

**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

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

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

Altaflur 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 Altaflur Benox in the eye as needed.

3 DOSAGE FORMS AND STRENGTHS:

Altaflur 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:

Altaflur 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.

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8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

There are no available data on the use of Altaflur 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. Altaflur 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 Altaflur 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 Altaflur Benox and any potential adverse effects on the breastfed infant from Altaflur Benox.

8.4 Pediatric Use

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

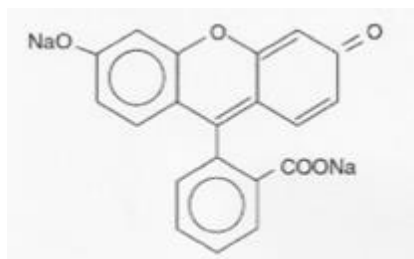
8.5 Geriatric Use

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

11 DESCRIPTION

Altaflur 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:



$C_{20}H_{10}Na_2O_5$

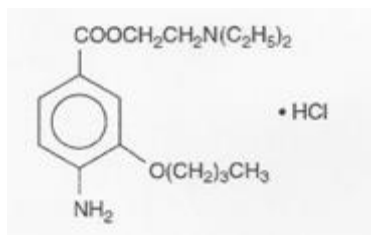
Mol. Wt. 376.27

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

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Benoxinate hydrochloride is represented by the following structural formula:



C₁₇H₂₈N₂O₃ • 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

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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.

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

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5 ml Carton Label



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5 mL Container Label

ATL dL ZDU%0


EXP: _____
LOT: _____
No Varnish

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

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.

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

Mfd. By  **Altaire Pharmaceuticals, Inc.**
Aquebogue, N Y 11931

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/s/

RENATA ALBRECHT
12/14/2017