




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

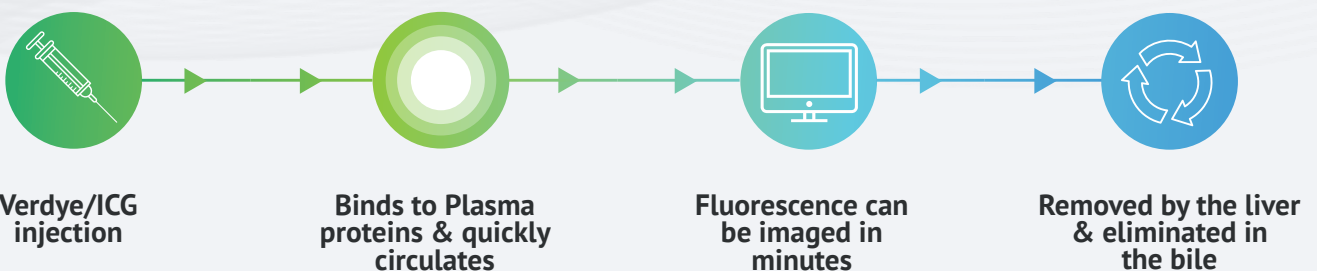
Appearance: Green powder

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

References:

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

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



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
- ⦿ Dosage depends on the indication and weight of the patient

SINGLE DOSE PER MEASUREMENT IN ADULTS, ELDERLY, CHILDREN

| VERDYE Indications* | Bolus injection |
|--|------------------------------|
| Cardiac, Circulatory & Micro-circulatory Diagnostics: <ul style="list-style-type: none">• 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 |
| Liver Function Diagnostics: <ul style="list-style-type: none">• Measurement of excretory function of the liver | 0.25 – 0.5 mg/kg body weight |
| Ophthalmic Angiography Diagnostics: <ul style="list-style-type: none">• Measurement of perfusion of the choroid | 0.1 to 0.3 mg/kg body weight |

TOTAL DAILY DOSE

| Age of the patient | Max. daily dose of ICG |
|---|--------------------------|
| Adults, elderly, adolescents (11-18 years) | < 5 mg/kg body weight |
| Children (2 – 11 years) | < 2.5 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
- ⊙ Mexico
- ⊙ Netherlands
- ⊙ Portugal
- ⊙ Russia
- ⊙ Spain
- ⊙ Sweden
- ⊙ UK
- ⊙ Ukraine
- ⊙ USA

Supplied under exemption

- ⊙ Australia
- ⊙ Bahrain
- ⊙ Baltic States
- ⊙ Belarus
- ⊙ Bosnia
- ⊙ Bulgaria
- ⊙ Croatia
- ⊙ Czech Republic
- ⊙ Denmark
- ⊙ Finland
- ⊙ Georgia
- ⊙ Greece
- ⊙ Hungary
- ⊙ Iceland
- ⊙ Ireland
- ⊙ Kazakhstan
- ⊙ Luxembourg
- ⊙ New Zealand
- ⊙ Norway
- ⊙ Poland
- ⊙ Romania
- ⊙ Saudi Arabia
- ⊙ Singapore
- ⊙ Slovakia
- ⊙ Slovenia
- ⊙ Sri Lanka
- ⊙ South Africa
- ⊙ Switzerland
- ⊙ Thailand
- ⊙ Turkey
- ⊙ UAE
- ⊙ 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 iodine; 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