FLUORESCEIN SODIUM AND BENOXINATE HYDROCHLORIDE- fluorescein sodium and benoxinate hydrochloride solution/ drops
Oceanside Pharmaceuticals

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use FLUORESCEIN SODIUM AND BENOXINATE HYDROCHLORIDE OPHTHALMIC SOLUTION, 0.3%/0.4% safely and effectively. See full prescribing information for FLUORESCEIN SODIUM AND BENOXINATE HYDROCHLORIDE OPHTHALMIC SOLUTION, 0.3%/0.4%.
FLUORESCEIN SODIUM AND BENOXINATE HYDROCHLORIDE OPHTHALMIC SOLUTION, 0.3%/0.4%, for topical ophthalmic use
Initial U.S. Approval: 2017

INDICATIONS AND USAGE

Fluorescein Sodium and Benoxinate Hydrochloride Ophthalmic Solution, 0.3%/0.4% is a combination of fluorescein sodium, a disclosing agent and benoxinate hydrochloride, a local ester anesthetic indicated for procedures in adult and pediatric patients 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 2.6 mg/mL (0.3%) and benoxinate hydrochloride 4.4 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 Oceanside Pharmaceuticals at 1-800-321-4576 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.
See 17 for PATIENT COUNSELING INFORMATION.

Revised: 3/2020

FULL PRESCRIBING INFORMATION: CONTENTS*

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

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

Fluorescein Sodium and Benoxinate Hydrochloride Ophthalmic Solution, 0.3%/0.4% is indicated for ophthalmic procedures in adult and pediatric patients requiring a disclosing agent in combination with a topical ophthalmic anesthetic agent.

2 DOSAGE AND ADMINISTRATION

Instill 1 to 2 drops topically in the eye as needed.

3 DOSAGE FORMS AND STRENGTHS

Fluorescein Sodium and Benoxinate Hydrochloride Ophthalmic Solution, 0.3%/0.4% is a yellow to orange-red ophthalmic solution containing fluorescein sodium 2.6 mg/mL (0.3%) and benoxinate hydrochloride 4.4 mg/mL (0.4%).

4 CONTRAINDICATIONS

Fluorescein Sodium and Benoxinate Hydrochloride Ophthalmic Solution, 0.3%/0.4% 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 and may manifest as epithelial defects which may progress to permanent corneal damage with accompanying visual loss.

5.2 Corneal Injury due to Insensitivity

Patients 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 serious 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, 0.3%/0.4%: ocular hyperemia, burning, stinging, eye irritation, blurred vision and punctate keratitis. Because these reactions are 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 Fluorescein Sodium and Benoxinate Hydrochloride Ophthalmic Solution, 0.3%/0.4% in pregnant women to inform any drug associated risk.

Adequate animal reproduction studies have not been conducted with fluorescein sodium and/or benoxinate hydrochloride. Fluorescein Sodium and Benoxinate Hydrochloride Ophthalmic Solution, 0.3%/0.4% 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 Fluorescein Sodium and Benoxinate Hydrochloride Ophthalmic Solution, 0.3%/0.4%, 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 Fluorescein Sodium and Benoxinate Hydrochloride Ophthalmic Solution, 0.3%/0.4%, and any potential adverse effects on the breastfed infant from Fluorescein Sodium and Benoxinate Hydrochloride Ophthalmic Solution, 0.3%/0.4%.

8.4 Pediatric Use

The safety and effectiveness of Fluorescein Sodium and Benoxinate Hydrochloride Ophthalmic Solution, 0.3%/0.4% have been established for pediatric patients. Use of

Fluorescein Sodium and Benoxinate Hydrochloride Ophthalmic Solution, 0.3%/0.4% is supported in pediatric patients by evidence from adequate and well controlled studies.

