

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*

- 1 INDICATIONS AND USAGE
- 2 DOSAGE AND ADMINISTRATION
- 3 DOSAGE FORMS AND STRENGTHS
- 4 CONTRAINDICATIONS
- 5 WARNINGS AND PRECAUTIONS
 - 5.1 Corneal Toxicity
 - 5.2 Corneal Injury due to Insensitivity
- 6 ADVERSE REACTIONS
- 8 USE IN SPECIFIC POPULATIONS
 - 8.1 Pregnancy
 - 8.2 Lactation
 - 8.4 Pediatric Use
 - 8.5 Geriatric Use

- 11 DESCRIPTION
- 12 CLINICAL PHARMACOLOGY
 - 12.2 Pharmacodynamics
- 13 NONCLINICAL TOXICOLOGY
 - 13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility
- 14 CLINICAL STUDIES
- 16 HOW SUPPLIED/STORAGE AND HANDLING
- 17 PATIENT COUNSELING INFORMATION

*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.

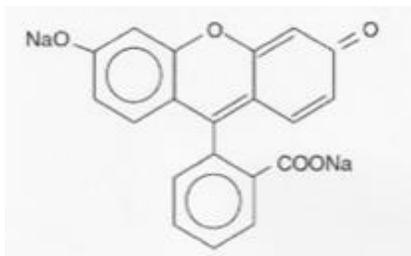
8.5 Geriatric Use

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:

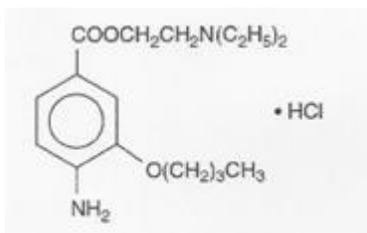


$C_{20}H_{10}Na_2O_5$

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:



$C_{17}H_{28}N_2O_3 \cdot HCl$

Mol. Wt. 344.88

Chemical Name: 2-(Diethylamino) ethyl 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

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.

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

NDA 208582

Page 8

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

5 ml Carton Label



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%).

DO NOT USE IF IMPRINTED SEAL ON CAP IS BROKEN OR MISSING.

USUAL DOSAGE: Instill 1 drop in the eye(s) as needed.

See package insert for dosage information.

KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.

STORAGE: Store in a refrigerator at 2°-8°C (36°-46°F). User may store at room temperature for up to one month. Keep tightly closed.

NDC XXXXX-XXX-XX

**ALTAFLUOR
BENOX**
Fluorescein Sodium
and Benoxinate
Hydrochloride
Ophthalmic
Solution, USP
0.25%/0.4%
(Sterile)

FOR TOPICAL OPHTHALMIC USE

5 mL
With Sterile Dropper

Rx only



Manufactured by
A Altair Pharmaceuticals, Inc.
Aquebogue, NY 11931



Void Aqueous

R1217

LOT:

EXP:

5 mL Container Label

Art de LCU70

<p>EXP: _____</p> <p>LOT: _____</p> <p>No Varnish</p>	<p>Rx Only USUAL DOSAGE: Instill 1 drop in the eye(s) as needed. STORAGE: Store in a refrigerator at 2°-8°C (36°-46°F). User may store at room temperature for up to 1 month. KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.</p>	<p>NDC XXXXX-XXX-XX</p> <p>ALTAFLUOR BENOX Fluorescein Sodium and Benoxinate Hydrochloride Ophthalmic Solution, USP 0.25% / 0.4% (Sterile) FOR TOPICAL OPHTHALMIC USE 5 mL</p> <p>Mfd. By  Altaire Pharmaceuticals, Inc. Aquebogue, N Y 11931</p>	<p>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 11 mg (1.1%). R1217</p> <p>DO NOT USE IF IMPRINTED SEAL ON CAP IS BROKEN OR MISSING.</p>
---	--	---	--

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

RENATA ALBRECHT
12/14/2017