FLURESS- fluorescein sodium and benoxinate hydrochloride solution/ drops
Akorn, 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.

FLURESS®

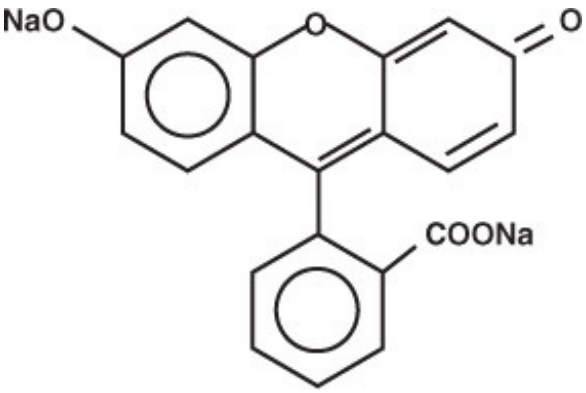
Fluorescein Sodium and Benoxinate Hydrochloride Ophthalmic Solution, USP
(0.25%/0.4%)

Rx only Sterile

DESCRIPTION:

Fluress® (Fluorescein Sodium and Benoxinate Hydrochloride Ophthalmic Solution, USP) is a sterile ophthalmic solution combining a disclosing agent with an anesthetic agent.

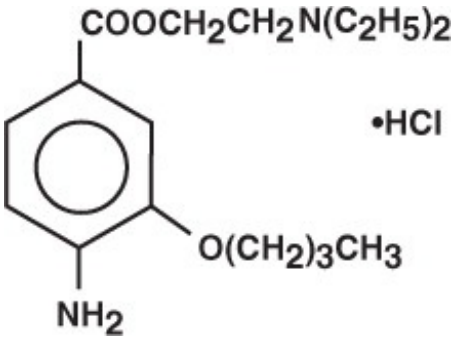
Fluorescein sodium is a disclosing agent with molecular formula $C_{20}H_{10}Na_2O_5$, molecular weight 376.28, and chemical structure:



Chemical Name:

Spiro[isobenzofuran-1 (3*H*), 9'-[9*H*]xanthene]-3-one. 3'6'-dihydroxy, Disodium salt

Benoxinate Hydrochloride is an anesthetic agent with molecular formula C17H28N2O3•HCl, molecular weight 344.88, and chemical structure:



Chemical Name:

Benzoic acid, 4-amino-3-butoxyl-,2-(diethylamino) ethyl ester, monohydrochloride

Each mL contains:

Actives: Benoxinate Hydrochloride 4 mg (0.4%). Fluorescein Sodium 2.5 mg (0.25%).

Preservative: Chlorobutanol 10 mg (1%).

Inactives: Boric Acid, Povidone, Sodium Hydroxide and/or Hydrochloric Acid may be added to adjust pH (4.3 to 5.3), and Purified Water USP.

CLINICAL PHARMACOLOGY:

Fluress® is the combination of a disclosing agent with a rapidly acting anesthetic agent of short duration.

INDICATIONS AND USAGE:

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:

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.

KEEP OUT OF REACH OF CHILDREN.

PRECAUTIONS:

Fluress® (Fluorescein Sodium and Benoxinate Hydrochloride Ophthalmic Solution, USP) 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, 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.

Pregnancy:

Pregnancy Category C. Animal reproduction studies have not been conducted with Fluress®. It is also not known whether Fluress® can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Fluress® should be given to a pregnant woman only if clearly needed.

Nursing Mothers:

Caution should be exercised when Fluress® is administered to a nursing woman.

Pediatric Use:

The safety and effectiveness of this product in pediatric patients has 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, apparently hyperallergic corneal reaction with acute, intense and diffuse epithelial keratitis, a gray, ground glass appearance, sloughing or 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:

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

Deep ophthalmic anesthesia: 2 drops in each eye at 90 second intervals for 3 instillations.

NOTE: The use of an eye patch is recommended.

