ALTAFLUOR- fluorescein sodium and benoxinate hydrochloride solution
Altaire Pharmaceuticals Inc.

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use ALTAFLUOR BENOX safely and effectively. See full prescribing information for ALTAFLUOR BENOX.

Altafluor Benox (fluorescein sodium and benoxinate hydrochloride ophthalmic solution) 0.25%/0.4% for topical ophthalmic use
Initial U.S. Approval: 2017

INDICATIONS AND USAGE

Altafluor Benox (fluorescein sodium and benoxinate hydrochloride ophthalmic solution) 0.25%/0.4% is a combination disclosing agent and local ester anesthetic indicated for procedures requiring a disclosing agent in combination with a topical ophthalmic anesthetic. (1)

DOSAGE AND ADMINISTRATION

Instill 1 to 2 drops topically in the eye as needed to achieve adequate anesthesia. (2)

DOSAGE FORMS AND STRENGTHS

Ophthalmic solution containing fluorescein sodium 2.5 mg/mL (0.25%) and benoxinate hydrochloride 4 mg/mL (0.4%). (3)

CONTRAINDICATIONS

Known hypersensitivity to any component of this product. (4)

WARNINGS AND PRECAUTIONS

- Corneal toxicity: Prolonged use or abuse may lead to corneal epithelial toxicity and manifest as epithelial defects which may progress to permanent corneal damage. (5.1)
- Corneal injury: Patients should not touch the eye for approximately 20 minutes after using anesthetic as accidental injuries can occur due to insensitivity of the eye. (5.2)

ADVERSE REACTIONS

The most common ocular adverse events are: stinging, burning and conjunctival redness. (6)

To report SUSPECTED ADVERSE REACTIONS, contact Altaire Pharmaceuticals, Inc., at 1-800-258-2471 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.
See 17 for PATIENT COUNSELING INFORMATION.

Revised: 12/2017

FULL PRESCRIBING INFORMATION: CONTENTS*

* Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

Altafluor Benox (fluorescein sodium and benoxinate hydrochloride ophthalmic solution) 0.25%/0.4% is indicated for ophthalmic procedures requiring a disclosing agent in combination with a topical ophthalmic anesthetic agent.

2 DOSAGE AND ADMINISTRATION

Instill 1 to 2 drops of Altafluor Benox in the eye as needed.

3 DOSAGE FORMS AND STRENGTHS:

Altafluor Benox is a yellow to orange-red ophthalmic solution containing fluorescein sodium 2.5 mg/mL (0.25%) and benoxinate hydrochloride 4 mg/mL (0.4%).

4 CONTRAINDICATIONS:

Altafluor Benox is contraindicated in patients with known hypersensitivity to any component of this product.

5 WARNINGS AND PRECAUTIONS

5.1 Corneal Toxicity

Prolonged use or abuse may lead to corneal epithelial toxicity which may manifest as epithelial defects and progress to permanent corneal opacification with accompanying visual loss.

5.2 Corneal Injury Due to Insensitivity

Patient should not touch the eye for approximately 20 minutes after using this anesthetic as accidental injuries can occur due to insensitivity of the eye.

6 ADVERSE REACTIONS

The following ocular adverse reactions are described elsewhere in the labeling:

- Corneal Toxicity *[see Warnings and Precautions (5.1)]*
- Corneal Injury due to Insensitivity *[see Warnings and Precautions (5.2)]*

The following adverse reactions have been identified following use of fluorescein sodium and benoxinate hydrochloride ophthalmic solution 0.25% / 0.4%: ocular hyperemia, burning, stinging, eye

irritation, blurred vision and punctate keratitis. Because these reactions were reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

There are no available data on the use of Altafluor Benox in pregnant women to inform any drug associated risk. Adequate animal reproduction studies have not been conducted with fluorescein sodium and/or benoxinate hydrochloride. Altafluor Benox should be given to a pregnant woman only if clearly needed.

8.2 Lactation

Risk Summary

There are no data on the presence of fluorescein sodium or benoxinate hydrochloride in human milk after ocular administration of Altafluor Benox, the effects on the breastfed infant, or the effects on milk production.

The developmental and health benefits of breastfeeding should be considered, along with the mother's clinical need for Altafluor Benox and any potential adverse effects on the breastfed infant from Altafluor Benox.

8.4 Pediatric Use

The safety and effectiveness of Altafluor Benox have been established for pediatric patients. Use of Altafluor Benox is supported in pediatric patients by evidence from adequate and well controlled studies.