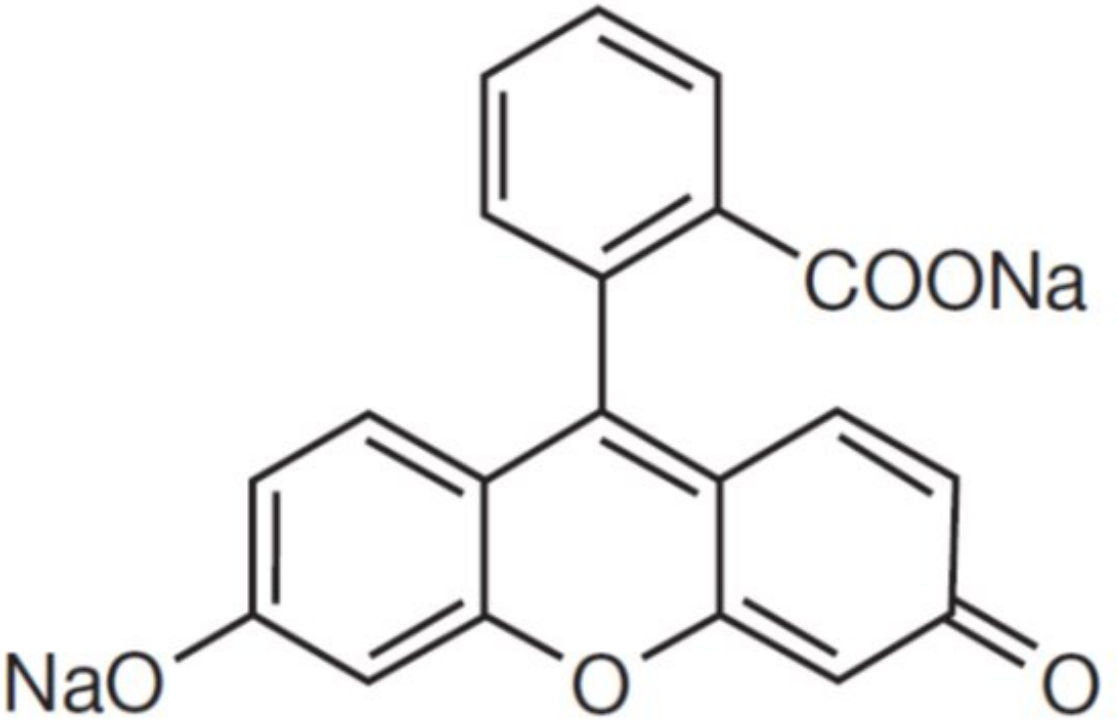
8.5 Geriatric Use

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

11 DESCRIPTION

Fluorescein Sodium and Benoxinate Hydrochloride Ophthalmic Solution, 0.3%/0.4% is a sterile solution containing a disclosing agent in combination with a short-acting ester anesthetic for topical ophthalmic use.

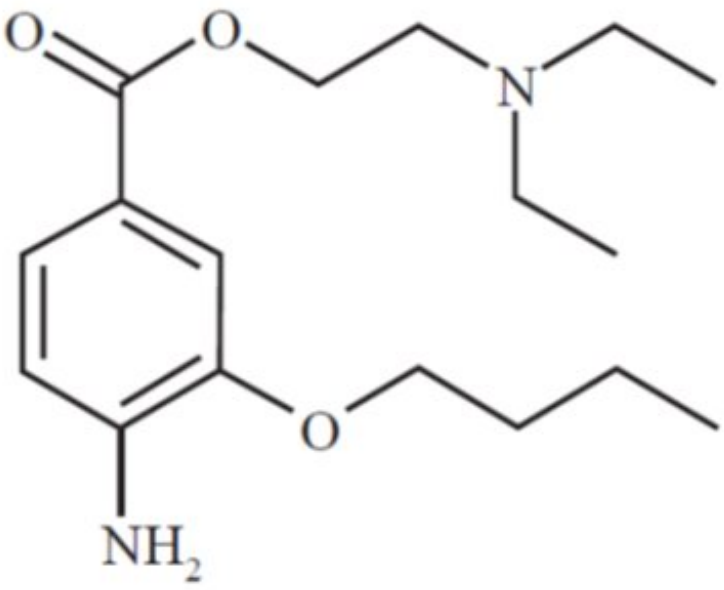
Fluorescein sodium is represented by the following structural formula:



$C_{20}H_{10}Na_2O_5$ Mol. Wt. 376.3

Chemical Name: 3’,6’ Dihydroxy-3H-spiro[isobenzofuran-1,9-xanthen]-3-one disodium salt.

Benoxinate hydrochloride is represented by the following structural formula:



. HCl

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

Chemical Name: 2-(Diethylamino) ethyl 4-amino-3-butoxybenzoate hydrochloride.

Each mL of Fluorescein Sodium and Benoxinate Hydrochloride Ophthalmic Solution 0.3%/0.4% contains:

- Active ingredients: fluorescein sodium 2.6 mg (0.3%) equivalent to fluorescein 2.3 mg (0.2%), benoxinate hydrochloride 4.4 mg (0.4%) equivalent to benoxinate 3.9 mg (0.4%)
- Preservative: chlorobutanol 12.6 mg (1.3%)
- Inactive ingredients: povidone, hydrochloric acid, boric acid, water for injection. Hydrochloric acid may be added to adjust pH (4.3 – 5.3)

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

Studies to evaluate the mutagenic or carcinogenic potential of Fluorescein Sodium and Benoxinate Hydrochloride Ophthalmic Solution, 0.3%/0.4% have not been conducted. Studies to evaluate impairment of fertility 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, 0.3%/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

Fluorescein Sodium and Benoxinate Hydrochloride Ophthalmic Solution, 0.3%/0.4% is supplied as a sterile, aqueous, topical ophthalmic solution with a fill volume of 5 mL in a 6 mL amber glass bottle and a black polypropylene cap with a sterilized rubber dropper bulb and glass pipette.

NDC 68682-732-05

Storage: Store in a refrigerator at 2°C to 8°C (36°F to 46°F). Protect from light. After opening, 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.

Distributed by:
Oceanside Pharmaceuticals, a division of
Bausch Health US, LLC
Bridgewater, NJ 08807 USA