HOW SUPPLIED:

Fluress® is supplied as 5 mL contained in a 10 mL plastic dropper bottle with a separate sterile dropper applicator. (NDC 17478-640-10)

STORAGE:

Refrigerate at 2° to 8°C (36° to 46°F). User may store at room temperature for up to one month. Store in carton until empty to protect from light. Keep tightly closed.

U.S. PATENT NO. 3306820

CANADIAN PATENT NO. 835940

Akorn

Manufactured by: Akorn, Inc.
Lake Forest, IL 60045

FS00N Rev 05/08

Principal Display Panel Text for Container Label:

NDC 17478-640-10 Akorn Logo

5 mL

FLURESS®

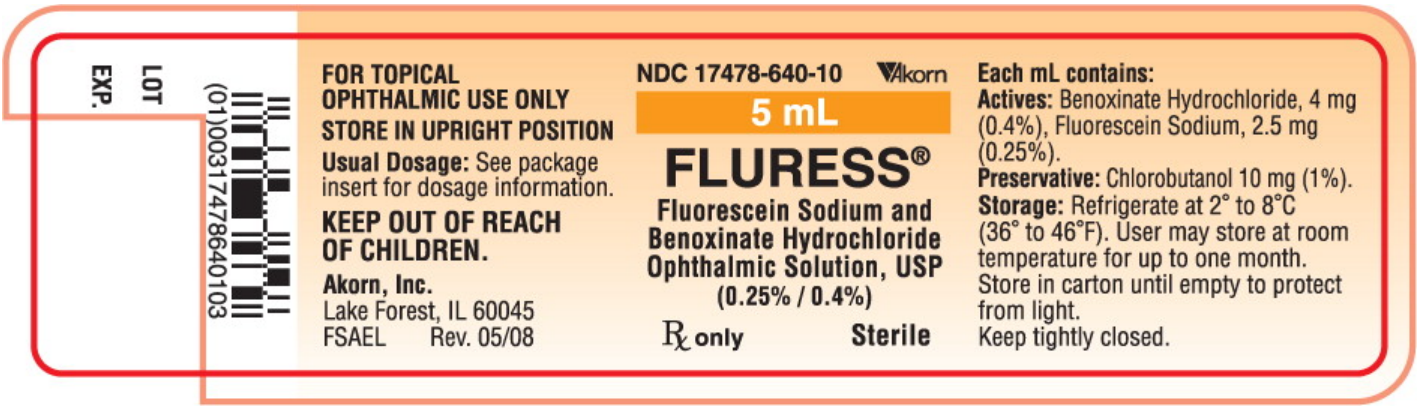
Fluorescein Sodium and

Benoxinate Hydrochloride

Ophthalmic Solution, USP

(0.25% / 0.4%)

Rx only Sterile



Principal Display Panel Text for Carton Label:

NDC 17478-640-10

With Sterile Dropper

FLURESS®

Fluorescein Sodium

and Benoxinate

Hydrochloride

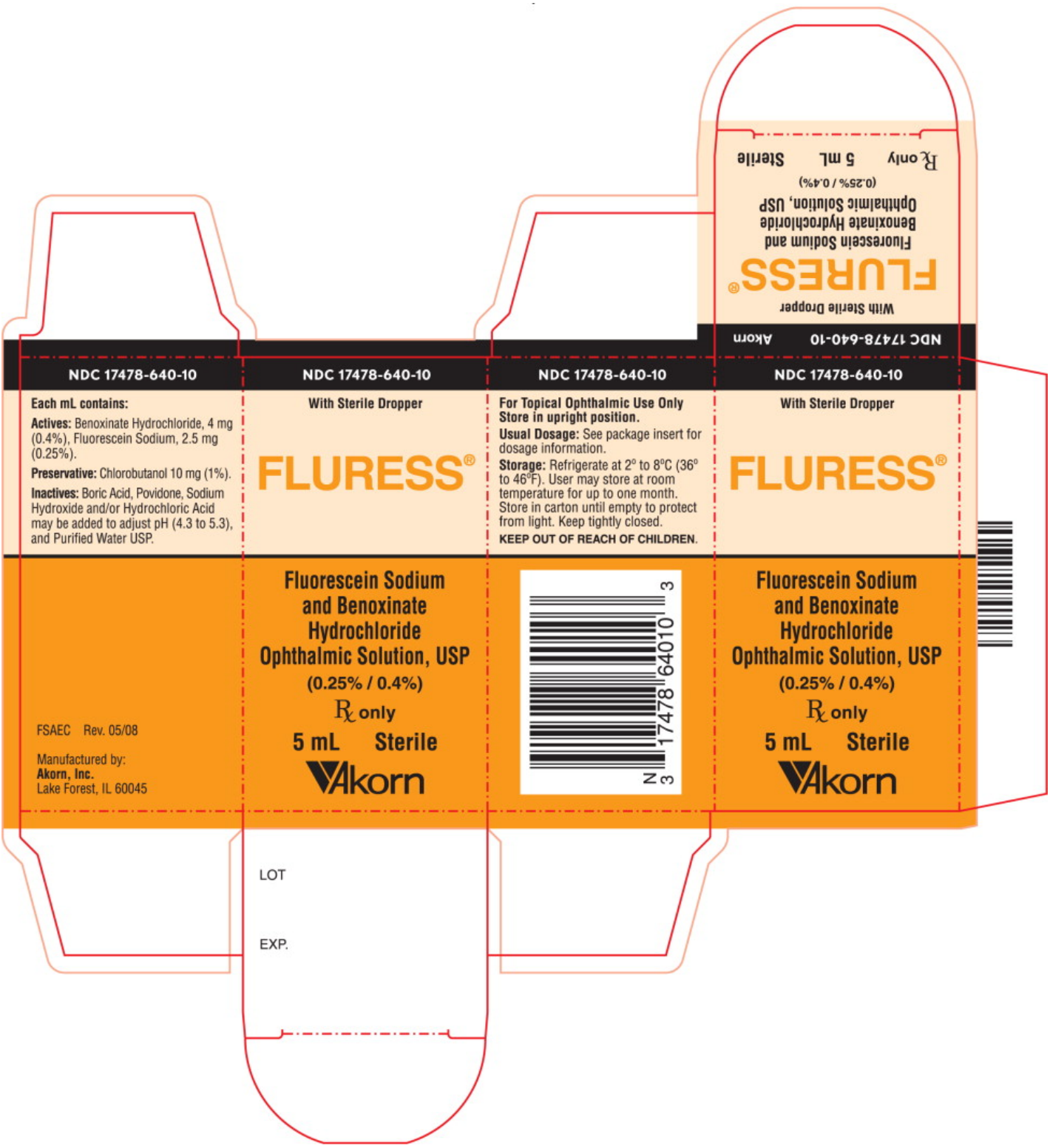
Ophthalmic Solution, USP

(0.25% / 0.4%)

Rx only

5 mL Sterile

Akorn Logo



FLURESS

fluorescein sodium and benoxinate hydrochloride solution/ drops

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:17478-640
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
Benoxinate Hydrochloride (UNII: 0VE4U49K15) (Benoxinate - UNII:AXQ0JYM303)	Benoxinate Hydrochloride	4 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
Boric Acid (UNII: R57ZHV85D4)	
Povidone (UNII: FZ989GH94E)	
Sodium Hydroxide (UNII: 55X04QC32I)	
Hydrochloric Acid (UNII: QTT17582CB)	
WATER (UNII: 059QF0KO0R)	
Chlorobutanol (UNII: HM4YQM8WRC)	10 mg in 1 mL

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:17478-640-10	1 in 1 CARTON	02/01/1995	
1		5 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		02/01/1995	

Labeler - Akorn, Inc. (062649876)

Establishment

Name	Address	ID/FEI	Business Operations
Akorn, Inc.		155135783	MANUFACTURE(17478-640) , REPACK(17478-640) , ANALYSIS(17478-640) , LABEL(17478-640) , PACK(17478-640) , RELABEL(17478-640) , STERILIZE(17478-640)

Revised: 1/2012 Akorn, Inc.