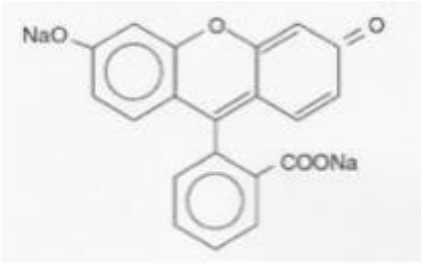
8.5 Geriatric Use

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

11 DESCRIPTION

Altafluor Benox (fluorescein sodium and benoxinate hydrochloride ophthalmic solution) 0.25%/0.4% is a sterile disclosing agent in combination with a short-acting ester anesthetic for topical ophthalmic use.

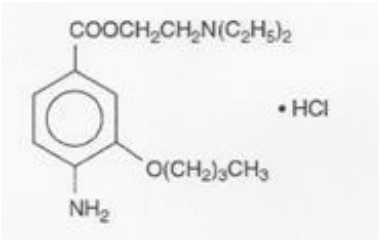
Fluorescein sodium is represented by the following structural formula:



$C_{20}H_{10}Na_2O_5$ Mol. Wt. 376.27

Chemical Name: Spiro [isobenzofuran-1 (3*H*),9'-9[9*H*] xanthene]-3-one, 3',6' dihydroxy, disodium salt.

Benoxinate hydrochloride is represented by the following structural formula:



$C_{17}H_{28}N_2O_3$ • HCl Mol. Wt. 344.88

Chemical Name: 2-(Diethylamino) etyl 4-amino-3-butoxybenzoate monohydrochloride.

Each mL contains: Actives: fluorescein sodium 2.5 mg (0.25%) equivalent to fluorescein 2.2 mg (0.22%), benoxinate hydrochloride 4 mg (0.4%) equivalent to benoxinate 3.6 mg (0.36%); Inactives: povidone, hydrochloric acid, boric acid, sodium hydroxide, water for injection. Hydrochloric acid and/or sodium hydroxide may be added to adjust pH (4.3 – 5.3). Preservative: chlorobutanol 11mg (1.1%).

12. CLINICAL PHARMACOLOGY

This product is the combination of a disclosing agent with a rapidly acting ester anesthetic of short duration.

12.2 Pharmacodynamics

Maximal corneal anesthesia usually occurs in about 5-45 seconds and lasts about 20 minutes after single administration. The anesthetic effect may be extended by subsequent administration 10-20 minutes after the last administration.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term studies to evaluate the carcinogenic potential of Altafluor Benox have not been conducted.

14 CLINICAL STUDIES

Controlled clinical studies in adults and pediatric patients have demonstrated that topical administration of fluorescein sodium and benoxinate hydrochloride ophthalmic solution 0.25%/0.4% enables visualization and corneal anesthesia sufficient to enable applanation tonometry, tear fluid dynamics evaluation and short conjunctival and corneal procedures. Maximal corneal anesthesia usually occurs in about 5-45 seconds and lasts about 20 minutes after single administration.

16 HOW SUPPLIED/STORAGE AND HANDLING

Altafluor Benox (fluorescein sodium and benoxinate hydrochloride ophthalmic solution) 0.25%/0.4% is a sterile, yellow to orange-red solution supplied in a 5 mL glass bottle with a sterilized dropper.

NDC #59390-218-05

Storage: Store in refrigerator at 2° to 8°C (36° to 46°F). After opening, Altafluor Benox can be stored up to one month if stored at room temperature or until the expiration date on the bottle if stored in refrigerated conditions. Keep tightly closed.

