FLUORESCEIN SODIUM AND PROPARACAINE HYDROCHLORIDE- fluorescein sodium and proparacaine hydrochloride solution/ drops
Altaire Pharmaceuticals 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.

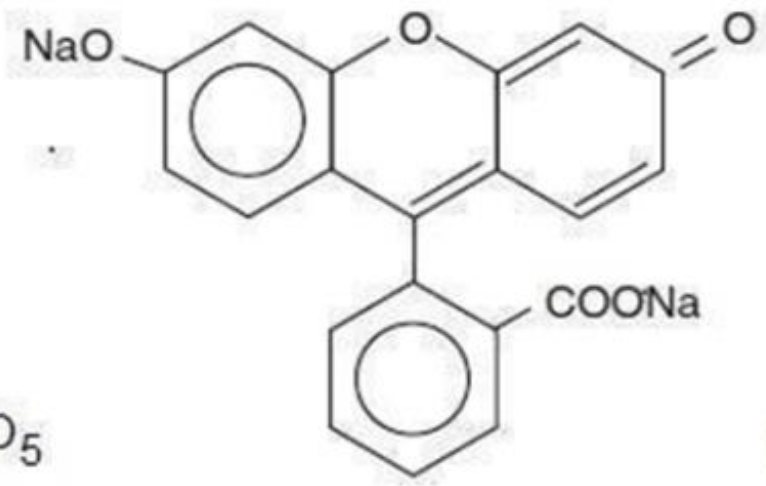
Fluorecein Sodium and Proparacaine Hydrochloride Opthahalmic Solution, USP

Fluorescein Sodium and Proparacaine Hydrochloride Ophthalmic Solution, USP

DESCRIPTION:

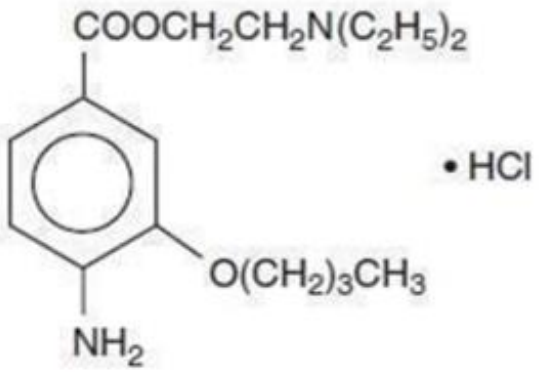
Fluorescein Sodium and Proparacaine Hydrochloride Ophthalmic Solution, USP (Sterile) is a sterile ophthalmic solution combining the disclosing action of Fluorescein with the anesthetic action of Proparacaine Hydrochloride.

The active ingredient, **Fluorescein Sodium**, has the chemical name Spiro [isobenzofuran-1 (3H), 9'-[9H]xanthene]-3-one, 3' ,6' dihydroxy-,disodium salt. It is represented by the following structural formula:



$C_{20}H_{10}Na_2O_5$ Mol. Wt. 376.27

The active ingredient, **Proparacaine Hydrochloride**, has the chemical name Benzoic acid, 3-amino-4-propoxy-, 2-[diethylamino]ethyl ester monohydrochloride. It is represented by the following structural formula:



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

EACH mL CONTAINS: ACTIVES: Fluorescein Sodium, USP, 0.25% [2.5 mg]. Proparacaine Hydrochloride, USP, 0.5% [5mg]; INACTIVES: Povidone, Boric Acid, Water for Injection, Sodium Hydroxide, or/and Hydrochloric Acid may be added to adjust pH. PRESERVATIVE: Methylparaben 0.1%.

CLINICAL PHARMACOLOGY

This product is the combination of a disclosing agent with a rapidly acting anesthetic of short duration.
For procedures requiring a disclosing agent in combination with an 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:

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

PRECAUTIONS:

This product 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 irritating 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.

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 descementitis. 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 to 2 drops (in single instillations) in each eye before operating.
Deep Ophthalmic Anesthesia: 1 drop in each eye every 5 to 10 minutes for 5-7 doses.

NOTE: The use of an eye patch is recommended.

STORAGE:

Store in refrigerator at 2°-8°C (36°-46°F). Can be stored at room temperature for up to 1 month.

HOW SUPPLIED:

Fluorescein Sodium and Proparacaine Hydrochloride Ophthalmic Solution, USP (Sterile) is supplied in a glass or plastic bottle with a controlled tip applicator in the following sizes:
5 mL fill (glass bottle) with dropper

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

KEEP OUT OF REACH OF CHILDREN

FOR OPHTHALMIC USE ONLY

Manufactured By:
Altaire Phamacueticals, Inc.
311 West Lane
Aquebogue, NY 119311

Tel: 631-722-5988

Principal Display Panel

Fluorescein Sodium and
Proparacaine Hydrochloride
Ophthalmic Solutions, USP
(STERILE)

Rx Only

5 mL

FLUORESCEIN SODIUM AND PROPARACAINE HYDROCHLORIDE OPHTHALMIC SOLUTION, USP (STERILE)

Rx Only

DESCRIPTION:

Fluorescein Sodium and Proparacaine Hydrochloride Ophthalmic Solution, USP (Sterile) is a sterile ophthalmic solution combining the disclosing action of Fluorescein with the anesthetic action of Proparacaine Hydrochloride.

