INDIGO CARMINE INJECTION (Indigotindisulfonate Sodium Injection, USP)

Rx Only

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:

![Structural formula of Indigo Carmine]

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 AND USAGE

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.

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.

OVERDOSAGE
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.

¹ ASHP 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

AMERICAN
REGENT, INC.
SHIRLEY, NY 11967

IN0375
Rev. 2/17

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL
PRINCIPAL DISPLAY PANEL - 5 mL Container

NDC 0517-0375-01

INDIGO CARMINE
INJECTION

(Indigotindisulfonate Sodium Injection, USP)
0.8% Solution

5 mL AMPULE
FOR IV OR IM USE

Rx Only

AMERICAN
REGENT, INC.
SHIRLEY, NY 11967
INDIGO CARMINE INJECTION
(Indigotindisulfonate Sodium Injection, USP)
0.8% Solution

5 mL AMPULES
FOR IV OR IM USE
Rx Only

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.

WARNING: PROTECT FROM LIGHT. 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).
Directions for Use: See Package Insert.

AMERICAN REGENT, INC.
SHIRLEY, NY 11967
Rev. 2/17
INDIGO CARMINE INJECTION
(Indigotin sulfate injection, USP)
0.8% Solution
Rx Only

FOR INTRAVENOUS OR INTRAMUSCULAR USE
Each mL contains: Indigotin sulfate 8 mg, Water for Injection q.s. pH adjusted, when necessary, with Citric Acid and/or Sodium Citrate. Sterile, nonpyrogenic.

WARNING: PROTECT FROM LIGHT. Store at 20°-25°C (68°-77°F); excursions permitted to 15°-30°C (59°-86°F) (See USP Controlled Room Temperature).
Directions for Use: See Package Insert.

AMERICAN REGENCY, INC.
SHIRLEY, NY 11967

Rev. 2/17

Serialization Label
# Product Information

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<tr>
<th>Product Type</th>
<th>Item Code (Source)</th>
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<th>Route of Administration</th>
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## Active Ingredient/Active Moiety

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<tr>
<td>INDIGOTINDISULFONATE SODIUM (UNII: D3741U8K7L)</td>
<td>INDIGOTINDISULFONATE SODIUM</td>
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## Inactive Ingredients

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## Packaging

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# Marketing Information

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## Labeler

- American Regent, Inc. (002033710)

## Establishment

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<td>002033710</td>
<td>ANALYSIS(0517-0375), MANUFACTURE(0517-0375)</td>
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Revised: 12/2019