DOSEAGE AND ADMINISTRATION

Indocyanine Green for Injection USP

Under sterile conditions, the Indocyanine Green for Injection USP powder should be dissolved under sterile conditions in Sterile Water for Injection, USP provided and the solution used within 6 hours after reconstitution. Theoretical dosages for adults and children are as follows:

<table>
<thead>
<tr>
<th>Age</th>
<th>Indocyanine Green for Injection USP (mg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adults</td>
<td>5.0 mg (based on calculation of 0.5 mg/kg)</td>
</tr>
<tr>
<td>Children</td>
<td>1.25 mg (based on calculation of 0.5 mg/kg)</td>
</tr>
<tr>
<td>Newborns</td>
<td>0.625 mg (based on calculation of 0.5 mg/kg)</td>
</tr>
</tbody>
</table>

ADVERSE REACTIONS

The most common adverse reactions are anaphylactic and anaphylactoid reactions, including urticaria, angioedema, hypotension, and Tachycardia. These have been reported with the use of Indocyanine Green for Injection USP in patients with and without a history of allergy to the product. Patients should be observed for these reactions during and for at least a week following the use of Indocyanine Green for Injection USP.

ADVERSE REACTIONS

Most common adverse reactions are anaphylaxis, anaphylactoid reactions (including urticaria, angioedema, hypotension, and tachycardia), and a decrease in blood pressure.

5.3 Ocular Use

Indocyanine Green for Injection USP is indicated for the dye to be administered in ophthalmic angiography in a 5 mL bolus of normal saline, unless otherwise indicated in this section.

ADVERSE REACTIONS

Most common adverse reactions are anaphylaxis, anaphylactoid reactions (including urticaria, angioedema, hypotension, and tachycardia), and a decrease in blood pressure.

DIAGNOSTIC GREEN GmbH

38146 GELSENKIRCHEN, GERMANY

Indocyanine Green for Injection USP

The product contains indocyanine green dye and must be used within 6 hours after reconstitution.

6. USE IN SPECIFIC POPULATIONS

6.1 Pregnancy

Indocyanine Green for Injection USP is contraindicated in women who are pregnant. There are no adequate and well-controlled studies in pregnant women. If Indocyanine Green for Injection USP is given to a pregnant woman, or if the patient becomes pregnant while receiving the drug, the patient should be apprised of the potential hazard to the fetus. Women of childbearing potential should be warned about the possible hazards of the drug to the fetus.

6.2 Nursing Mothers

Indocyanine Green for Injection USP is contraindicated in nursing mothers. The product contains indocyanine green dye and should not be used by nursing mothers.

6.3 Children

Indocyanine Green for Injection USP is not recommended for use in children.

6.4 Adolescents

Indocyanine Green for Injection USP is not recommended for use in adolescents.

6.5 Elderly Patients

Indocyanine Green for Injection USP is not recommended for use in elderly patients.

6.6 Renal Impairment

Indocyanine Green for Injection USP is not recommended for use in patients with renal impairment.

6.7 Hepatic Impairment

Indocyanine Green for Injection USP is not recommended for use in patients with hepatic impairment.

6.8 Pregnancy/Breastfeeding

Indocyanine Green for Injection USP is not recommended for use in pregnant or breastfeeding women.

7. DRUG INTERACTIONS

Indocyanine Green for Injection USP is not recommended for use in combination with other drugs.

8. USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Indocyanine Green for Injection USP is contraindicated in women who are pregnant. There are no adequate and well-controlled studies in pregnant women. If Indocyanine Green for Injection USP is given to a pregnant woman, or if the patient becomes pregnant while receiving the drug, the patient should be apprised of the potential hazard to the fetus. Women of childbearing potential should be warned about the possible hazards of the drug to the fetus. Women who are pregnant or breast-feeding should not use Indocyanine Green for Injection USP.

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Indocyanine Green for Injection USP is not recommended for use in pregnant or breastfeeding women.

