HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use FLUORESCITE safely and effectively. See full prescribing information for FLUORESCITE.

FLUORESCITE® (fluorescein injection, USP) 10%, for intravenous use
Initial U.S. Approval: 1976

----------INDICATIONS AND USAGE----------
FLUORESCITE® Injection 10% is a diagnostic dye indicated in diagnostic fluorescein angiography or angioscopy of the retina and iris vasculature. (1)

----------DOSAGE AND ADMINISTRATION----------
- Adult Dose: The normal adult dose of FLUORESCITE® Injection 10% (100 mg/mL) is 500 mg via intravenous (IV) administration. (2.1)
- Pediatric Dose: For children, the dose should be calculated on the basis of 7.7 mg for each kg of actual body weight (or 35 mg for each 10 pounds of body weight) up to a maximum of 500 mg via IV administration. (2.1)
- Do not mix or dilute with other solutions or drugs. (2.2)

----------DOSAGE FORMS AND STRENGTHS----------
Injection: 500 mg/5 mL (100 mg/mL) in a single-dose vial. (3)

----------CONTRAINDICATIONS----------
FLUORESCITE® Injection 10% is contraindicated in patients with known hypersensitivity to fluorescein or any other ingredients in this product. (4.1)

----------WARNINGS AND PRECAUTIONS----------
- Respiratory reactions may require intervention. (5.1)
- Severe local tissue damage can occur with extravasation during injection. (5.2)
- Nausea and/or vomiting may occur within minutes following injection. (5.3)

----------ADVERSE REACTIONS----------
The most common adverse reactions include skin discoloration, urine discoloration, nausea, vomiting, and gastrointestinal distress. (6)

To report SUSPECTED ADVERSE REACTIONS, contact Alcon Laboratories, Inc. at 1-800-757-9195 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

----------USE IN SPECIFIC POPULATIONS----------
Caution should be exercised when fluorescein is administered to a nursing woman. (8.2)

See 17 for PATIENT COUNSELING INFORMATION.

Revised: 11/2021

FULL PRESCRIBING INFORMATION: CONTENTS*

*Sections or subsections omitted from the full prescribing information are not listed

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

FLUORESCITE® Injection 10% is indicated in diagnostic fluorescein angiography or angioscopy of the retina and iris vasculature.

2 DOSAGE AND ADMINISTRATION

2.1 Dosing

Adult Dose
The normal adult dose of FLUORESCITE® Injection 10% (100 mg/mL) is 500 mg via intravenous (IV) administration.

Pediatric Dose
For children, the dose should be calculated on the basis of 7.7 mg for each kg of actual body weight (or 35 mg for each 10 pounds of body weight) up to a maximum of 500 mg via IV administration.

2.2 Preparation for Administration

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration. Do not mix or dilute with other solutions or drugs. Flush IV cannulas before and after drugs are injected to avoid physical incompatibility reactions.

2.3 Administration

Inject the dose rapidly (1 mL per second is normally recommended) intravenously into the antecubital vein, after taking precautions to avoid extravasation. A syringe, filled with FLUORESCITE, may be attached to transparent tubing and a 23 gauge butterfly needle for injection. Insert the needle and draw the patient's blood to the hub of the syringe so that a small air bubble separates the patient's blood in the tubing from the fluorescein. With the room lights on, slowly inject the blood back into the vein while watching the skin over the needle tip. If the needle has extravasated, the patient's blood will be seen to bulge the skin and the injection should be stopped before any fluorescein is injected. When assured that extravasation has not occurred, the room light may be turned off and the fluorescein injection completed. Luminescence usually appears in the retina and choroidal vessels in 7 to 14 seconds and can be observed by standard viewing equipment.

Reduction in dose from 5 mL to 2 mL of FLUORESCITE Injection 10% may be appropriate in cases when a highly sensitive imaging system e.g., scanning laser ophthalmoscope is used.

3 DOSAGE FORMS AND STRENGTHS

Injection: 500 mg/5 mL (100 mg/mL) in a single-dose vial.

4 CONTRAINDICATIONS

4.1 Hypersensitivity

FLUORESCITE® Injection 10% is contraindicated in patients with known hypersensitivity to fluorescein or any other ingredients in this product. Rare cases of death due to anaphylaxis have been reported *[see Warnings and Precautions (5.1), Adverse Reactions (6.3, 6.4)]*.

Fluorescein can induce serious intolerance reactions. These reactions of intolerance are unpredictable but they are more frequent in patients who have previously experienced an adverse reaction after fluorescein injection (symptoms other than nausea and vomiting) or in patients with history of allergy such as food or drug induced urticaria, asthma, eczema, allergic rhinitis.

Detailed questioning of each patient is recommended before the angiography to evaluate any prior history of allergy.

5 WARNINGS AND PRECAUTIONS

5.1 Respiratory Reactions

Monitor closely when used in patients with a history of allergy or bronchial asthma. An emergency tray should be available in the event of possible reaction to FLUORESCITE® Injection 10%.

