

Verdye (Indocyanine Green)

Diagnostic Green's Indocyanine Green (ICG), Verdye is the leading fluorescence product trusted by physicians worldwide, to guide their treatment procedures, based on fluorescence.



APPROVED INDICATIONS



Ophthalmic angiography diagnostics

Measurement of perfusion of the choroid



Liver function diagnostics

Measurement of excretory function of the liver



Cardiac, circulatory & micro-circulatory diagnostics

- Measurement of cardiac output and stroke volume
- Measurement of circulating blood volumes
- Measurement of cerebral perfusion

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 extrahepatic or enterohepatic circulation

CHEMICAL DESCRIPTION

Chemical Description: Tricarbocyanine Dye

Appearance: Green powder

Empirical Formula: C₄₃H₄₇N₂NaO₆S₂

References:

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



Verdye/ICG injection

Binds to Plasma proteins & quickly circulates

Flouresence can be imaged in minutes Removed by the liver & eliminated in the bile



HOW IT IS SUPPLIED

Active Substance: Indocyanine Green (ICG)

Package configuration: ICG Pharmaceutical Product is available in packs of 5 vials

Drug Content: Vials are available in 25mg and 50mg, depending on territory

ICG Pharmaceutical Product is a Prescription Only Medicine (POM)

CONDITIONS OF USE AND STORAGE

- Storage: See Product Information Leaflet (PIL) for storage instructions
- Under sterile conditions, the Indocyanine Green Diagnostic Product, Verdye should be dissolved with water for injection
- Once reconstituted, the solution must be used immediately
- Sterile product, intended for a single patient use only
- O Dosage depends on the indication and weight of the patient

SINGLE DOSE PER MEASUREMENT IN **ADULTS, ELDERLY, CHILDREN**

TOTAL DAILY DOSE

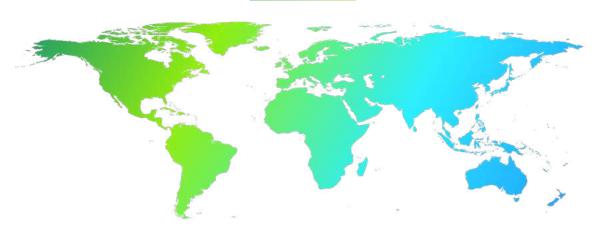
dose of ICG

VERDYE Indications*	Bolus injection	Age of the patient	Max. daily dose of
Cardiac, Circulatory & Micro-circulatory Diagnostics: • Measurement of cardiac output and stroke volume • Measurement of circulating blood volumes • Measurement of circulating blood volumes	0.1 to 0.3 mg/kg body weight	Adults, elderly, adolescents (11-18 years)	< 5 mg/kg body weight
Liver Function Diagnostics: • Measurement of excretory function of the liver	0.25 – 0.5 mg/kg body weight	Children (2 – 11 years)	< 2.5 mg/kg body weight
Ophthalmic Angiography Diagnostics: • Measurement of perfusion of the choroid	0.1 to 0.3 mg/kg body weight	Children (0 – 2 years)	< 1.25 mg/kg body weight

^{*}For prescribing information by territory visit www.diagnosticgreen.com and go to product information page



WORLDWIDE REGISTRATION & DISTRIBUTION



Currently registered for distribution

- Austria
- Belgium
- Canada
- Chile
- Germany
- Israel
- Italy

- Malta
- Netherlands
- Portugal
- Sweden
- Ukraine
- USA

Supplied under exemption

- Argentina Australia
- Greece Hungary
- Saudi Arabia

- Bahrain
- Iceland
- Singapore

Spain

- Baltic States
- Ireland
- Slovakia Slovenia

- Belarus
- Kazakhstan
- Sri Lanka

UK

- Bosnia
- Luxembourg
- South Africa

- Bulgaria Croatia
- New Zealand Norway
- Switzerland Thailand

- Czech Republic
- Panama
- Turkey

- Denmark Finland
- Poland
- UAE

- Georgia
- Romania
- Vietnam

VERDYE 25 mg/50 mg. Active substance: indocyanine green, monosodium salt. Composition: 25 mg/50 mg powder for producing an injectable solution; 1 ml of the injectable solution contains 5 mg of the active substance. Other ingredients: none. Indications: diagnostic drug which is used to determine the effectiveness of the blood supply to the heart, brain and other organs and to one of the inner layers of the eye (choroid), as well as for monitoring the circulation of blood and determining liver function. Contraindications: hypersensitivity (allergy) to indocyanine green, sodium iodide or jodine; overactive thyroid or discrete benign thyroid tumours or if parts of your thyroid are no longer under hormonal influence. Do not use if you have ever had any side effects after receiving an ICG injection (risk of anaphylactic reaction). No use in premature babies and newborns suffering from hyperbilirubinaemia. Side-effects: very rare (<1 in 10.000): nausea and hypersensitivity reactions (allergies); the possibility of an allergic reaction is greater in patients with extremely serious kidney failure. Possible symptoms: restlessness, hot flushes, nausea, itching, hives (skin rash), faster heartbeat, facial redness, swelling of the face (facial edema), drop in blood pressure, shortness of breath, spasms of the bronchia and larynx, cardiac/circulatory arrest, death. Associated with the allergic reaction an increase of special white blood cells can occur. Prescription only. Diagnostic Green GmbH, Aschheim-Dornach, Germany. May. 2016.

To report SUSPECTED ADVERSE REACTIONS and all SAFETY RELATED INFORMATION

All suspected drug reactions and product compliance associated with our ICG Pharmaceutical Product should be reported to: Email: ICG@drugsafety.de; Phone: +49 171 3860445; Email: info@diagnosticgreen.com



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