17 PATIENT COUNSELING INFORMATION

Accidental Injury Precaution

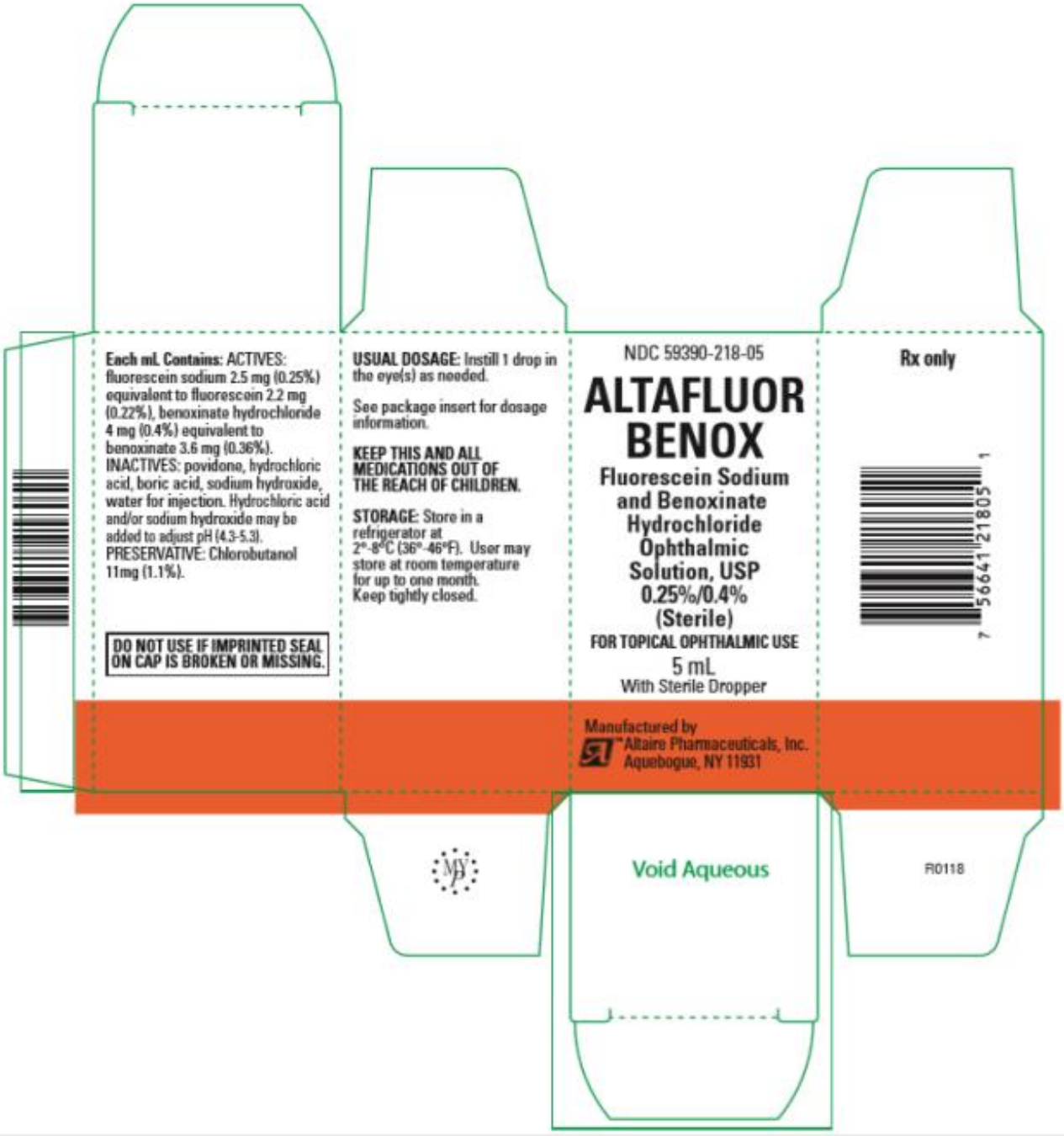
Advise patients not to touch their eyes for approximately 20 minutes after application. Their eyes will be insensitive due to the effect of the anesthetic, and care should be taken to avoid accidental injuries.

Rev. 12/2017

Manufactured by:
ALTAIRE Pharmaceuticals, Inc.
Aquebogue, NY 11931

PRINCIPAL DISPLAY PANEL

NDC 59390-218-05
ALTAFLUOR
BENOX
Fluorescein Sodium and
Benoxinate Hydrochloride
Ophthalmic Solution, USP
0.25%/0.4%
(Sterile)
5 mL
Rx Only



ALTAFLUOR

fluorescein sodium and benoxinate hydrochloride solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:59390-218
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
FLUORESCEIN SODIUM (UNII: 93X55PE38X) (FLUORESCEIN - UNII:TPY09G7XIR)	FLUORESCEIN	2.5 mg in 1 mL

BENOXINATE HYDROCHLORIDE (UNII: 0VE4U49K15) (BENOXINATE - UNII:AXQ0JYM303)	BENOXINATE HYDROCHLORIDE	4 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
CHLOROBUTANOL (UNII: HM4YQM8WRC)	11 mg in 1 mL
POVIDONE (UNII: FZ989GH94E)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
BORIC ACID (UNII: R57ZHV85D4)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59390-218-05	5 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	03/01/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA208582	03/01/2018	

Labeler - Altaire Pharmaceuticals Inc. (786790378)

Revised: 12/2017 Altaire Pharmaceuticals Inc.