

Diagnostic  
**Green**

Indocyanine Green for Injection, USP  
**Ophthalmology Focus**



[www.diagnosticgreen.com](http://www.diagnosticgreen.com)

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

Indocyanine Green Angiography (ICGA) is the gold standard in diagnosing a number of serious eye conditions and is a key diagnostic tool used by ophthalmology specialists worldwide. ICGA is particularly useful in the differential diagnosis of Polypoidal Choroidal Vasculopathy (PCV), Central Serous Chorioretinopathy (CSCR), and Retinal Angiomatous Proliferation (RAP), which can be misdiagnosed as nAMD (Neovascular Age-related Macular Degeneration)<sup>1</sup>.

### INDOCYANINE GREEN FOR INJECTION, USP (ICG)

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**Indocyanine Green for Injection (ICG) is a tricarboyanine dye with both hydrophilic and lipophilic properties.**

The retention of ICG in the fenestrated choroidal circulation, combined with its low permeability, makes ICG angiography ideal for viewing the choroidal blood vessels. Once injected, Indocyanine Green for Injection, USP, binds to plasma proteins and quickly circulates to the choroid layer, delineating the choroidal veins within 15-20 secs.

Indocyanine Green for Injection, USP, is cleared exclusively through the liver and then excreted through the bile. It does not undergo metabolism. Indocyanine Green for Injection, USP, has an excellent safety profile and adverse reactions occur very rarely (<1/10,000). Using ICGA at initial presentation helps identify disorders of the choroidal circulation, allowing differential treatment approaches that may improve outcomes and safety for patients.

### INDOCYANINE GREEN FOR INJECTION, USP, IS COMMONLY USED FOR:

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- ⦿ Investigation of complex posterior uveitis and white dot syndromes
- ⦿ Assessment of patients with “wet” AMD where the presence of polypoidal choroidal vasculopathy (PCV) is in question
- ⦿ The assessment of choroidal hyperpermeability in patients with central serous chorioretinopathy

## “ICG imaging is an essential requirement for specialised retinal clinics at tertiary referral hospital eye services”

THE ROYAL COLLEGE OF OPHTHALMOLOGISTS<sup>2</sup>

### INDICATIONS FOR ICG ANGIOGRAPHY INCLUDE:

- ⊙ Choroidal Neovascularization (CNV)
- ⊙ Pigment Epithelial Detachment
- ⊙ Polypoidal Choroidal Vasculopathy
- ⊙ Retinal Angiomatous Proliferation (RAP)
- ⊙ Central Serous Chorioretinopathy (CSCR)
- ⊙ Intraocular Tumors
- ⊙ Choroidal Inflammatory Conditions

### ICGA VERSUS OCTA:

ICGA and OCTA (Optical Coherence Tomographic Angiography) are useful tools when diagnosing a number of serious eye conditions. Below are some of the advantages of ICGA and limitations associated with OCTA including the determination of accurate visualization of neovascularization.

ICGA	OCTA
ICGA fluorescence can penetrate blood, fluid and retinal pigment epithelium to reveal underlying abnormalities of the inner choroidal vasculature and is essential for making a definitive diagnosis of PCV.	Extremely motion sensitive, requiring a patient to fixate on precise point for several seconds. Patient compliance required, which is often difficult, particularly for older patients.
Excellent visualisation within minutes, of the medium & large choroidal vessels.	OCTA takes more time than structural scans and requires trade-offs in flow resolution, scan quality and speed.
ICGA is beneficial in the differential diagnosis of PCV, Chronic CSC, and RAP.	Limited field of view leading to a greater likelihood that lesions may be missed.
ICGA has been shown to optimize detection of capillary macro aneurysms in longstanding diabetic macular edema (DME) or retinal vein occlusion (RVO).	Failure to recognize OCTA Projection Artifact (blood vessels seem at erroneous location), may lead to inaccurate clinical assessment.
A recent study demonstrated that late leakage in ICGA occurred in all RAP cases <sup>3</sup> .	Image processing for OCTA can alter blood vessel appearance through segmentation defects, and image display software can lead to false impressions of vessel location and density.
Duration of ICGA procedure only 15-20mins, very quick analysis.	The analysis of these images is time-consuming - may involve many hours of post hoc manual segmentation work, which may be difficult to accommodate during daily medical work routines.

### HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use Indocyanine Green for Injection USP safely and effectively. See full prescribing information for Indocyanine Green for Injection USP.

For Intravenous Injection - Initial U.S. Approval: 1959

### INDICATIONS AND USAGE

Indocyanine Green for Injection USP a tricarboyanine dye, is indicated:

- For determining cardiac output, hepatic function and liver blood flow.
- For ophthalmic angiography.

### DOSAGE AND ADMINISTRATION

#### Indicator-Dilution Studies.

Under sterile conditions, the Indocyanine Green for Injection USP powder should be dissolved with the Sterile Water for Injection, USP provided and the solution used within 6 hours after it is prepared. The usual doses of Indocyanine Green for Injection USP for dilution curves are: Adults 5.0 mg, Children - 2.5 mg, and Infants - 1.25 mg.

#### Hepatic Function Studies.

Under sterile conditions, the Indocyanine Green for Injection USP powder should be dissolved with the Sterile Water for Injection, USP provided. The patient should be weighed and the dosage calculated on the basis of 0.5 mg/kg of body weight. Exactly 5 mL of Sterile Water for Injection, USP should be added to the 25 mg vial giving 5 mg of dye per mL of solution.

#### Ophthalmic Angiography Studies.

Dosages up to 40 mg Indocyanine Green for Injection USP dye in 2 mL of Sterile Water for Injection, USP should be administered. A 5 mL bolus of normal saline should immediately follow the injection of the dye.

### DOSAGE FORMS AND STRENGTHS

Indocyanine Green for Injection USP is a sterile, lyophilized green powder containing 25 mg of indocyanine green with no more than 5% sodium iodide.

### 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

- Deaths due to anaphylaxis have been reported following Indocyanine Green for Injection USP administration during cardiac catheterization.
- Indocyanine Green for Injection USP is unstable in aqueous solution and must be used within 6 hours.
- Radioactive iodine uptake studies should not be performed for at least a week following the use of Indocyanine Green for Injection USP.

### ADVERSE REACTIONS

Most common adverse reactions are anaphylactic or urticarial reactions. These have been reported in patients with and without a history of allergy to iodides.

To report SUSPECTED ADVERSE REACTIONS, contact Diagnostic Green LLC at 1-844-424-3784 (1-844-ICG-DRUG) or e-mail: [drugsafety@diagnosticgreen.com](mailto:drugsafety@diagnosticgreen.com); or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

### DRUG INTERACTIONS

Products containing sodium bisulfite reduce the absorption peak of Indocyanine Green for Injection USP in blood.

**For full prescribing information go to [www.diagnosticgreen.com](http://www.diagnosticgreen.com)**

### REFERENCES

<sup>1</sup>Amoaku WM, Chakravarthy U, Gale R, Gavin M, Ghanchi F, Gibson J et al. Defining response to anti VEGF therapies in neovascular AMD. *Eye (London)* 2015.

<sup>2</sup>Ophthalmic Services Guidance Ophthalmic Imaging, November 2016, The Royal College of Ophthalmologists 2016.

<sup>3</sup>Ravera V, et al.. RETINAL ANGIOMATOUS PROLIFERATION DIAGNOSIS: A Multiimaging Approach. *Retina*. 2016;36(12):2274–2281.