Diagnostic Green

Indocyanine Green for Injection, USP

Overview

www.diagnosticgreen.com

Company Vision
and Strategy

The Diagnostic Green company is the leading provider of trusted high quality fluorescence products for physicians worldwide.

Diagnostic Green

Our Vision

Diagnostic Green was established to provide high quality fluorescence imaging products to physicians worldwide. Our vision is to ensure that fluorescence imaging becomes the standard in tissue visualization worldwide, to help improve clinician outcomes, minimize procedure complications and thereby reduce overall healthcare costs.

We aspire to maintain our global leadership in the manufacture and distribution of ICG Diagnostic Products with guaranteed availability of high quality products – anytime, anywhere.

Diagnostic Green

Core Values

The Diagnostic Green's core values serve as a foundation for the way we conduct business with our **distributors, customers** and **physicians**.

Integrity

Professionalism

Accountability

Teamwork

Excellence

Flexibility

Company

History

1991

Registration file for ICG Diagnostic Product acquired

2007

Marketing Authorization for ICG by the US FDA

2015

Renew Group Private Ltd acquire both Diagnostic Green GmbH, and Diagnostic Green LLC

2017

Acquired US distributor – Hub Pharmaceuticals as platform to expand business in USA

2019

Diagnostic Green's ICG pharmaceutical product expands to new territories worldwide

Indocyanine Green for Injection, USP

Diagnostic Green's Indocyanine Green for Injection, USP is the leading fluorescence product trusted by physicians worldwide, to guide their treatment procedures, based on fluorescence.

*Indocyanine Green (ICG), is well known and accepted by surgeons worldwide (over 11,000 published articles on use and applications)**

Key Features of Indocyanine Green for Injection, USP

- Safe and well tolerated**
- Excellent safety profile***
- Half-life of 3-4 minutes
- Rapidly bound to plasma protein
- Undergoes no significant extrahepatic or enterohepatic circulation
- Secreted entirely into the bile

**Pubmed*
*** https://radiologykey.com/clinical-applications-of-diagnostic-indocyanine-green-angiography/*
**** https://www.ncbi.nlm.nih.gov/pubmed/635011*

Diagnostic Green

Approved Indocyanine Green for Injection, USP*

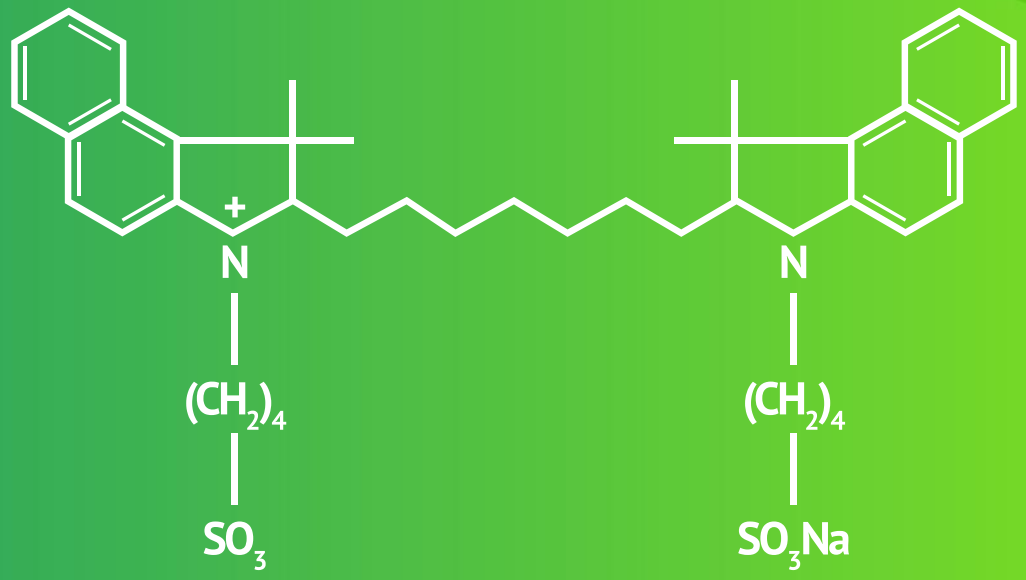
Product Indications

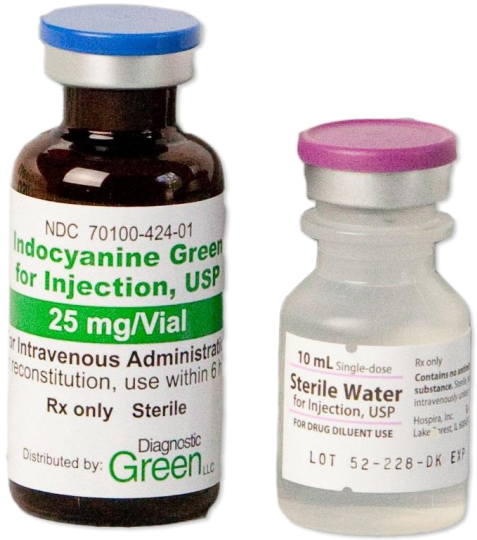
To determine cardiac output, hepatic function and liver blood flow

