AK-FLUOR® (fluorescein injection, USP) is a sterile solution for use intravenously as a diagnostic aid

- Indicated in diagnostic fluorescein angiography or angioscopy of the retina and iris vasculature
- Meets strict USP quality standards
- AK-FLUOR® is contraindicated in patients with known hypersensitivity to fluorescein sodium or any other ingredients in this product
- Rare cases of death due to anaphylaxis have been reported [see Warnings and Precautions (5.1) and Adverse Reactions (6.2)]
- Available direct or through your authorized wholesaler or distributor

### **AK-FLUOR® (fluorescein injection, USP)**

<table>
<thead>
<tr>
<th>NDC #</th>
<th>DESCRIPTION</th>
<th>SIZE</th>
<th>UNIT OF SALE</th>
<th>ORANGE BOOK CODE</th>
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<tbody>
<tr>
<td>17478-253-10</td>
<td>10% Single-dose Vial</td>
<td>5 mL</td>
<td>12</td>
<td>AP</td>
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<tr>
<td>17478-250-20</td>
<td>25% Single-dose Vial</td>
<td>2 mL</td>
<td>12</td>
<td>AP</td>
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**EACH mL CONTAINS:**

**ACTIVE:**
- 17478-253-10: Fluorescein Sodium (equivalent to Fluorescein 10% w/v, 100 mg/mL);
- 17478-250-20: Fluorescein Sodium (equivalent to Fluorescein 25% w/v, 250 mg/mL);

**PRESERVATIVE:** None;

**INACTIVES:** Sodium Hydroxide and/or Hydrochloric Acid may be used to adjust pH (8.3 to 9.8), and Water for Injection.

**STORAGE:** Store at 20° to 25°C (68° to 77°F). Do not freeze.

<table>
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<tr>
<th>NDC #</th>
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<th>AMERISOURCEBERGEN</th>
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<td>089-829</td>
<td>1257831</td>
<td>TBA</td>
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</table>

To order products call 800-932-5676 or fax 800-943-3694 • www.akorn.com
NOT FOR PRESCRIBING PURPOSES. PLEASE REFER TO PACKAGE INSERT FOR FULL PRESCRIBING INFORMATION.
AK-FLUOR® (fluorescein injection, USP) only

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use AK-FLUOR® 10% and AK-FLUOR® 25% safely and effectively. See full prescribing information for the products in AK-FLUOR® 10% and AK-FLUOR® 25%.

AK-FLUOR® (fluorescein injection, USP) 10%
AK-FLUOR® (fluorescein injection, USP) 25%
Intravenous Injection

Initial US Approval: 1976

FULL PRESCRIBING INFORMATION:

See 17 for PATIENT COUNSELING INFORMATION.

Revised: 07/2008

FULL PRESCRIBING INFORMATION:

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2 DOSAGE AND ADMINISTRATION
3 DOSAGE FORMS AND STRENGTHS
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6 ADVERSE REACTIONS
7 USE IN SPECIFIC POPULATIONS
8 USE IN SPECIFIC POPULATIONS
9 NURSING MOTHERS
10 USE IN CHILDREN
11 DESCRIPTION
12 CLINICAL PHARMACOLOGY
13 NONCLINICAL TOXICOLOGY
14 USE SUPPLIED/STORAGE AND HANDLING
15 PATIENT COUNSELING INFORMATION

* Sections or subsections omitted from the Full Prescribing Information are not relevant.

FULL PRESCRIBING INFORMATION:

1 INDICATIONS AND USAGE

AK-FLUOR® 10% (100 mg/mL) and 25% (250 mg/mL) is indicated in diagnostic fluorescein angiography or angiography of the retina and iris vasculature.

2 DOSAGE AND ADMINISTRATION

2.1 Dosing

2.1.1 Adult Dose

The recommended dosage of AK-FLUOR® 10% (100 mg/mL) and 25% (250 mg/mL) is 500 mg via intravenous administration.

Pediadric Dose

For children, the dose is 7.7 mg/kg (actual body weight) up to a maximum of 500 mg, via intravenous infusion calculated on the basis of 35 mg for each 10 Ls. (4.24 kg) of body weight.

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.

2.3 Administration

Inject the dose (over 5-10 seconds is normally recommended) into the antecubital vein, after taking precautions to avoid extravasation. A syncope, filled with AK-FLUOR®, may be attached to transparent tubing or a test tube. 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 extravasation has occurred. 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 500 mg to 200 mg of AK-FLUOR® 10% may be appropriate in cases when a highly sensitive imaging system e.g., scanning laser ophthalmoscope is used.

3 DOSAGE FORMS AND STRENGTHS

AK-FLUOR® (fluorescein injection, USP) 10%, 100 mg/mL in a 5 mL single use vial (3)

AK-FLUOR® (fluorescein injection, USP) 25%, 250 mg/mL in a 2 mL single dose vial (3)

4 CONTRAINDICATIONS

4.1 Hypersensitivity

AK-FLUOR® is contraindicated in patients with hypersensitivity to fluorescein or any other ingredients in this product.

