DISCLAIMER

All labeling reflected on this website is for informational and promotional purposes only. It is not intended to be used by healthcare professionals or patients for the purpose of prescribing or administering these products. Questions regarding the current content of product labeling should be directed to Akorn's Customer Service department at 800.932.5676.
WARNINGS AND PRECAUTIONS

IC-GREEN® is a sterile, lyophilized green powder containing 25 mg of indocyanine green with no more than 5% iodide solution. (3)

— CONTRAINDICATIONS—
IC-GREEN® contains sodium iodide and should be used with caution in patients who have a history of allergy to iodides because of the risk of anaphylaxis. (4)

WARRNINGS AND PRECAUTIONS —

• Deaths due to anaphylaxis have been reported following IC-GREEN® administration during cardiac catheterization. (5.1)
• IC-GREEN® is unstable in aqueous solution and must be used within 6 hours. (5.2)
• Radioactive iodine studies should not be performed for at least a week following the use of IC-GREEN®, (5.3)

ADVERSE REACTIONS —
Most common adverse reactions are anaphylactic or urticarial reactions. These have been reported in patients with and without a history of allergy to iodides. (6)

To report SUSPECTED ADVERSE REACTIONS, contact Akorn, Inc. at 1-800-932-5876 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

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FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

IC-GREEN® is indicated:

1.1 For determining cardiac output, hepatic function, and liver blood flow
1.2 For ophthalmic angiography

2 DOSAGE AND ADMINISTRATION

2.1 Indicator-Dilution Studies

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FULL PRESCRIBING INFORMATION

Under sterile conditions, the IC-GREEN® powder should be dissolved with the Sterile Water for Injection, USP provided and the solution used within 6 hours after it is prepared. The usual doses of IC-GREEN® for dilution curves are:
Adults - 5.0 mg
Children - 2.5 mg
Infants - 1.25 mg

Hepatic Function Studies. (2.2)

Under sterile conditions, the IC-GREEN® powder should be dissolved with the Sterile Water for Injection, USP provided. The patient should be weighed and the dosage calculated on the basis of 0.5 mg/kg of body weight. Exactly 5 mL of Sterile Water for Injection, USP should be added to the 25 mg vial giving 5 mg of dye per mL of solution.

Ophthalmic Angiography Studies. (2.3)
Dosages up to 40 mg IC-GREEN® dye in 2 mL of Sterile Water for Injection, USP should be administered. A 5 mL bolus of normal saline should immediately follow the injection of the dye.

DOSAGE FORMS AND STRENGTHS

IC-GREEN® is a sterile, lyophilized green powder containing 25 mg of indocyanine green with no more than 5% sodium iodide solution. (3)

— CONTRAINDICATIONS—

IC-GREEN® contains sodium iodide and should be used with caution in patients who have a history of allergy to iodides because of the risk of anaphylaxis. (4)

WARRNINGS AND PRECAUTIONS —

• Deaths due to anaphylaxis have been reported following IC-GREEN® administration during cardiac catheterization. (5.1)
• IC-GREEN® is unstable in aqueous solution and must be used within 6 hours. (5.2)
• Radioactive iodine studies should not be performed for at least a week following the use of IC-GREEN®, (5.3)

ADVERSE REACTIONS —

Most common adverse reactions are anaphylactic or urticarial reactions. These have been reported in patients with and without a history of allergy to iodides. (6)

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DRUG INTERACTIONS —

Products containing sodium bisulfite reduce the absorption peak of IC-GREEN® in blood. (7)

Revised 06/2016

Photometric Method - Determining Use Percentage Retention of Dye:
A typical curve obtained by plotting dye concentration versus optical density is shown. The percent retention can be read from this plot. If more accurate results are desired, a curve using the patient's blood and the vial of IC-GREEN® being used in the determination can be constructed as follows:

1. Take 6 mL of non-dye-containing venous blood from the patient's arm. Place in a test tube and allow the blood to clot. The serum should be separated by centrifugation.
2. Pipette 1 mL of the serum into a microcentrifuge.
Dosages up to 40 mg IC-GREEN® dye in 2 mL of Sterile Water for Injection, USP should be used, depending on the imaging equipment and technique used. The antecubital vein can be injected with IC-GREEN® dye, but the bolus and should immediately be followed by a 5 mL bolus of normal saline.

3 DOSAGE FORMS AND STRENGTHS

IC-GREEN® is a sterile, lyophilized green powder containing 25 mg of indocyanine green with no more than 5% sodium iodide.

4 CONTRAINDICATIONS

IC-GREEN® contains sodium iodide and should be used with caution in patients who have a history of allergy to iodides because of the risk of anaphylaxis.

5 WARNINGS AND PRECAUTIONS

5.1 Anaphylaxis

Deaths from anaphylaxis have been reported following IC-GREEN® administration during cardiac catheterization.