Ophthalmic angiography

*approved indications in USA and Canada. For full prescribing details, go to www.diagnosticgreen.com

Chemical
Description

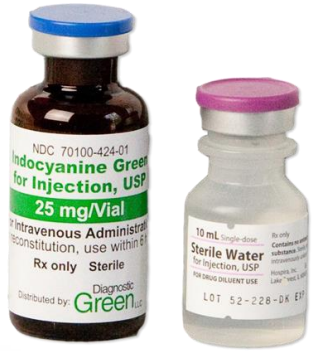




- **Chemical Description:** *Tricarbocyanine Dye*
- **Appearance:** Lypophilized green powder
- **Empirical Formula:** $C_{43}H_{47}N_2NaO_6S_2$

Indocyanine Green for Injection, USP

How it is Supplied



- **Active Substance:** Indocyanine Green (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
- **Vial strength:** 25 mg

Indocyanine Green for Injection, USP

Prescription only Medicine (Rx Only)

Active substance: *Indocyanine Green (lyophilized powder)*

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

Conditions of Use for Indocyanine Green for Injection, USP:

- 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 with this product
- Once reconstituted, the solution must be 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
- Dosage depends on the indication and weight of the patient

Safety Information:

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 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.

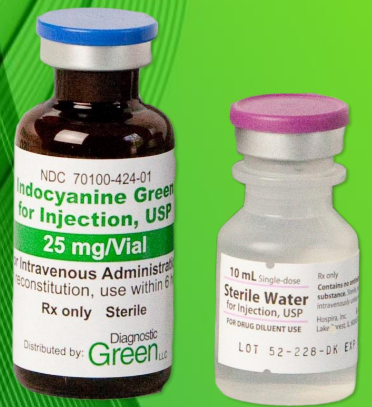
To report **SUSPECTED ADVERSE REACTIONS** *Contact Diagnostic Green LLC (24/7) at 1-844-424-3784 (1-844-ICG-DRUG) or e-mail: Pharmacovigilance at drugsafety@diagnosticgreen.com or the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.*

www.diagnosticgreen.com

Diagnostic Green

Indocyanine Green for Injection, USP

Prescription only Medicine (Rx Only)



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 AND PRECAUTIONS

- Anaphylaxis: Deaths from anaphylaxis have been reported following Indocyanine Green for Injection USP administration during cardiac catheterization.
- 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. If a precipitate is present, discard the solution.
- Drug/Laboratory Test InteractionsRadioactive iodine uptake studies should not be performed for at least a week following the use of Indocyanine Green for Injection USP.

Safety Information:

INDICATIONS AND USAGE: For determining cardiac output, hepatic function and liver blood flow, and for ophthalmic angiography. 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.*

www.diagnosticgreen.com

Diagnostic Green

Indocyanine Green for Injection, USP

USA and Canada Distributors

United States

HUB Pharmaceuticals
800 Junction Street,
Plymouth,
MI 48170, USA

Website: **www.hubrx.coma**
Phone: +1-909-476-8394
Fax: +1-909-948-2193
E-mail: **orders@hubrx.com**

Canada

Seaford Pharmaceuticals InC.,
28 – 1530 Drew Road,
Mississauga, ON,
L5S 1W8 Canada

Website: **www.seaford.ca**
Phone: +1 (888) 292-3192
E-mail: **info@seaford.ca**

Diagnostic Green

ICG Worldwide

Registration & Distribution

Currently registered for distribution

- USA
- Germany
- Austria
- Belgium
- Netherlands
- Italy
- Sweden
- Canada
- Portugal
- UK
- Israel
- Chile
- Spain
- Malta

Supplied under exemption

- Australia
- Baltic States
- Czech Republic
- Croatia
- Denmark
- South Africa
- Luxembourg
- Belarus
- Bosnia
- Slovenia
- Finland
- Greece
- Hungary
- Iceland
- Norway
- Poland
- Spain
- Switzerland
- Thailand

Diagnostic Green

Contact Us

Diagnostic Green LLC
38955 Hills Tech Drive
Farmington Hills
MI 48331
United States

European Head Office
Renew Health Limited
IDA Business Park
Garrycastle, Athlone
Co Westmeath
Ireland N37 RF70

Diagnostic Green GmbH
Otto-Hahn-Straße 20
85609 Aschheim-
Dornach
Germany