Diagnostic Green

Revolutionise Animal Health

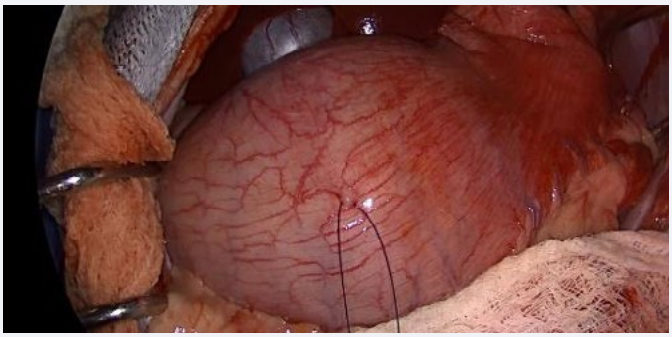
with Fluorescence Guided Surgery

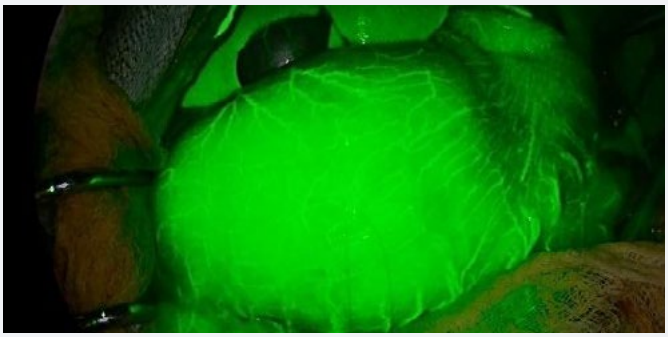
www.diagnosticgreen.com

Diagnostic Green

PRECISION • SAFETY • SUCCESS

Verdye (Indocyanine Green, ICG) is the world's leading fluorescence imaging product trusted by surgeons to visualise fluorescence and guide surgical and mapping procedures. Approved for use in humans, Verdye is available for use in animals through the EU 'Cascade' Directive[1].





Images courtesy of Jeffrey J. Runge DVM, DACVS ACVS Founding Fellow, Minimally Invasive Surgery

WHAT IS FLUORESCENCE-GUIDED SURGERY?

Fluorescence-guided surgery is an innovative technique that uses fluorescent imaging to enhance the precision of surgical procedures in animals. It allows surgeons to operate with more information and therefore with more precision.

KEY BENEFITS OF FLUORESCENCE

Improved Vascular Visualisation:

Surgeons can use ICG to better visualise blood flow and identify areas of poor perfusion, thus helping to reduce anastomotic leaks during surgery.

Real-time Imaging:

Fluorescence imaging provides real-time feedback to surgeons during the procedure, allowing them to make immediate decisions based on the visual information they receive. This can be particularly useful for identifying hidden or hard-to-see structures.

Reduced Risk of Potential Complications:

By providing better visibility and precision, fluorescence-guided surgery may reduce the risk of damaging critical structures or causing complications during the procedure. This may lead to shorter recovery times and better outcomes.

Allow for use of Minimally Invasive Surgery:

Fluorescence can be used in minimally invasive procedures such as laparoscopic or robotic surgery to improve the surgeon's ability to locate tissues and anatomical structures with greater precision.

While use of ICG in animals have been limited to date, studies have highlighted a number of potential uses of fluorescence in companion and large animals including tumour identification, lymph node mapping, cardiac output and ocular examinations[5].

[1]Articles 112, 113 and 114 of European Regulation 2019/6 (the so-called 'cascade' provisions), when a suitable veterinary medicinal product is not available in this country, veterinary practitioners are entitled to use certain human medicines under particular circumstances. https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019R0006

[2]Intraoperative near-infrared imaging can identify canine mammary tumors, a spontaneously occurring, large animal model of human breast cancer. Newton A, et al., PLoS One. 2020 Jun 17;15(6):e0234791. doi: 10.1371/journal.pone.0234791

[3]Evaluating the Feasibility and Efficacy of a Dual-Modality Nanoparticle Contrast Agent (Nanotrast-CF800) for Image-Guided Sentinel Lymph Node Mapping in the Oral Cavity of Healthy Dogs. Jennifer Wan et al., Front Vet Sci, 2021 Sep 23:8:721003. doi: 10.3389/fvets.2021.721003

[4]Cardiac output technologies with special reference to the horse. Kevin T T Corley et al., J Vet Intern Med 2003 May-Jun;17(3):262-72. doi: 10.1111/j.1939-1676.2003.tb02447.x.

[5]Indocyanine green angiography for examining the normal ocular fundus in dogs. Shinsuke Wakaiki et al., J Vet Med Sci, 2007 May;69(5):465-70. doi: 10.1292/jvms.69.465.

