





















# NEW ZEALAND DATA SHEET

## **Elimination**

Indocyanine green is taken up from the plasma almost exclusively by the hepatic parenchymal cells and is secreted entirely into the bile.

The plasma fractional disappearance rate at a 0.5 mg/kg dose has been reported to be significantly greater in women than in men, although there was no significant difference in the calculated value for clearance.

## **5.3 Preclinical safety data**

No studies have been performed to evaluate the carcinogenicity, mutagenicity or impairment of fertility with indocyanine green.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Sodium iodide

Sodium hydroxide (pH adjustment)

Hydrochloric acid (pH adjustment)

Water for Injections

### **6.2 Incompatibilities**

SPY AGENT GREEN must not be mixed with any other medicinal products, except those mentioned in **6.6 Special precautions for disposal and other handling**.

### **6.3 Shelf life**

5 years

Use in one patient on one occasion only.

SPY AGENT GREEN contains no antimicrobial preservative. To reduce microbiological hazard, use reconstituted SPY AGENT GREEN as soon as practicable after preparation. If storage is necessary, hold at room temperature (Below 25°C) and use within 6 hours.

### **6.4 Special precautions for storage**

Store below 25°C.

Do not use after the expiry date.

For storage conditions after reconstitution of SPY AGENT GREEN, see **6.3 Shelf life**.

### **6.5 Nature and contents of container and special equipment for use**

Powder for injection, in a glass vial with a rubber stopper and aluminium seal.

Packs contain 1 vial or 6 vials.

SPY AGENT GREEN may be used with an appropriate Stryker Camera System that is specifically intended for fluorescence imaging with indocyanine green.

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### 6.6 Special precautions for disposal and other handling

SPY AGENT GREEN is for intravenous and interstitial administration.

Once a vial has been opened and the powder reconstituted (with Water for Injections), the contents must be used within 6 hours.

Any unused portion should be discarded appropriately.

#### Reconstitution Instructions

Prepare SPY AGENT GREEN under sterile conditions prior to surgery. SPY AGENT GREEN is reconstituted with 10 mL or 20 mL of sterile Water for Injections prior to use to form a 2.5 mg/mL or 1.25 mg/mL solution of indocyanine green. The reconstitution volume is dictated by the type of imaging to be undertaken. Refer below for further instructions.

Inspect the reconstituted solution for particulate matter. The reconstituted solution should be a clear, green solution. If precipitation is noted, continue to gently swirl the vial until SPY AGENT GREEN is dissolved. If precipitation persists, discard and prepare a new vial.

#### Visualization of Vessels, Blood Flow, and Tissue Perfusion and Visualization of Extrahepatic Biliary Ducts

Dissolve SPY AGENT GREEN with 10 mL Sterile Water for Injection to form a concentration of 2.5 mg indocyanine green/mL.

#### Visualization of Lymph Nodes and Lymphatic Vessels During Lymphatic Mapping

Dissolve SPY AGENT GREEN with 20 mL Sterile Water for Injection to form a concentration of 1.25 mg indocyanine green/mL.

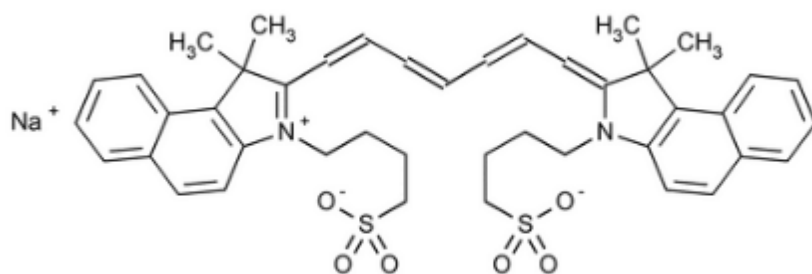
### 6.7 Physicochemical properties

SPY AGENT GREEN (indocyanine green for injection, USP) is a water soluble, optical imaging agent which is reconstituted with sterile Water for Injection, for intravenous or interstitial use. Each vial contains a sterile, lyophilized green powder containing 25 mg of indocyanine green with not more than 5% sodium iodide.

The chemical name for Indocyanine Green is 1 HBenzo[e]indolium, 2-[7-[1,3-dihydro-1,1-dimethyl-3-(4-sulfobutyl)-2H-benz[e] indol-2-ylidene]-1,3,5-heptatrienyl]-1,1-dimethyl-3-(4-sulfobutyl)-, hydroxide, inner salt, sodium salt.

Molecular Formula:  $C_{43}H_{47}N_2NaO_6S_2$ ; Molecular Mass: 774.96 g/mol, with the following structural formula:

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Indocyanine green has a peak spectral absorption at 800 nm. SPY AGENT GREEN has a pH of 5.5 to 7.5 when reconstituted with sterile Water for Injection.

CAS Number: 3599-32-4

### **7 MEDICINE SCHEDULE**

General Sale Medicine

### **8 SPONSOR**

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### **9 DATE OF FIRST APPROVAL**

Not yet advised

### **10 DATE OF REVISION OF THE TEXT**

April 2020.

### **SUMMARY TABLE OF CHANGES**

Not applicable

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