Diagnostic Green

Indocyanine Green for Injection, USP

Diagnostic Green's Indocyanine Green for Injection, USP is the leading fluorescence product trusted by physicians, to visualize fluorescence and guide their procedures.

www.diagnosticgreen.com

Diagnostic Green

Verdye/ICG injection

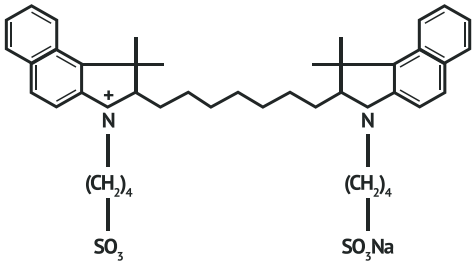
Binds to Plasma proteins & quickly circulates

Flouresence can be imaged in minutes

Removed by the liver & eliminated in the bile

KEY FEATURES

- Well tolerated*
- Excellent safety profile**
- Cleared exclusively through the liver
- Half-life of 3-4 minutes
- Rapidly bound to plasma protein
- Undergoes no significant or enterohepatic circulation
- Secreted entirely into the bile



CHEMICAL DESCRIPTION

Chemical Description: Tricarbocyanine Dye

Appearance: Lypophilized green powder

Empirical Formula: $C_{43}H_{47}N_2NaO_6S_2$

HOW SUPPLIED

Active Substance: Indocyanine Green for Injection, USP (lyophilized powder)

Package configuration: Available in vial kit of 6 vials of the lyophilized green powder and 6 vials of 10 mL Sterile Water for Injection, USP (USA and Canada)

Vials Strength: 25 mg

References:

* https://radiologykey.com/clinical-applications-of-diagnostic-indocyanine-green-angiography/

**https://www.ncbi.nlm.nih.gov/pubmed/635011

INDICATION

Indocyanine Green for Injection USP, a tricarbocyanine dye, is indicated for: determining cardiac output, hepatic function and liver blood flow; and for ophthalmic angiography.

STORAGE AND HANDLING

- Storage: Store at 20° to 25°C (68° to 77°F)
- Under sterile conditions, the Indocyanine Green for Injection, USP powder should be dissolved with the Sterile Water for Injection, USP provided for this product, and the solution used within 6 hours after it is prepared. If a precipitate is present, discard the solution
- Sterile product, intended for a single patient use only
- Keep away from light after it is reconstituted
- Dosage depends on the indication and weight of the patient

INDICATIONS AND USAGE: For determining cardiac output, hepatic function and liver blood flow, and for ophthalmic angiography. CONTRAINDICATIONS: Indocyanine Green for Injection USP 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. WARNINGS Deaths from anaphylaxis have been reported following Indocyanine Green for Injection USP administration during cardiac catheterization. PRECAUTIONS: Drug Instability: Indocyanine Green for Injection USP 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. Drug Interactions: Preparations containing sodium bisulfite, including some heparin products reduce the absorption peak of Indocyanine Green for Injection USP in blood and, therefore, should not be used as an anticoagulant for the collection of samples for analysis. Drug/ Laboratory Test Interactions: Radioactive iodine uptake studies should not be performed for at least a week following the use of Indocyanine Green for Injection USP. Carcinogenesis, Mutagenesis, Impairment of Fertility: No studies have been performed to evaluate the carcinogenicity, mutagenicity, or impairment of fertility. Pregnancy and Nursing Mothers: Teratogenic Effects: Animal reproduction studies have not been conducted with Indocyanine Green for Injection USP. It is also not known whether Indocyanine Green for Injection USP can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Indocyanine Green for Injection USP should be given to a pregnant woman only if clearly indicated. 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 Indocyanine Green for Injection USP is administered to a nursing woman. Pediatric Use: Safety and effectiveness in pediatric patients have been established. Geriatric Use: No overall differences in safety or effectiveness have been observed between elderly and younger patients. 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., epinephrine, antihistamines, and corticosteroids. OVERDOSAGE: There are no data available describing the signs, symptoms, or laboratory findings accompanying overdosage. The LD50 after I.V. administration ranges between 60 and 80 mg/kg in mice, 50 and 70 mg/kg in rats and 50 and 80 mg/kg in rabbits.

To report SUSPECTED ADVERSE REACTIONS
Contact Diagnostic Green LLC (24/7) at 1-844-424-3784 (1-844-ICG-DRUG) or e-mail: Pharmacovigilance at drugsafety@diagnosticgreen.com or the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

Diagnostic Green

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