5 WARNINGS AND PRECAUTIONS

5.1 Respiratory Reactions

Caution should be exercised in patients with a history of allergy or bronchial asthma. An emergency tray should always be available.

5.3 Adverse Reactions

The most common adverse reactions include skin discoloration, urine discoloration, nausea, vomiting, and gastrointestinal distress. To report SUSPECTED ADVERSE REACTIONS, contact Akorn at 1-800-336-6600 (FAX 10-888 or www.fda.gov/medwatch).

6 ADVERSE REACTIONS

6.1 Skin and urine discoloration

The most common reaction is discoloration of the skin and urine. 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 fades out of urine in 24 to 36 hours.

6.2 Gastrointestinal Reaction

The most common reaction is nausea, vomiting, and gastrointestinal distress have also occurred. 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. (see Contraindications (4.1) and Warnings and Precautions (5.1)).

6.4 Cardiopulmonary Reactions

Syndrome of hypotension and cardiac arrest occur. Cardiac arrest, basilar artery ischemia, severe shock and death may occur rarely. [see Warnings and Precautions (5.1)].

6.5 Neurologic Reactions

Headache may occur. convulsions 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 Administration (2.3) and Warnings and Precautions (5.2)].

7 USE IN SPECIFIC POPULATIONS

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Category C. Adequate animal reproduction studies have not been conducted with fluorescein sodium. It is also not known whether fluorescein sodium can cause fetal harm when administered to a pregnant woman. Fluorescein sodium should be given to a pregnant woman only if clearly needed.

8.2 Nursing Mothers

Fluorescein sodium has been demonstrated to be excreted in human milk. Caution should be exercised when fluorescein sodium is administered to a nursing woman.

8.3 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.

8.4 Geriatric Use

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

11 DESCRIPTION

AK-FLUOR® (fluorescein injection, USP) is a sterile solution for use intravenously as a diagnostic aid. It is a dark reddish orange solution with a pH of 8.3 to 9.8 and an osmolarity of 372 to 858 mOsm/kg for the 10% and 1800 to 2200 mOsm/kg for the 25%. Its chemical name is spiro[isobenzofuran-1 (3H),9'-[9H]xanthene]-3,6-dihydroxy, diiodohydrate.

MW = 376.27

AK-FLUOR® 10% contains:

Active: fluorescein sodium (equivalent to fluorescein 10% w/v, 100 mg/mL).

Inactives: Sodium Hydroxide and/or Hydrochloric Acid may be used to adjust pH (8.3 to 9.8), and Water for Injection.

AK-FLUOR® 25% contains:

Active: fluorescein sodium (equivalent to fluorescein 25% w/v, 250 mg/mL).

Inactives: Sodium Hydroxide and/or Hydrochloric Acid may be used to adjust pH (8.3 to 9.8), and Water for Injection.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Fluorescein responds to electromagnetic radiation and light between the wavelengths of 465 to 490 nm and fluoresces, i.e., emits light at wavelengths of 520 to 530 nm. Thus, the hydrocarbon is excited by blue light and emits light that appears yellowish green. Following intravenous injection of fluorescein sodium 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 fluorescein of the dye demarcates the retinal and/or choroidal vasculature under observation, distinguishing it from adjacent areas/structures.

12.2 Pharmacokinetics

Distribution:

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

Metabolism:

Fluorescein is metabolized to fluorescein monoglucuronide. After IV administration of fluorescein sodium (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.

Excretion:

Fluorescein and its metabolite are mainly eliminated via renal excretion. After IV administration, the urine remains slightly fluorescent for 24 to 36 hours. A peak urinary concentration of 1.75 mg/mL or has been noted (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.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

There have been no long-term studies done using fluorescein in animals to evaluate carcinogenic potential.

16 HOW SUPPLIED/STORAGE AND HANDLING

AK-FLUOR® (fluorescein injection, USP) is supplied in a single-use 5 mL single dose vials in a package of 12.

AK-FLUOR® (fluorescein injection, USP) is supplied in a single-use 2 mL glass vial with a gray bromobutyl rubber serum stopper and orange flip-off cap. It contains a sterile dark reddish orange solution of fluorescein sodium. (NDC 17478-253-50) 5 mL, single dose vials in a package of 12.

AK-FLUOR® (fluorescein injection, USP) is supplied in a single-use 2 mL glass vial with a gray bromobutyl rubber serum stopper and orange flip-off cap. It contains a sterile dark reddish orange solution of fluorescein sodium. (NDC 17478-250-20) 2 mL, single dose vials in a package of 12.

AK-FLUOR® should be stored at 20° to 25°C (68° to 77°F). Do not freeze.

17 PATIENT COUNSELING INFORMATION

After administration of fluorescein sodium, 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 fades out of urine in 24 to 36 hours. (see Warnings and Precautions (5.1)).