Indocyanine Green for Injection, USP

FULL PRESCRIBING INFORMATION

INDICATIONS AND USAGE

Indocyanine Green for Injection USP (Indocyanine Green for Injection USP) is indicated:

• For determining cardiac output, hepatic function and blood flow, hepatic function, hepatic clearance, hepatic function and liver blood flow, hepatic function studies, and hepatic function and liver blood flow.

• For hepatic function studies.

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DOSAGE AND ADMINISTRATION

1. Indicator-Dilution Studies

The dosage administered must be the same as the dye concentration added to the test animal or patient. The dye concentration must be halved by diluting the stock solution with distilled water. The dye solution is made by accurately diluting 1 mL of the 2.5 mg/mL dye with 7 mL of distilled water. This dye solution is then successively halved by diluting 1 mL of this concentration with 2 mL of a 2.5 mg/mL dye solution. This dye solution is then successively halved by diluting 1 mL of the 25 mg/mL dye solution with 7 mL of distilled water. This dilution curve, 1 mL of the 25 mg/mL dye is then added to the 25 mg vial giving 5 mg of dye per mL.

Children - 2.5 mg, and Infants - 1.25 mg.

2.1 Indicator-Dilution Studies

To quantitate the dilution of the dye in blood, the dye is introduced into the vascular system of the subject. A recording instrument (oximeter or densitometer) is attached to selected sites in the vascular system. A known weight of dye is injected as a single bolus injection and then the dye concentration versus optical density is shown. The normal subject then has a stable measurement of hepatic retention which can be read from this plot.

The patient should be studied in a fasting, basal state. A dosage of 0.5 mg/kg of body weight should be administered. Any 1 to 2 mL of normal saline, should immediately follow the injection of the dye.

OSAGE FORMS AND STRENGTHS

Indocyanine Green for Injection USP is sterile and is available in 25 mg vials.

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FACTORS AFFECTING HEPAIC FUNCTION

The patient should be weighed and the dosage calculated on the basis of 0.5 mg/kg of body weight. The patient should be weighed and the dosage calculated on the basis of 0.5 mg/kg of body weight. The patient should be weighed and the dosage calculated on the basis of 0.5 mg/kg of body weight. The patient should be weighed and the dosage calculated on the basis of 0.5 mg/kg of body weight.

Dosages up to 40 mg Indocyanine Green for Injection USP should be dissolved in 250 mL of isotonic saline solution. Indocyanine Green for Injection USP can be used to detect drug-induced alterations of hepatic function in patients with and without a history of allergy to the dye. Use of the dye should be administered. A 5 mL bolus of normal saline should immediately follow the injection of the dye.

DOSAGE AND FORM STRENGTHS

Indocyanine Green for Injection USP is a sterile, isotonic solution of Indocyanine Green for Injection USP, USP with more than 5% sodium chloride.

HIGHLIGHTS OF PRESCRIBING INFORMATION

Indocyanine Green for Injection USP contains sodium iodide. (3)

Radioactive iodine uptake studies should not be performed in patients with and without a history of allergy to the dye. (4)

The dye should be used in detecting drug-induced alterations of hepatic function and in the absence of extra-hepatic removal, Indocyanine Green for Injection USP was found to be suited for serial study of severe chronic liver disease and hepatic clearance of Indocyanine Green for Injection USP is being used in the determination of cardiac output, blood volume and hepatic and cardiac output.

Photometric method - Calibration of Ear Densitometer

Ear densitometry has also been used and makes it possible to monitor the appearance of the dye in blood and to provide a stable measurement of hepatic retention. For calibration, an ear densitometer which has been calibrated is used. This reference solution and spectrophotometric analysis of blood samples for calibration. For the reference solution, a 1:1000 dilution of Indocyanine Green for Injection USP is used. This device permits simultaneous measurement of cardiac output, blood volume and makes it possible to monitor the appearance of the dye in blood.

Ear oximetry has also been used and makes it possible to monitor the appearance of the dye in blood and to provide a stable measurement of hepatic retention. For calibration, an ear densitometer which has been calibrated is used. This reference solution and spectrophotometric analysis of blood samples for calibration. For the reference solution, a 1:1000 dilution of Indocyanine Green for Injection USP is used. This device permits simultaneous measurement of cardiac output, blood volume and makes it possible to monitor the appearance of the dye in blood. Photometric method - Measurement of cardiac output, blood volume and hepatic retention.

Dosage and administration of 0.5 mg/kg of body weight should be administered. Any 1 to 2 mL of normal saline should immediately follow the injection of the dye. Photosensitizing properties of Indocyanine Green for Injection USP....
Indocyanine Green for Injection USP is a sterile, lyophilized green powder containing 25 mg of indocyanine green with no more than 5% sodium iodide and should be used with caution in patients with a history of allergic reactions to Indocyanine Green for Injection USP. It is also not known whether Indocyanine Green for Injection USP can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Indocyanine Green for Injection USP can cause fetal harm when administered to a nursing woman. It is not known whether this drug is excreted in human milk, so breast-feeding should be avoided.

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