

**INDIGO CARMINE
INJECTION**
(Indigotindisulfonate Sodium
Injection, USP)
Rx Only



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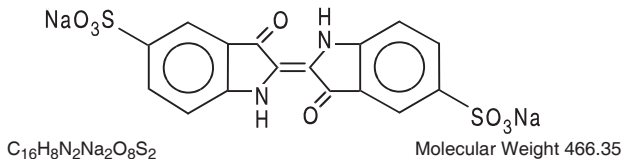


DESCRIPTION:

Each mL contains: Indigotindisulfonate Sodium 8 mg, Water for Injection q.s. pH adjusted, when necessary, with Citric Acid and/or Sodium Citrate. Sterile, nonpyrogenic.

Sufficient Indigo Carmine is contained in each 5 mL ampule to permit accurate withdrawal and administration of the full dose. It gives a deep blue solution when dissolved in water.

The structural formula is:



CLINICAL PHARMACOLOGY:

Indigo Carmine is excreted largely by the kidneys, retaining its blue color during passage through the body.

Elimination of the dye begins soon after injection, appearing in the urine within 10 minutes in average cases. The biological half-life is 4 to 5 minutes following intravenous injection. Larger quantities are necessary when intramuscular injection is employed. Appearance time and elimination are delayed following intramuscular injection.

INDICATIONS:

Originally employed as a kidney function test, the chief application of Indigo Carmine at present is localizing ureteral orifices during cystoscopy and ureteral catheterization.

CONTRAINDICATIONS:

Indigo Carmine is contraindicated in patients who have previously experienced an adverse reaction following its use.

WARNINGS:

An occasional idiosyncratic drug reaction may occur. A mild pressor effect may be encountered in some patients.

PRECAUTIONS:

Pregnancy:

Animal Reproduction studies have not been conducted with indigotindisulfonate sodium injection. It is also not known whether indigotindisulfonate sodium injection can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Indigotindisulfonate sodium injection should be given to a pregnant woman only if clearly needed.

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It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Indigo Carmine is administered to a nursing woman.

ADVERSE REACTIONS:

See **WARNINGS**.

DRUG ABUSE AND DEPENDENCE:

Indigo Carmine is not a controlled substance listed in any of the Drug Enforcement Administration Schedules. Its use is not known to lead to dependence or abuse.

OVERDOSE:

There are no data available describing the signs, symptoms or laboratory findings accompanying overdosage.

No discernible symptoms of toxicity have been observed in mice with an intravenous dose of 200 mg/kg. After intravenous administration the LD₅₀ was established at 300 mg/kg in mice.

DOSAGE AND ADMINISTRATION:

Indigo Carmine solution is injected either by the intravenous or intramuscular route, and its appearance at the ureteral orifices is watched with the cystoscope in place. The intravenous method is preferred because a 5 mL injection is sufficient. A lesser dosage in infants, children and underweight patients will prevent skin coloration.

Since precipitation of indigotindisulfonate sodium may occur, Indigo Carmine Solution must not be diluted prior to injection or injected with infusion assemblies which were used with other solutions.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

NOTE: *Since Indigo Carmine is a dark blue solution, visual inspection for particulate matter prior to use may not be possible. To ensure that the withdrawn solution contains no particulates, 5 micron filter straws/filter needles must be used when withdrawing contents of ampules¹. The 5 micron nylon mesh filter is suitable for withdrawing the drug product, Indigo Carmine.*

¹ASHP Guidelines on Compounding Sterile Preparations

PROTECT FROM LIGHT. Indigo Carmine should be stored in the dark, away from direct light, preferably in the original package.

Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F) (See USP Controlled Room Temperature).

HOW SUPPLIED: Indigo Carmine Injection

NDC 0517-0375-05

5 mL ampules

packaged in boxes of 5

IN0375
Rev. 2/17
MG #14082

**AMERICAN
REGENT, INC.**
SHIRLEY, NY 11967