If a potential allergy is suspected, an intradermal skin test may be performed prior to IV administration, (i.e., 0.05 mL injected intra-dermally to be evaluated 30 to 60 minutes following injection). Given the sensitivity and specificity of skin testing, a negative skin test is not proof that a patient is not allergic to fluorescein.

5.2 Severe Local Tissue Damage

Avoid extravasation during injection as the high pH of fluorescein solution can result in severe local tissue damage. The following complications resulting from extravasation of fluorescein have been reported: severe pain in the arm for several hours, sloughing of the skin, superficial phlebitis, subcutaneous granuloma, and toxic neuritis along the median curve in the antecubital area. When significant extravasation occurs, the injection should be discontinued and conservative measures to treat damaged tissue and to relieve pain should be implemented *[see Dosage and Administration (2.3), Adverse Reactions (6.6)]*.

5.3 Nausea and/or Vomiting

Nausea and/or vomiting and gastrointestinal distress occur commonly within the first few minutes following injection. These reactions usually subside within 10 minutes.

6 ADVERSE REACTIONS

6.1 Skin and Urine Discoloration

The most common reaction is temporary yellowish discoloration of the skin and urine. Urine may attain a bright yellow color. Discoloration of the skin usually fades in 6 to 12 hours and usually fades in urine in 24 to 36 hours.

6.2 Gastrointestinal Reactions

Nausea, vomiting, and gastrointestinal distress are common adverse events. A strong taste may develop after injection.

6.3 Hypersensitivity Reactions

Symptoms and signs of hypersensitivity have occurred. Generalized hives and itching, bronchospasm and anaphylaxis have been reported. Rare cases of death have been reported *[see Contraindications (4.1), Warnings and Precautions (5.1)]*.

6.4 Cardiopulmonary Reactions

Cardiac arrest, basilar artery ischemia, severe shock and death may occur rarely.

6.5 Neurologic Reactions

Headache may occur. Convulsions and syncope may rarely occur following injection.

6.6 Thrombophlebitis

Thrombophlebitis at the injection site has been reported. Extravasation of the solution at the injection site causes intense pain at the site and a dull aching pain in the injected arm *[see Dosage and Administration (2.3), Warnings and Precautions (5.2)]*.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

There is insufficient data with the use of fluorescein in pregnant women to inform a drug-associated risk.

Adequate animal reproduction studies have not been conducted with fluorescein. Fluorescein should only be given to a pregnant woman if clearly needed.

The background risk of major birth defects and miscarriage for the indicated population is unknown; however, in the U.S. general population, the estimated background risk of major birth defects is 2%-4% and of miscarriage is 15%-20% of clinically recognized pregnancies.

Data

Animal Data

Intravenous administration of a single dose of fluorescein to pregnant rats resulted in rapid distribution into the amniotic fluid and fetus.

8.2 Lactation

Risk Summary

Fluorescein injection has been demonstrated to be transferred into human milk for up to 4 days following IV administration.

8.4 Pediatric Use

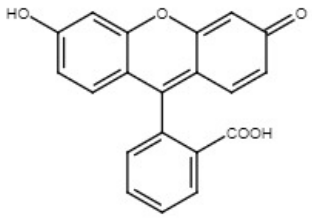
Pediatric patients have been included in clinical studies. No overall differences in safety or effectiveness have been observed between pediatric and adult patients.

8.5 Geriatric Use

No overall differences in safety or effectiveness have been observed between elderly and other adult patients.

11 DESCRIPTION

FLUORESCITE® (fluorescein injection, USP) 10% contains 10% w/v fluorescein. It is a sterile solution for use intravenously as a diagnostic aid. Its chemical name is 3',6'-dihydroxyspiro[isobenzofuran-1(3H),9'-[9H]xanthene]-3-one. The molecular weight is 332.31 g/mol. The active ingredient is represented by the chemical structure:



FLUORESCITE (fluorescein injection, USP) 10% is supplied as a sterile, unpreserved, unit dose aqueous solution, that has a pH of 8.0-9.8 and an osmolality of 572-858 mOsm/kg.

Active ingredient: fluorescein

Inactive Ingredients: Sodium hydroxide and/or hydrochloric acid (to adjust pH), and water for injection.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Fluorescein responds to electromagnetic radiation and light between the wavelengths of 465-490 nm and fluoresces, i.e., emits light at wavelengths of 520-530 nm. Thus, the hydrocarbon is excited by blue light and emits light that appears yellowish-green. Following IV injection of fluorescein in an aqueous solution, the unbound fraction of the fluorescein can be excited with a blue light flash from a fundus camera as it circulates through the ocular vasculature, and the yellowish green fluorescence of the dye is captured by the camera. In the fundus, the fluorescence of the dye demarcates the retinal and/or choroidal vasculature under observation, distinguishing it from adjacent areas/structures.

