FLUORESCEIN SODIUM AND BENOXINATE HYDROCHLORIDE- fluorescein sodium and benoxinate hydrochloride solution/ drops
Bausch & Lomb Incorporated

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

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Fluorescein Sodium and Benoxinate Hydrochloride Ophthalmic Solution USP, 0.25%/0.4%
(Sterile)
Rx only
FOR USE IN THE EYES ONLY

DESCRIPTION

Fluorescein Sodium and Benoxinate Hydrochloride Ophthalmic Solution USP, 0.25%/0.4% is a disclosing agent with rapid anesthetic action and short duration.

Fluorescein sodium is represented by the following structural formula:

\[
\text{C}_{20}\text{H}_{10}\text{Na}_2\text{O}_5 \\
\text{Mol. Wt. 376.28}
\]

Chemical Name: Spiro (isobenzofuran-1 (3\text{H}),9\text{'}-(9\text{H}) xanthene)-3-one, 3\text{'}6\text{' dihydroxy-, disodium salt.}

Benoxinate hydrochloride is represented by the following structural formula:

\[
\text{C}_{17}\text{H}_{26}\text{N}_2\text{O}_3 \cdot \text{HCl} \\
\text{Mol. Wt. 344.88}
\]
Chemical Name: 2-(Diethylamino) ethyl 4-amino-3-butoxybenzoate monohydrochloride.

Each mL Contains: ACTIVES: Fluorescein Sodium 2.5 mg (0.25%), Benoxinate Hydrochloride 4 mg (0.4%); INACTIVES: Boric Acid, Povidone, Purified Water. Hydrochloric Acid may be added to adjust pH (4.3 – 5.3). PRESERVATIVE ADDED: Chlorobutanol 1%.

CLINICAL PHARMACOLOGY

Fluorescein Sodium and Benoxinate Hydrochloride Ophthalmic Solution USP, 0.25%/0.4% is the combination of a disclosing agent with a rapidly acting anesthetic of short duration.

INDICATIONS AND USAGE

For procedures requiring a disclosing agent in combination with a topical ophthalmic anesthetic agent such as tonometry, gonioscopy, removal of corneal foreign bodies and other short corneal or conjunctival procedures.

CONTRAINDICATIONS

Known hypersensitivity to any component of this product.

WARNINGS NOT FOR INJECTION- FOR TOPICAL OPHTHALMIC USE ONLY.

Prolonged use of a topical ocular anesthetic is not recommended. It may produce permanent corneal opacification with accompanying visual loss.

PRECAUTIONS

Fluorescein Sodium and Benoxinate Hydrochloride Ophthalmic Solution USP, 0.25%/0.4% should be used cautiously and sparingly in patients with known allergies, cardiac disease, or hyperthyroidism. The long-term toxicity is unknown; prolonged use may possibly delay wound healing. Although exceedingly rare with ophthalmic application of local anesthetics, it should be borne in mind that systemic toxicity manifested by central nervous system stimulation followed by depression may occur. Protection of the eye from irritation chemicals, foreign bodies and rubbing during the period of anesthesia is very important. Tonometers soaked in sterilizing or detergent solutions should be thoroughly rinsed with sterile distilled water prior to use. Patients should be advised to avoid touching the eye until the anesthesia has worn off.

Pregnancy

Pregnancy Category C. Animal reproduction studies have not been conducted with Fluorescein Sodium and Benoxinate Hydrochloride Ophthalmic Solution USP, 0.25%/0.4%. It is also not known whether Fluorescein Sodium and Benoxinate Hydrochloride Ophthalmic Solution USP, 0.25%/0.4% can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Fluorescein Sodium and Benoxinate Hydrochloride Ophthalmic Solution USP, 0.25%/0.4% should be given to a pregnant woman only if clearly needed.

Nursing Mothers

Caution should be exercised when Fluorescein Sodium and Benoxinate Hydrochloride Ophthalmic Solution USP, 0.25%/0.4% is administered to a nursing woman.

Pediatric Use

Safety and effectiveness in pediatric patients have not been established.
ADVERSE REACTIONS
Occasional temporary stinging, burning, and conjunctival redness have been reported after use of ocular anesthetics, as well as a rare, severe, immediate-type, apparent hyper-allergic corneal reaction, with acute, intense and diffuse epithelial keratitis, a gray, ground glass appearance, sloughing of large areas of necrotic epithelium, corneal filaments and sometimes, iritis with descemetitis.

Allergic contact dermatitis with drying and fissuring of the fingertips has been reported.

DOSAGE AND ADMINISTRATION
Usual Dosage: Removal of foreign bodies and sutures, and for tonometry, 1 to 2 drops (in single instillations) in each eye before operating.

HOW SUPPLIED
Fluorescein Sodium and Benoxinate Hydrochloride Ophthalmic Solution USP, 0.25%/0.4% is supplied in a glass bottle with a sterilized dropper in the following size:
5 mL – NDC 24208-732-05

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

DO NOT USE IF IMPRINTED BODY SEAL IS NOT INTACT.
KEEP OUT OF REACH OF CHILDREN.

Revised: November 2012

Bausch & Lomb Incorporated
Tampa, FL 33637
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9117602 (Folded)
9117702 (Flat)
Prod. No. 30107

PACKAGE/LABEL PRINCIPAL DISPLAY PANEL
NDC 24208-732-05
BAUSCH + LOMB
Fluorescein Sodium and Benoxinate Hydrochloride Ophthalmic Solution USP, 0.25% / 0.4% (Sterile) (with Sterilized Dropper)
5 mL
Rx only
9115101
AB30107
FLUORESCEIN SODIUM AND BENOXINATE HYDROCHLORIDE
fluorescein sodium and benoxinate hydrochloride solution/ drops

Product Information

Product Type: HUMAN PRESCRIPTION DRUG
Route of Administration: OPHTHALMIC

Item Code (Source): NDC:24208-732

Active Ingredient/Active Moiety

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<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
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<tr>
<td>BENOXINATE HYDROCHLORIDE (UNII: 0VE4U49K15) (BENOXINATE - UNII:AXQ0JYM303)</td>
<td>BENOXINATE HYDROCHLORIDE</td>
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<td>FLUORESCEIN SODIUM (UNII: 93X55PE38X) (FLUORESCEIN - UNII:TPY09G7XIR)</td>
<td>FLUORESCEIN SODIUM</td>
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Inactive Ingredients

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<td>WATER (UNII: 059QF0KO0R)</td>
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<td>HYDROCHLORIC ACID (UNII: QT17582CB)</td>
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<td>CHLOROBUTANOL (UNII: HM4YQM8WRC)</td>
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<td>Povidone, Unspecified (UNII: FZ989GH94E)</td>
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Packaging

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<td>1 in 1 CARTON</td>
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<td>5 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product</td>
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Marketing Information

Marketing Category: Unapproved drug other
Application Number or Monograph Citation: |
Marketing Start Date: 01/01/1995
Marketing End Date: 01/01/1995

Labeler - Bausch & Lomb Incorporated (196603781)

Establishment

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<td>MANUFACTURE(24208-732)</td>
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Revised: 11/2012