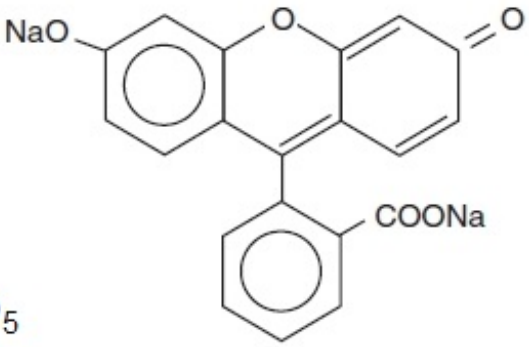
FLUROX - fluorescein sodium 2.5mg (0.25%), benoxinate hydrochloride 4mg (0.4%) solution
OCuSOFT, Inc.

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.

Flurox™

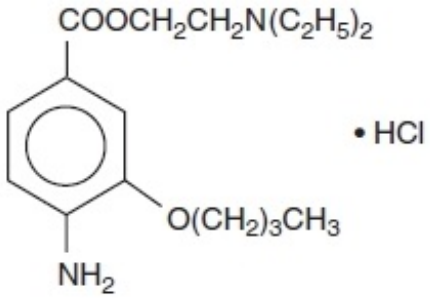
FOR USE IN THE EYES ONLY
DESCRIPTION:

Flourescein Sodium and Benoxinate Hydrochloride Opthalmic Solution USP, 0.25%/0.4% is a disclosing agent with rapid anesthetic action of short duration.
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*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-3butoxybenzoate monohydrochloride.

EACH mL CONTAINS:

ACTIVES: Fluorescein Sodium 2.5mg (0.25%), Benoxinate Hydrochloride 4mg (0.4%)
INACTIVES: Povidone, Boric Acid, Water For Injection. Hydrochloric Acid may be added to adjust pH (4.3 - 5.3).
PRESERVATIVE: Methylparaben 0.1%

CLINICAL PHARMACOLOGY:

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

INDICATIONS & 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:

Prolonged use of a topical ocular anesthetic is not recommended. It may produce permanent corneal opacification with accompanying visual loss. Avoid contamination - do not touch tip of sterile dropper used to dispense solution to any surface. Replace container closure immediately after using.

PRECAUTIONS:

This product should be used cautiously and sparingly in patients with known allergies, cardiac disease, or
hyperthyroidism. The long-term toxicity is unknow; prolonged use may possible delay woundhealing. Although
exceedingly rare with ophthalmic application of local anesthetics, it should be borne in mind that systemic toxicity
manifested by central nervous sytem 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 anesthsia has worn off.

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 someimes, iritis with descemetitis.
Allergic contact dermatitis with drying and fissuring of the fingertips has been reported.
To report SUSPECTED ADVERSE REACTIONS, contact Altaire Pharmaceuticals, Inc. at (631) 722-5988

DOSAGE and ADMINISTRATION:

Usual Dosage: Removal of foreign bodies and sutures, and for tonometry, 1 or 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: 5mL

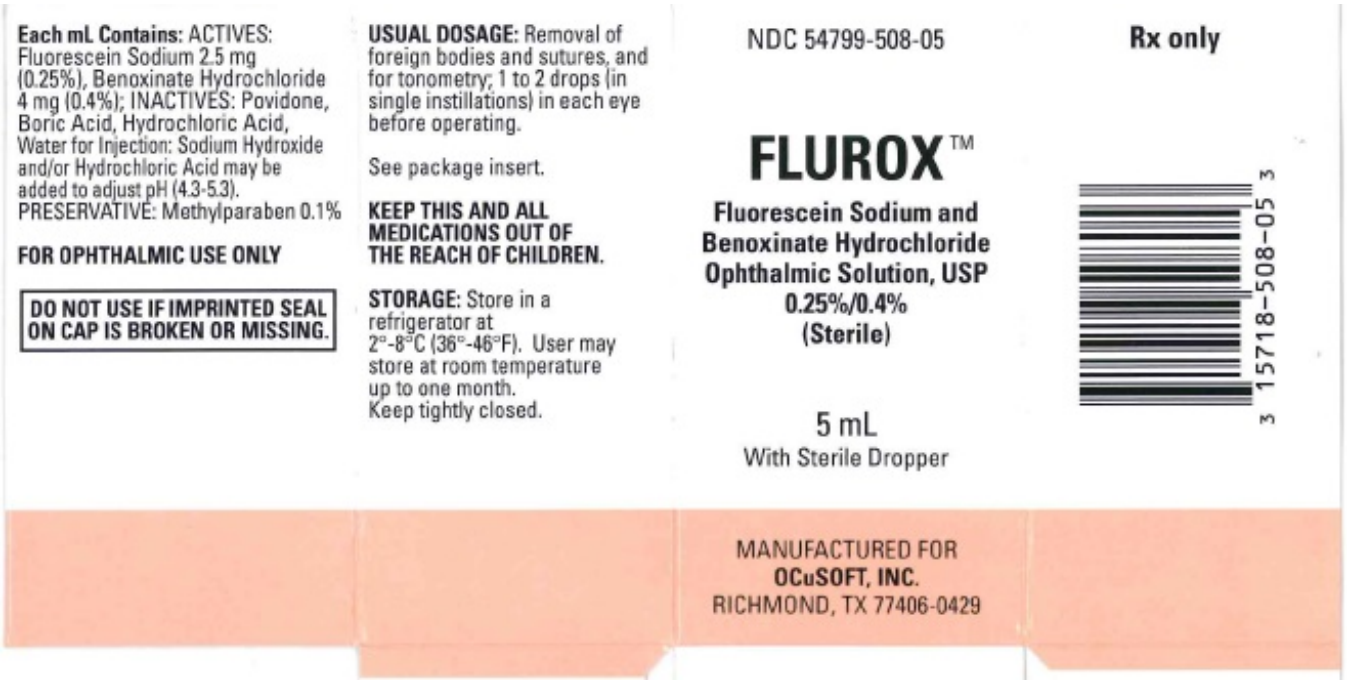
STORAGE AND HANDLING:

Store in a refrigerator at 2°-8°C (36°-46°F). Can be stored at room temperature for up to one month. Keep tightly closed.

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

KEEP OUT F REACH OF CHILDREN

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



FLUROX

fluorescein sodium 2.5mg (0.25%), benoxinate hydrochloride 4mg (0.4%) solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:54799-508
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**
Povidone, Unspecified (UNII: FZ989GH94E)	
Boric Acid (UNII: R57ZHV85D4)	

Hydrochloric Acid (UNII: QTT17582CB)	
Water (UNII: 059QF0KO0R)	
Methylparaben (UNII: A2I8C7HI9T)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54799-508-05	5 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	01/29/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		01/29/2014	

Labeler - OCuSOFT, Inc. (174939207)

Revised: 11/2019 OCuSOFT, Inc.