12.3 Pharmacokinetics

Distribution

Within 7 to 14 seconds after IV administration into antecubital vein, fluorescein usually appears in the central artery of the eye. Within a few minutes of IV administration of fluorescein, a yellowish discoloration of the skin occurs, which begins to fade after 6 to 12 hours of dosing. Various estimates of volume of distribution indicate that fluorescein distributes well into interstitial space (0.5 L/kg).

Elimination

Metabolism

Fluorescein undergoes rapid metabolism to fluorescein monoglucuronide. After IV administration of fluorescein (14 mg/kg) to 7 healthy subjects, approximately 80% of fluorescein in plasma was converted to glucuronide conjugate after a period of 1 hour post dose, indicating relatively rapid conjugation.

Excretion

Fluorescein and its metabolites are mainly eliminated via renal excretion. After IV administration, the urine remains slightly fluorescent for 24 to 36 hours. A renal clearance of 1.75 mL/min/kg and a hepatic clearance (due to conjugation) of 1.50 mL/min/kg have been estimated. The systemic clearance of fluorescein was essentially complete by 48 to 72 hours after administration of 500 mg fluorescein.

16 HOW SUPPLIED/STORAGE AND HANDLING

How Supplied

FLUORESCITE® (fluorescein injection, USP) 10% is supplied in a single-dose 5 mL glass vial with a gray FluroTec coated chlorobutyl stopper and purple flip-off aluminum seal.

The vial stopper is not made with natural rubber latex. The vial contains a sterile, red-orange solution of fluorescein.

NDC 0065-0092-65

Storage and Handling

Store at 2°C to 25°C (36°F to 77°F).

Do Not Freeze.

17 PATIENT COUNSELING INFORMATION

Skin and Urine Discoloration

After administration of fluorescein, skin will attain a temporary yellowish discoloration. Urine attains a bright yellow color. Discoloration of the skin usually fades in 6 to 12 hours and usually fades in urine in 24 to 36 hours *[see Adverse Reactions (6.1)]*.

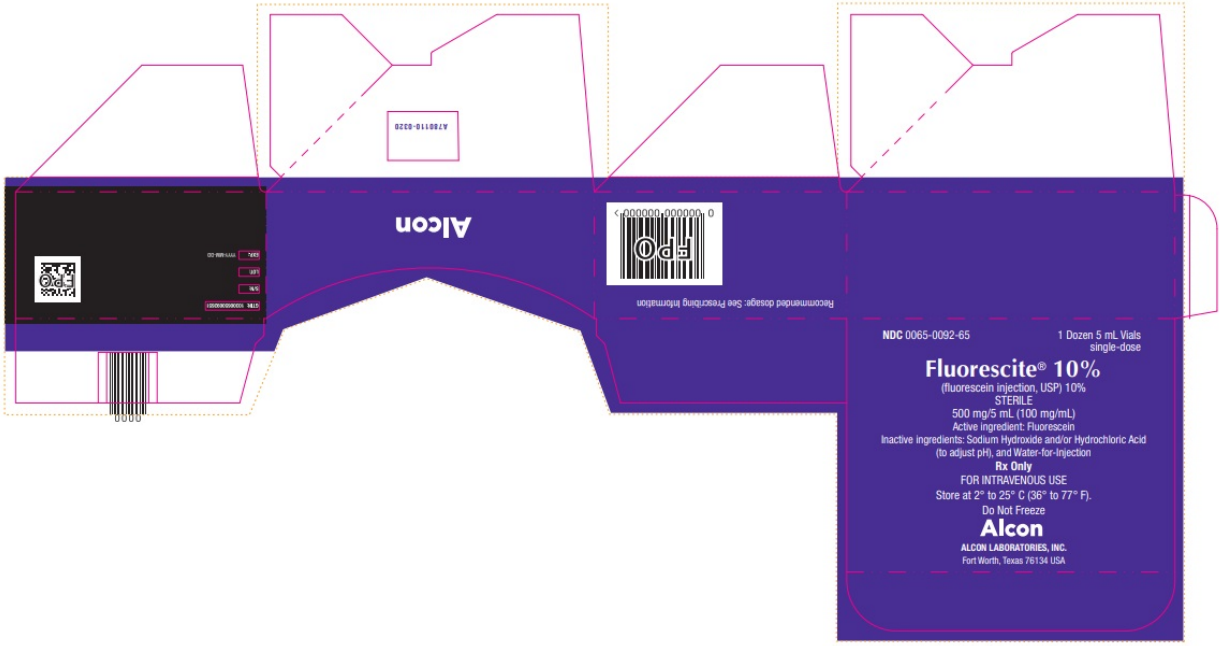
Distributed by:
Alcon Laboratories, Inc.
Fort Worth, Texas 76134

A780189-0320

Alcon Logo

Container Label

Carton Labeling



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