5.2 Drug Instability

IC-GREEN® is unstable in aqueous solution and must be used within 6 hours. However, the dye is stable in plasma and whole blood so that samples obtained in discontinuous sampling techniques may be read hours later. Sterile techniques should be used in handling the dye solution as well as in the performance of the dilution curves. If a precipitate is present, discard the solution.

5.3 Drug/Laboratory Test Interactions

Radioactive iodine uptake studies should not be performed for at least a week following the use of IC-GREEN®.

6 ADVERSE REACTIONS

Anaphylactic or urticarial reactions have been reported in patients with or without history of allergy to iodides. If such reactions occur, treat with the appropriate agents, e.g., epi nephrine and corticosteroids.

7 DRUG INTERACTIONS

Preparations containing sodium bisulfite, including some heparin products reduce the absorption peak of IC-GREEN® in blood and, therefore, should not be used as an anticoagulant for the collection of samples for analysis.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Animal reproduction studies have not been conducted with IC-GREEN®. It is also not known whether IC-GREEN® can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. IC-GREEN® should be given to a pregnant woman only if clearly indicated.

8.3 Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when IC-GREEN® is administered to a nursing woman.

8.4 Pediatric Use

Safety and effectiveness in pediatric patients have been established. See DOSAGE AND ADMINISTRATION (2) for specific dosing information in pediatric patients.

8.5 Geriatric Use

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

10 OVERDOSAGE

There are no data available describing the signs, symptoms, or laboratory findings accompanying overdosage. The LD₅₀ after intravenous administration ranges between 60 and 80 mg/kg in rabbits. Based on body surface area, these doses are 2.4 to 13-fold the maximum recommended human (MRHD) dose of 2 mg/kg for indicator-dilution studies, 10 to 52-fold the MRHD of 0.5 mg/kg for hepatic-function studies, and 7 to 39-fold the MRHD of 0.67 mg/kg for ophthalmic angiography studies.

11 DESCRIPTION

IC-GREEN® is a sterile, lyophilized green powder containing 25 mg of indocyanine green with no more than 5% sodium iodide. IC-GREEN® is to be administered intravenously.

Indocyanine green is a water soluble, tricarbocyanine dye with a peak spectral absorption at 800 nm. The chemical name for Indocyanine Green is 1H-Benz[e][indolium, 2-[[3,13-dihydroxy-1,1-dimethyl-3-(4-sulfobutyl)-2H-benz[e] indol-2-ylidene]-1,3,5-heptatrienyl]-1,1-dimethyl-3-(4-sulfobutyl)-2H-benzoxides, inner salt, sodium salt. IC-GREEN® has a pH of approximately 6.5 when reconstituted. Each vial of IC-GREEN® contains 25 mg of indocyanine green as a sterile lyophilized powder.

12 CLINICAL PHARMACOLOGY

IC-GREEN® permits the recording of the indicator-dilution curves for both diagnostic and research purposes independently of fluctuations in oxygen saturation. Following intravenous injection, IC-GREEN® is rapidly bound to plasma protein, of which albumin is the principal carrier (95%). IC-GREEN® undergoes no significant extrahepatic or enterohepatic circulation; simultaneous arterial and venous blood estimations have shown negligible renal, peripheral, lung or cerebro-spinal uptake of the dye. IC-GREEN® is taken up from the plasma almost exclusively by the hepatic parenchymal cells and is secreted entirely into the bile. After biliary obstruction, the dye appears in the hepatic lymph, independently of the bile, suggesting that the biliary mucosa is sufficiently intact to prevent diffusion of the dye, though allowing diffusion of bilirubin. These characteristics make IC-GREEN® a helpful index of hepatic function.

The peak absorption and emission of IC-GREEN® lie in a region (800 to 850 nm) where transmission of energy by visible light is more efficient than in the region of visible light energy. IC-GREEN® also has the property of being nearly 98% bound to blood protein, and therefore, excessive dye extravasation does not take place in the highly fenestrated choroidal vasculature. It is, therefore, useful in both absorption and fluorescence infrared angiography of the choroidal vasculature when using appropriate filters and film in a fundus camera. IC-GREEN® has a peak absorption wavelength at 750 nm which is not significantly more intense than the wavelength at which the indocyanine green is rapidly bound to plasma protein, of which albumin is the principal carrier (95%). IC-GREEN® undergoes no significant extrahepatic or enterohepatic circulation; simultaneous arterial and venous blood estimations have shown negligible renal, peripheral, lung or cerebro-spinal uptake of the dye. IC-GREEN® is taken up from the plasma almost exclusively by the hepatic parenchymal cells and is secreted entirely into the bile. After biliary obstruction, the dye appears in the hepatic lymph, independently of the bile, suggesting that the biliary mucosa is sufficiently intact to prevent diffusion of the dye, though allowing diffusion of bilirubin. These characteristics make IC-GREEN® a helpful index of hepatic function.

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