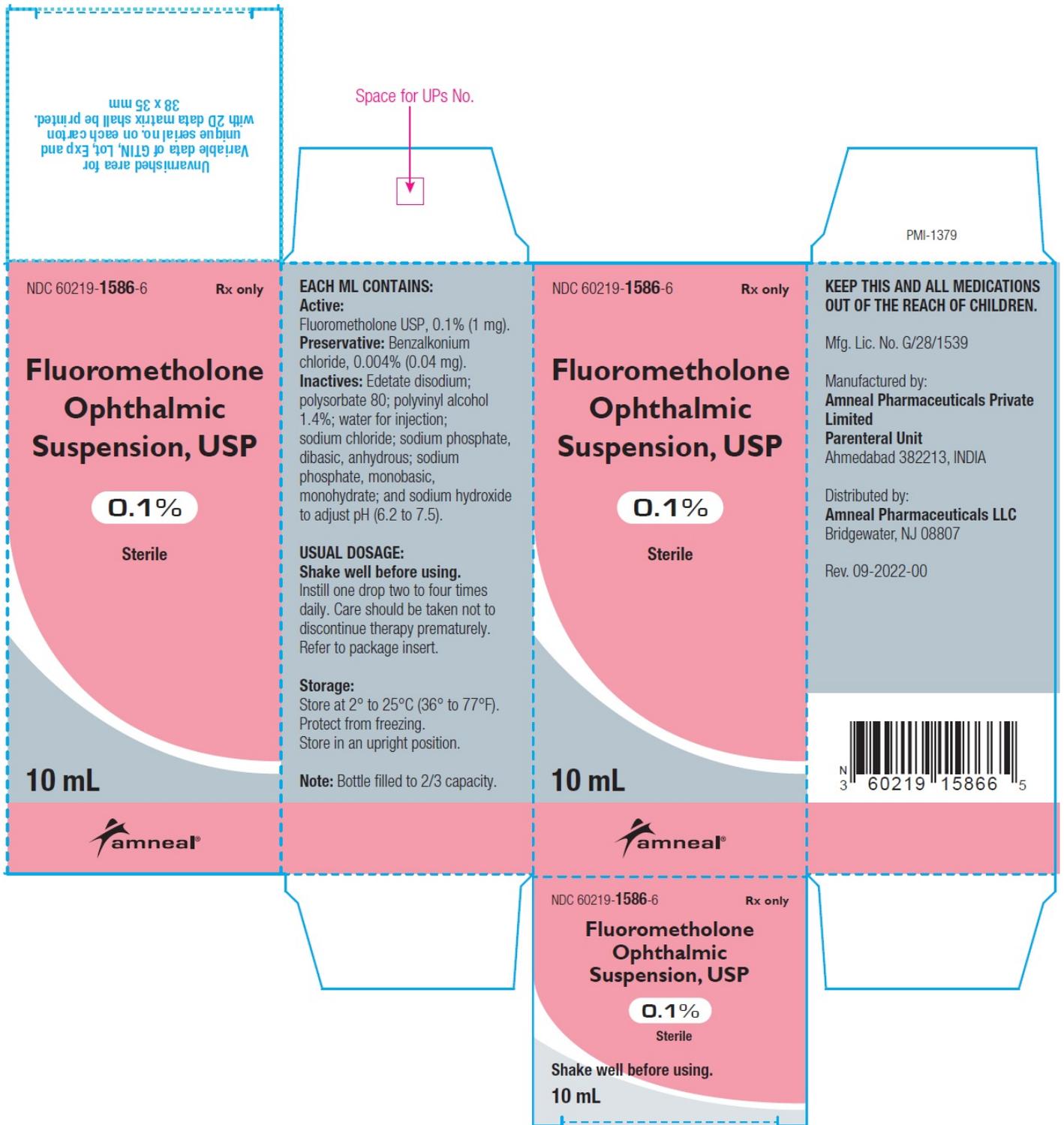
EACH ML CONTAINS: Active:
Fluorometholone USP, 0.1% (1 mg).
Preservative: Benzalkonium chloride,
0.004% (0.04 mg).
**USUAL DOSAGE: Shake well before
using.** Instill one drop two to four times
daily. Care should be taken not to
discontinue therapy prematurely.
Refer to package insert.
Storage: Store at 2° to 25°C (36° to 77°F).
Protect from freezing. Store in an upright
position.
Note: Bottle filled to 2/3 capacity.
Mfg. Lic. No. G/28/1539
Distributed by:
Anneal Pharmaceuticals LLC
Rev. 11-2023-01 Made in INDIA.



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Unvarnished Area for,
Lot. & Exp.
(10 x 28 mm)

NDC 60219-1586-6
Fluorometholone Ophthalmic Suspension USP, 0.1%
Rx only
10 mL Carton Label
Anneal Pharmaceuticals LLC



FLUOROMETHOLONE OPHTHALMIC SUSPENSION

fluorometholone suspension/ drops

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:60219-1585
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety				
Ingredient Name			Basis of Strength	Strength
FLUOROMETHOLONE (UNII: SV0CSG527L) (FLUOROMETHOLONE - UNII:SV0CSG527L)			FLUOROMETHOLONE	1 mg in 1 mL
Inactive Ingredients				
Ingredient Name			Strength	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)				
EDETATE DISODIUM (UNII: 7FLD91C86K)				
POLYSORBATE 80 (UNII: 6OZP39ZG8H)				
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)				
SODIUM CHLORIDE (UNII: 451W47IQ8X)				
SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74)				
SODIUM PHOSPHATE, MONOBASIC (UNII: 3980JIH2SW)				
SODIUM HYDROXIDE (UNII: 55X04QC32I)				
WATER (UNII: 059QF0KO0R)				
Product Characteristics				
Color	white (white to off-white homogenous suspension)		Score	
Shape			Size	
Flavor			Imprint Code	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60219-1585-3	1 in 1 CARTON	01/09/2023	
1		5 mL in 1 BOTTLE, DROPPER; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA216348	01/09/2023		

FLUOROMETHOLONE OPHTHALMIC SUSPENSION

fluorometholone suspension/ drops

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:60219-1586
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
FLUOROMETHOLONE (UNII: SV0CSG527L) (FLUOROMETHOLONE - UNII:SV0CSG527L)	FLUOROMETHOLONE	1 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74)	
SODIUM PHOSPHATE, MONOBASIC (UNII: 3980JIH2SW)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	white (white to off-white homogenous suspension)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60219-1586-6	1 in 1 CARTON	01/09/2023	
1		10 mL in 1 BOTTLE, DROPPER; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA216348	01/09/2023	

Labeler - Amneal Pharmaceuticals NY LLC (123797875)**Registrant** - Amneal Pharmaceuticals of New York, LLC (123797875)