Verdye (Indocyanine Green, ICG) key features and Indications for use

KEY FEATURES

Well tolerated, excellent safety profile

Cleared exclusively through the liver; half life 3-4 minutes

Rapidly binds to plasma proteins; rapid visualisation

Undergoes no significant extrahepatic or enterohepatic circulation

APPROVED INDICATIONS (FOR HUMAN USE)

Perfusion Assessment

- measurement of cardiac, circulatory and micro-circulatory diagnostics including perfusion

Liver Function Diagnostics

- Measurement of excretory function of the liver

Ophthalmic Angiography Diagnostics

- Measurement of perfusion of the choroid

RECONSTITUTION

Verdye powder should be reconstituted immediately prior to use by adding 5mL sterile water for injection to the vial containing 25mg of active substance, which is a concentration of 5mg/mL (0.5% w/v). Visually inspect the reconstituted solution. Only use clear solutions free from visible particles. Verdye is a sterile product, intended for single use only.

ADMINISTRATION AND DOSAGE

- Diagnostic procedures with Verdye should be performed under the supervision of a veterinary surgeon
- Verdye is intended for intravenous injection via an injection needle, a central or peripheral catheter or cardiac catheter
- Verdye binds to plasma proteins and quickly circulates, enabling image capture within minutes.
- To view fluorescence, a Near Infra-Red (NIR) camera is required

VERDYE PRESCRIBING INFORMATION

Name of the Medicinal Product Verdye 5 mg/ml Injection
25 mg / 50 mg, Powder for Solution for Injection

Pharmaceutical Form
Powder for Solution for Injection Dark-green powder

Clinical Particulars Therapeutic indications
This medicinal product is for diagnostic use only.

Diagnostic Indications

Cardiac, circulatory and micro-circulatory diagnostics:
- measurement of cardiac output and stroke volume
- measurement of circulating blood volumes
- measurement of cerebral perfusion

Liver function diagnostics:
- measurement of liver blood flow
- measurement of excretory function of the liver

Ophthalmic angiography diagnostics:
- measurement of perfusion of the choroid

Posology and method of administration

Method of administration
Before administration the powder must be reconstituted with water for injection.

Shelf Life
5 years. After reconstitution, the solution should be used immediately, protected from light.

Instructions for use and handling
This medicinal product should be reconstituted immediately prior to use. This medicinal product is reconstituted by addition of 5 ml water for injections to the vial containing 25 mg of active substance or 10 ml water for injections to the vial con-taining 50 mg of active substance, respectively, giving in both cases a dark-green solution for injection with a concentration of 5 mg/ml (0.5 % w/v). If an incompatibility is noted in the form of unclear solution then the reconstituted solution should be discarded. Visually inspect the reconstituted solution. Only use clear solutions free from visible particles. This medicinal product is for single use only.

The reconstituted solution is clear and free from visible particles.

Diagnostic procedures with Verdye should be performed under the supervision of a physician. Verdye is intended for intravenous injection via an injection needle, a central or peripheral catheter or cardiac catheter.

The administration and site of Verdye are of critical importance for the quality of the measurements. In principle, for obtaining optimal quality first pass indicator dilution curves, the injection should be as close as possible to the vascular bed, organ or tissue of interest.

On peripheral injection the injection should be made immediately after application of tourniquet and the arm should be raised after release of tourniquet. This ensures rapid transport of the dye from the site of injection and peripheral injection is then practically equivalent to central venous injection.

Dosage
Single dose per measurement in adults, elderly, children:
Cardiac, circulatory, micro-circulatory and tissue perfusion **diagnostics** as well as **cerebral blood flow**: 0.1 to 0.3 mg/kg body weight as bolus injection
Liver function diagnostics: 0.25 – 0.5 mg/kg body weight as bolus injection
Ophthalmic angiography: 0.1 to 0.3 mg/kg body weight as bolus injection
Total daily dose:
Adults, elderly, adolescents 11-18 years:
The total daily dose of Verdye should be kept below 5 mg/kg body weight.
Children 2 – 11 years:
The total daily dose should be kept below 2.5 mg/kg body weight.
Children 0 - 2 years:
The total daily dose should be kept below 1.25 mg/kg body weight.

Contraindications
Verdye is contraindicated for safety reasons in:
- patients with hypersensitivity to indocyanine green or to sodium iodide unless special precautions are taken,
- patients with hypersensitivity to iodine,
- patients with hyper-thyroidism, patients with autonomic thyroid adenomas
- as in-vitro experiments have shown that indocyanine green displaces bilirubin from its protein binding, Verdye should not be used in premature infants or neonates in whom an exchange transfusion is indicated due to of hyperbilirubinemia,
- if injection of Verdye was poorly tolerated in the past it must not be used again, since severe anaphylactic reactions might occur.

For full prescribing information go to www.diagnosticgreen.com

This flyer is for informational purposes only and does not constitute medical advice. Please consult a qualified veterinarian for your animal's specific healthcare needs.

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