9. DRUG INTERACTIONS

Indocyanine Green for Injection USP is not recommended for use in combination with other drugs.

10. OVERDOSAGE

In the event of an overdosage, the patient should be observed for the potential hazards of the drug to the fetus. Women of childbearing potential should be warned about the possible hazards of the drug to the fetus.

11. HOW SUPPLIED/STORAGE AND HANDLING

Indocyanine Green for Injection USP is supplied as a lyophilized green powder containing 25 mg of indocyanine green dye. The product is supplied in boxes of 6 vials. Each vial contains 2.5 mg of Indocyanine Green for Injection USP and 5 mL of Sterile Water for Injection, USP, totaling 7.5 mL per vial. The solution is used within 6 hours after reconstitution. The product contains indocyanine green dye and must be used within 6 hours after reconstitution.

12. CLINICAL PHARMACOLOGY

12.1 Pharmacokinetics

Indocyanine Green for Injection USP is indicated for the dye to be administered in ophthalmic angiography in a 5 mL bolus of normal saline, unless otherwise indicated in this section.

12.2 Pharmacokinetics

Indocyanine Green for Injection USP is indicated for the dye to be administered in ophthalmic angiography in a 5 mL bolus of normal saline, unless otherwise indicated in this section.

12.3 Pharmacodynamics

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12.4 Pharmacodynamics

Indocyanine Green for Injection USP is indicated for the dye to be administered in ophthalmic angiography in a 5 mL bolus of normal saline, unless otherwise indicated in this section.
Pipette 1 mL of the serum into a microcuvette.

**DILUTION CURVES**

If a precipitate is present, discard the solution. If a precipitate is not present, dilute the solution with the patient's normal serum as well as in the performance of the dye solution as well as in the performance of the dye solution.

**DETERMINATION OF DISAPPEARANCE RATES BY UV**

*To calculate the percentage retention, 4, and draw a line connecting this point with the zero coordinates.*

4. The percentage retention is calculated as:

\[
\text{Percentage Retention} = \frac{\text{optical density of this solution}}{\text{optical density of the concentrated sample}} \times 100
\]

**DESCRIPTION**

Indocyanine Green for Injection USP is a sterile, lyophilized green powder containing 25 mg of 1,1-dimethyl-3-(4-sulfobutyl)-2\(\text{H}\) indolium, 2-[7-(1,3-dihydro-2\(\text{H}\) indol-2-yl) benzene]-4-(2H)-benzimidazole, sodium salt. It is packaged with Sterile Water for Injection, USP, 10 mL fill in 10 mL Sterile Water for Injection USP vial. 25 mg fill in 25 mL vial.

**INDICATIONS**

Indocyanine Green for Injection USP is a sterile, lyophilized green powder containing 25 mg of indocyanine green as a sterile lyophilized powder for use in percutaneous coronary angiography studies.

**CLINICAL PHARMACOLOGY**

**DOSAGE AND ADMINISTRATION**

**Hepatic Function Studies**

Indocyanine Green for Injection USP is administered as a single bolus injection of 5 mg/liter, the standard for 50% disappearance at 805 nm using the patient's normal serum as the control. This corresponds to a dose of 0.5 mg/kg which is recommended as the upper limit of the therapeutic dose range.

**Hepatic Function Studies**

Indocyanine Green for Injection USP is a helpful index of hepatic function. The peak absorption and emission of Indocyanine Green for Injection USP is 700 nm and 800 nm, respectively. The chemical name for Indocyanine Green for Injection USP is 1,1-dimethyl-3-(4-sulfobutyl)-2\(\text{H}\) indolium, 2-[7-(1,3-dihydro-2\(\text{H}\) indol-2-yl) benzene]-4-(2H)-benzimidazole, sodium salt. It is packaged with Sterile Water for Injection, USP, 10 mL fill in 10 mL Sterile Water for Injection USP vial. 25 mg fill in 25 mL vial.

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