Manufactured by:
Siegfried-Irvine,
9342 Jeronimo Road,
Irvine, CA 92618 USA

9677800

PACKAGE/LABEL PRINCIPAL DISPLAY PANEL

NDC 68682-732-05

Rx Only

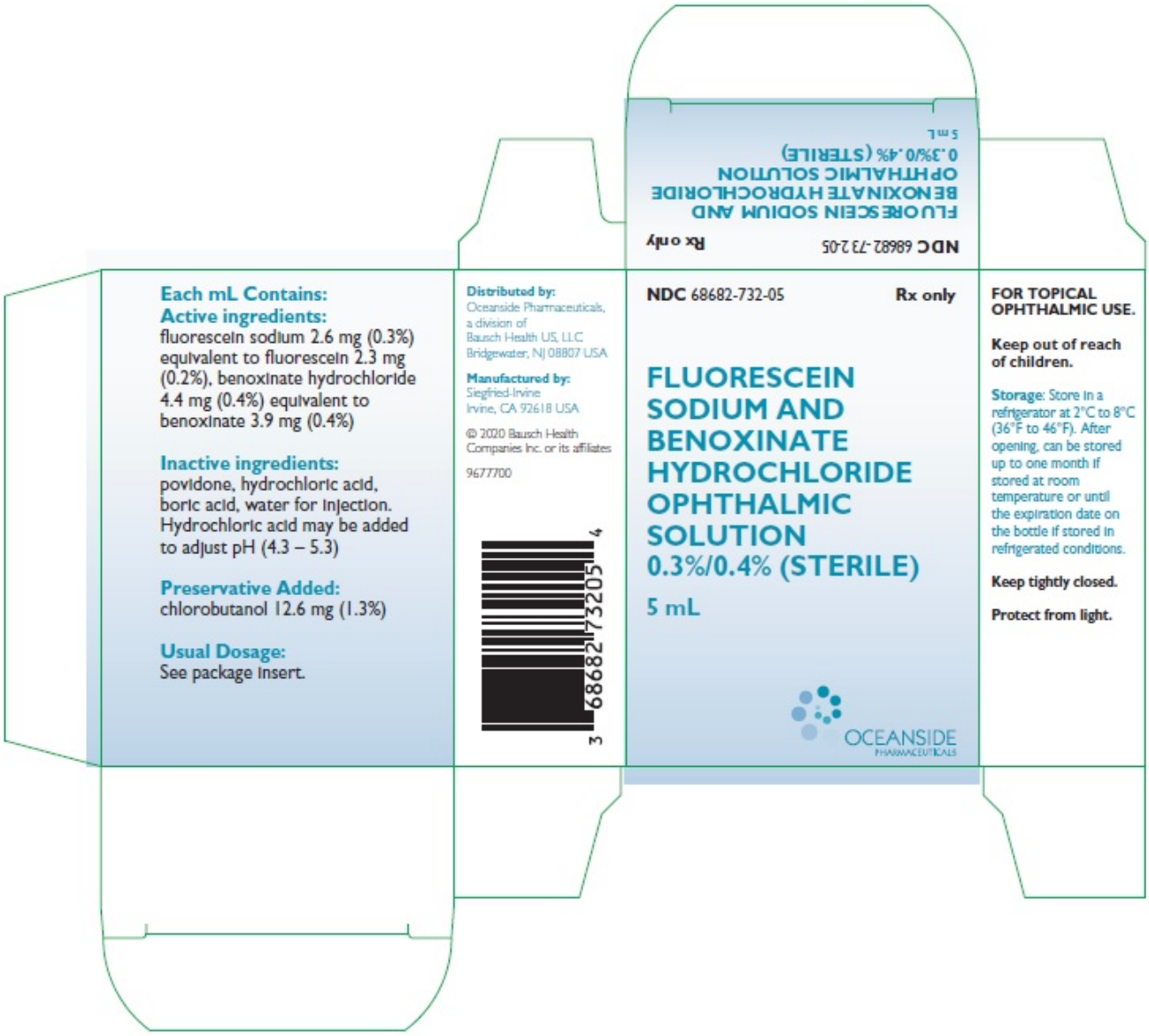
Fluorescein

Sodium and Benoxinate Hydrochloride Ophthalmic Solution, 0.3%/0/4% (STERILE)

5 mL

OCEANSIDE

PHAMACEUTICALS



FLUORESCEIN SODIUM AND BENOXINATE HYDROCHLORIDE

fluorescein sodium and benoxinate hydrochloride solution/ drops

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:68682-732
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
FLUORESCEIN SODIUM (UNII: 93X55PE38X) (FLUORESCEIN - UNII:TPY09G7XIR)	FLUORESCEIN SODIUM	2.6 mg in 1 mL
BENOXINATE HYDROCHLORIDE (UNII: 0VE4U49K15) (BENOXINATE - UNII:AXQ0JYM303)	BENOXINATE HYDROCHLORIDE	4.4 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
BORIC ACID (UNII: R57ZHV85D4)	
WATER (UNII: 059QF0KO0R)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68682-732-05	1 in 1 CARTON	03/25/2021	
1		5 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA authorized generic	NDA211039	03/25/2021	

Labeler - Oceanside Pharmaceuticals (832011691)

Establishment

Name	Address	ID/FEI	Business Operations
Alliance Medical Products, Inc. (dba Siegfried Irvine)		102688657	MANUFACTURE(68682-732) , PACK(68682-732) , LABEL(68682-732)

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