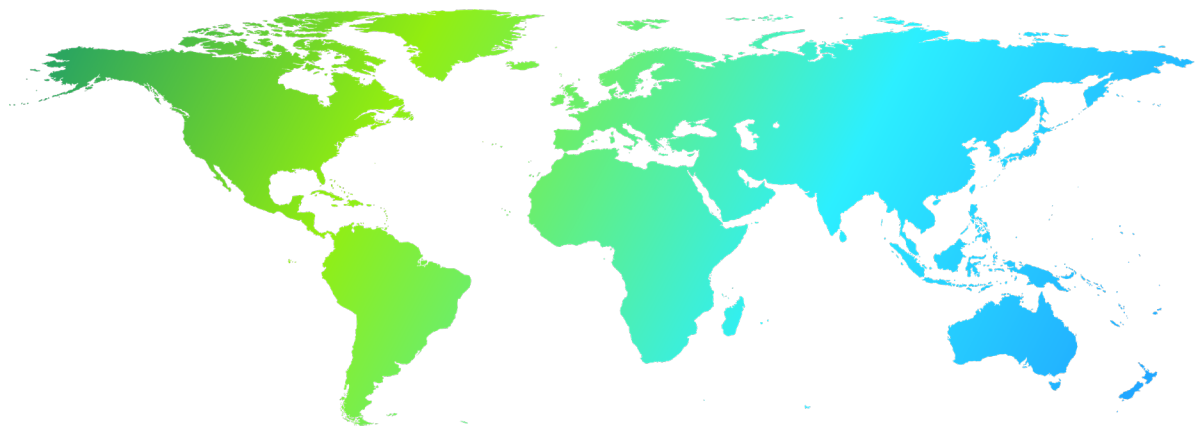


WORLDWIDE REGISTRATION & DISTRIBUTION



Currently registered for distribution

- | | | | | |
|-------------|---------------|---------------|----------------|---------------|
| ○ Argentina | ○ Denmark | ○ Israel | ○ New Zealand | ○ Slovenia |
| ○ Australia | ○ EL Salvador | ○ Italy | ○ Panama | ○ Spain |
| ○ Austria | ○ Finland | ○ Iran | ○ Philippines | ○ Sweden |
| ○ Belgium | ○ Germany | ○ Kuwait | ○ Poland | ○ Switzerland |
| ○ Canada | ○ Greece | ○ Malta | ○ Portugal | ○ UK |
| ○ Chile | ○ Guatemala | ○ Mexico | ○ Romania | ○ Ukraine |
| ○ Croatia | ○ Hungary | ○ Mongolia | ○ Saudi Arabia | ○ USA |
| ○ Czechia | ○ Ireland | ○ Netherlands | ○ Singapore | |

Verdyne 5 mg/ml powder for solution for injection

Composition: Active substance: Indocyanine green (ICG); vials containing 25 mg and 50 mg (to be reconstituted with 5 ml respectively 10 ml water for injections).

Indications: Cardiac, circulatory and micro-circulatory diagnostic agent for measurement of cardiac output and stroke volume, circulating blood volumes and cerebral perfusion; liver function diagnostic agent for measurement of liver blood flow and excretory function of the liver; ophthalmic angiography diagnostic agent for measurement of perfusion of the choroid. Intraoperative identification of sentinel lymph nodes and visualization of lymphatic pathways in breast cancer (registered only in some European countries).

Posology: Cardiac, circulatory, micro-circulatory and tissue perfusion diagnostics as well as cerebral blood flow (adults and children): 0.1-0.3 mg/kg body weight (BW) as single i.v. bolus per measurement; liver function diagnostics (adults and children): 0.25-0.5 mg/kg BW as single i.v. bolus per measurement; ophthalmic angiography (adults and children): 0.1-0.3 mg/kg BW as single i.v. bolus per measurement. Total daily dose: ≥12 yrs: <5 mg/kg BW, 2-11 yrs: <2.5 mg/kg BW, <2 yrs: <1.25 mg/kg BW. Identification of sentinel lymph nodes and visualization of lymphatic pathways regardless of BW (adults): 5-10 mg per single injection (intradermal, subcutaneous or peritumoral). Total daily dose: ≤10 mg.

Contraindications: Hypersensitivity to ICG, sodium iodide or iodine, hyperthyroidism, autonomic thyroid adenomas, hyperbilirubinemia requiring exchange transfusion in premature infants or neonates, history of poor tolerance to Verdyne.

Interactions: Anticonvulsants, bisulphite compounds, haloperidol, heroin, pethidine, metamizole, methadone, morphine, nitrofurantoin, opium alkaloids, phenobarbital, phenylbutazone, cyclopropane, probenecid, rifamycin.

Undesirable effects: Very rare (<1 in 10.000): nausea, urticaria, anaphylactic/anaphylactoid reaction, coronary arteriospasm. Frequency not known: injection site discoloration.

Prescription only.

This product information may differ in some countries. For detailed information see prescribing information by territory visit {website}.

Diagnostic Green Ltd.

Date of last revision: 08/2026

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

Verdyne™ (Indocyanine Green)

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



APPROVED INDICATIONS



Ophthalmic Angiography Diagnostics



Liver Function Diagnostics

- Measurement of liver blood flow
- 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



Intraoperative Identification of Sentinel Lymph Nodes ± Visualisation of Lymphatic Pathways in Breast Cancer

Disclaimer: Approved indications may vary by country. Please refer to your local Summary of Product Characteristics (SmPC) for full prescribing information.

KEY FEATURES

- Excellent safety profile*
- Cleared almost exclusively through the liver
- Initial half-life of 3-4 minutes followed by a secondary half-life of 60-80 minutes
- Rapidly binds to proteins (plasma & lymphatic)
- Undergoes no significant extrahepatic or enterohepatic circulation

CHEMICAL DESCRIPTION

Chemical Description: Tricarbocyanine Dye

Appearance: Green powder

Empirical Formula: $C_{45}H_{47}N_2NaO_6S_2$

References:

*<https://pmc.ncbi.nlm.nih.gov/articles/PMC8869881/>



Verdyne/ICG injection



Binds to proteins (plasma and lymphatic)



Fluorescence 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/50mg

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, Verdyne should be dissolved with water for injection
- Once reconstituted, the solution must be used immediately
- Sterile product, intended for 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: - Measurement of cardiac output and stroke volume - Measurement of circulating blood volumes - Measurement of cerebral perfusion	0.1 to 0.3 mg/kg body weight
Liver Function Diagnostics: - Measurement of liver blood flow** - Measurement of excretory function of the liver***	0.25 – 0.5 mg/kg body weight
Ophthalmic Angiography Diagnostics: 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
≥ 12 yrs:	< 5 mg/kg body weight
2-11 yrs:	< 2.5 mg/kg body weight
< 2 yrs:	< 1.25 mg/kg body weight
≥ 18 years (Intraoperative identification of sentinel lymph nodes and visualization of lymphatic pathways in breast cancer):	≤ 10mg

SINGLE DOSE PER MEASUREMENT IN ADULTS

Intraoperative identification of sentinel lymph nodes and visualisation of lymphatic pathways in breast cancer regardless of bodyweight:****

- 5 - 10 mg per injection (intradermal, subcutaneous or peritumoral).
- The volume per injection should not exceed 2mL.

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

** Excluding Germany & Spain

*** Adults only - Germany & Spain

**** Registered in some European countries & UK only

