

Now Available from Akorn

FLURESS[®]

**Fluorescein Sodium 0.25% and Benoxinate Hydrochloride 0.4%
Ophthalmic Solution, USP Sterile**

- Sterile Ophthalmic solution combining the benefits of a disclosing agent with an anesthetic
- Same trusted brand, innovative and unique new packaging
- Improved plastic closure containment system to prevent leakage and eliminate breakage
- Separate, sterile dropper for ease in administration
- Cost effective and convenient for Ophthalmic diagnostic procedures
- Available direct from Akorn, through your authorized distributor or wholesaler



NDC	DESCRIPTION	SIZE	UNIT OF SALE	AMERISOURCE*	BERGENBRUNSWIG*	CARDINAL*	MCKESSON*	MORRIS DICKSON*
17478-640-10	Fluorescein Sodium 0.25% and Benoxinate Hydrochloride 0.4% Ophthalmic Solution, USP Sterile	5mL	Each	4666228	367607	3495371	1161058	479402

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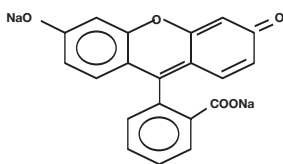
FLURESS® Fluorescein Sodium and Benoxinate Hydrochloride Ophthalmic Solution USP Sterile

FS00N Rev 5/04

DESCRIPTION:

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

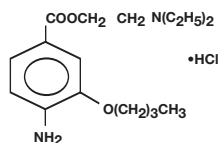
Fluorescein sodium is a disclosing agent with molecular formula $C_{20}H_{10}Na_2O_5$, molecular weight 376.28, and chemical structure:



Chemical Name:

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

Benoxinate Hydrochloride is an anesthetic agent with molecular formula $C_{17}H_{28}N_2O_3 \cdot HCl$, molecular weight 344.88, and chemical structure:



Chemical Name:

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

Each mL contains:

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

Preservative: Chlorobutanol 10 mg (1%).

Inactive: Povidone, Boric Acid, Sodium Hydroxide and/or Hydrochloric Acid (to adjust pH), 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.

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 bottle with a separate sterile dropper applicator. (NDC 17478-640-10)

Storage:

Refrigerate at 2°-8°C (36°-46°F). User may store at room temperature for up to one month. Protect from light. Keep tightly closed.

U.S. PATENT NO. 3306820

CANADIAN PATENT NO. 835940

Rx only

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