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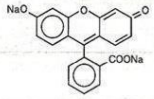
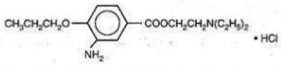


$C_{20}H_{10}Na_2O_5$ Mol. Wt. 376.27

The active ingredient, **Proparacaine Hydrochloride,** has the chemical name Benzoic acid, 3-amino-4-propoxy-, 2-[diethylamino]ethyl ester monohydrochloride. It is represented by the following structural formula:



$C_{16}H_{26}N_2O_3 \bullet HCl$ Mol. Wt. 330.85

EACH mL CONTAINS: ACTIVES: Fluorescein Sodium, USP, 0.25% [2.5 mg], Proparacaine Hydrochloride, USP, 0.5% [5 mg]; INACTIVES: Povidone, Boric Acid, Water for Injection, Sodium Hydroxide and/or Hydrochloric Acid may be added to adjust pH.

PRESERVATIVE: Methylparaben 0.1%.

CLINICAL PHARMACOLOGY

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PRECAUTIONS:

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ADVERSE REACTIONS:

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Deep Ophthalmic Anesthesia: 1 drop in each eye every 5 to 10 minutes for 5-7 doses.

NOTE: The use of an eye patch is recommended.

STORAGE:

Store in a refrigerator at 2°-8°C (36°-46°F). Can be stored at room temperature for up to 1 month.

HOW SUPPLIED:

Fluorescein Sodium and Proparacaine Hydrochloride Ophthalmic Solution, USP (Sterile) is supplied in a glass or plastic bottle with a controlled tip applicator in the following sizes:

5 mL fill (glass bottle) / 5 mL fill (10 mL plastic bottle)

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

KEEP OUT OF REACH OF CHILDREN
FOR OPHTHALMIC USE ONLY

Rev. 04/10
MG #15856

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

Each mL Contains: ACTIVES: Proparacaine Hydrochloride, USP, 0.5% (5 mg), Fluorescein Sodium, USP, 0.25% (2.5 mg); INACTIVES: Povidone, Boric Acid, Water for Injection. Sodium Hydroxide and/or Hydrochloric Acid may be added to adjust pH. PRESERVATIVE: Methylparaben 0.1%.

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

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

See package insert.

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

STORAGE: Store in a refrigerator at 2°-8°C (36°-46°F). Can be stored at room temperature for up to 1 month.

FOR OPHTHALMIC USE ONLY.

NDC 59390-205-05

Fluorescein Sodium and Proparacaine Hydrochloride Ophthalmic Solution, USP (Sterile)

5 mL

With Sterile Dropper

Rx only

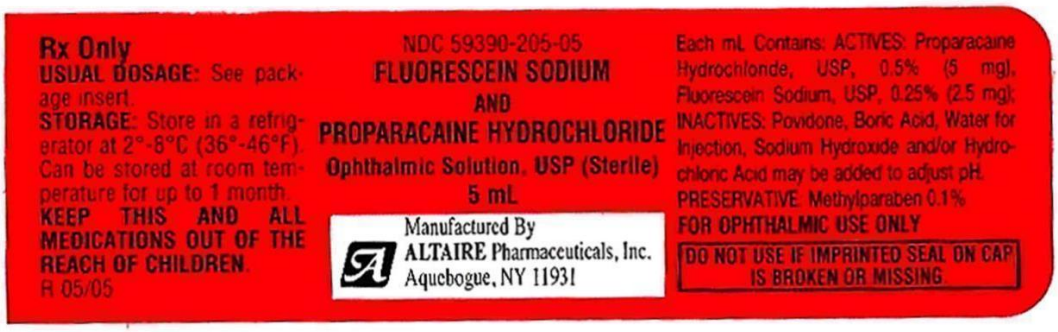
7 56641-205-05 1

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

MY

8 8

R 05/05



FLUORESCEIN SODIUM AND PROPARACAINE HYDROCHLORIDE

fluorescein sodium and proparacaine hydrochloride solution/ drops

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:59390-205
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
FLUORESCEIN SODIUM (UNII: 93X55PE38X) (FLUORESCEIN - UNII:TPY09G7XIR)	FLUORESCEIN SODIUM	2.5 mg in 1 mL
PROPARACAINE HYDROCHLORIDE (UNII: U96OL57GOY) (PROPARACAINE - UNII:B4OB0JHI1X)	PROPARACAINE HYDROCHLORIDE	5 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
POVIDONE (UNII: FZ989GH94E)	
BORIC ACID (UNII: R57ZHV85D4)	
WATER (UNII: 059QF0KO0R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
METHYLPARABEN (UNII: A2I8C7HI9T)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:59390-205-05	1 in 1 CARTON	06/14/2000	
1		5 mL in 1 BOTTLE, DROPPER; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		06/14/2000	

Labeler - Altaire Pharmaceuticals Inc. (786790378)

Establishment

Name	Address	ID/FEI	Business Operations
Altaire Pharmaceuticals Inc.		786790378	manufacture(59390-205)

Establishment

Name	Address	ID/FEI	Business Operations
Siegfried AG		482824026	api manufacture(59390-205)

Revised: 10/2022 Altaire Pharmaceuticals Inc.