

Fluorescein Injection U.S.P. 10% w/v Lite 10% 100 mg/mL

FOR INTRAVENOUS INJECTION ONLY

Each mL contains: Fluorescein Sodium USP 10% in Water for Injection USP, pH adjusted with Sodium Hydroxide and/or Hydrochloric Acid. Protect from light. Store between 15°-25°C (59°-77°F).

12 x 5 mL Sterile SINGLE DOSE VIALS

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Fluorescein Injection U.S.P. 25% 250 mg/mL

FOR INTRAVENOUS INJECTION ONLY

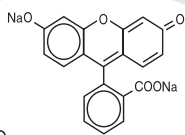
Each mL contains: Fluorescein Sodium USP 25% in Water for Injection USP, pH adjusted with Sodium Hydroxide and/or Hydrochloric Acid. Protect from light. Store between 15°-25°C (59°-77°F). DO NOT PERMIT TO FREEZE.

12 x 2 mL Sterile SINGLE DOSE VIALS

FLUORESCEIN SODIUM INJECTION

DESCRIPTION

FLUORESCEIN SODIUM INJECTION is a sterile, aqueous solution for intravenous injection. Each 5 mL vial contains: Fluorescein sodium 500 mg (100 mg/mL) in Water for Injection. Each 2 mL vial contains: Fluorescein sodium 500 mg (250 mg/mL) in Water for Injection. pH (range 8.0-9.8) adjusted with Sodium Hydroxide and/or Hydrochloric Acid. Fluorescein sodium is the simplest of the fluorane dyes and is chemically related to the phenolphthalein dyes. The chemical name for fluorescein sodium is: Spiro [isobenzofuran-1(3H), 9'-[9H]xanthene]-3-one,3',6'-dihydroxy, disodium salt; and the structural formula is:



Molecular Formula: $C_{20}H_{10}Na_2O_5$

Molecular Weight: 376.27

CLINICAL PHARMACOLOGY

Fluorescein sodium is a diagnostic dye that produces a yellowish-green fluorescence which appears readily in the extracellular fluid, and gains access only to viable cells. The fluorescence distinguishes the area under observation from adjacent areas.

After intravenous injection, the dye is rapidly distributed through the body. Fluorescence of the retinal vessels should occur within 12-30 seconds. The dye is excreted by the kidneys and appears in the urine. The urine attains a bright yellow color that fades in 24-36 hours. It is not known whether any of the dye is metabolized.

INDICATIONS AND USAGE

Fluorescein sodium is indicated for ophthalmic angiography and angioscopy in diagnostic examination of the fundus; in evaluation of the iris vasculature; to differentiate between viable and non-viable tissue; to assess aqueous flow; in differential diagnosis of malignant and non-malignant tumors; and in determination of circulation time and adequacy of the circulation.



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