**INDIGO CARMINE- indigotindisulfonate sodium injection, solution**
**Akorn, Inc.**

*Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.*

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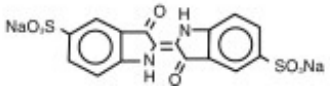
**Indigo Carmine Injection**
**(Indigotindisulfonate Sodium Injection, USP)**

$C_{16}H_8N_2Na_2O_8S_2$ Molecular Weight 466.35




**Rx only**

## DESCRIPTION:

Each mL contains:

**Active:** Indigotindisulfonate Sodium 8 mg **Inactives:** Water for injection. q.s. pH adjusted when necessary with Citric Acid and/or Sodium Citrate.

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.

## 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.

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.

**PRECAUTIONS:**

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

**Pregnancy Category C:**

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" section.

**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 $LD_{80}$ 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.

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

PROTECT FROM LIGHT

Storage: Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

**HOW SUPPLIED:**

NDC 17478-808-01

5 mL ampules packaged in boxes of 10.



Manufactured by: Akorn, Inc.

Lake Forest, IL 60045

**NOVAPLUS®**

NVIC00N Rev. 08/12

**Principal Display Panel Text for Container Label:**

NDC 17478-808-01 Rx only

INDIGO CARMINE™

Indigotindisulfonate Sodium

Injection USP, 0.8% Solution 8 mg/mL

5 mL Ampule

Sterile, nonpyrogenic solution

For Intramuscular or Intravenous Use

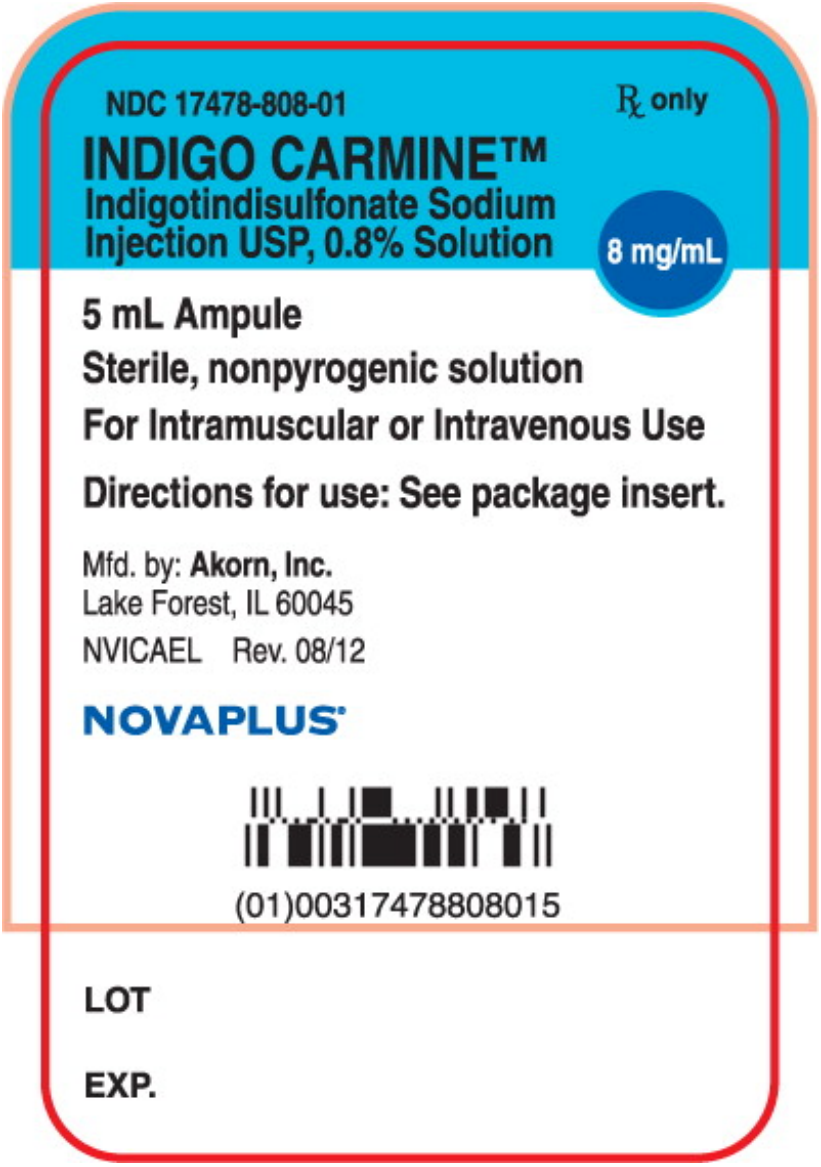
Direction for use: See package insert.

Mfd. by: Akorn, Inc.

Lake Forest, IL 60045

NVICAEL Rev. 08/12

NOVAPLUS®




**Principal Display Panel Text for Carton Label:**

NDC 17478-808-01 Rx only ®Novaplus logo

INDIGO CARMINE™

Indigotindisulfonate Sodium Injection USP, 0.8% Solution

For Intramuscular or Intravenous Use 8 mg/mL

Sterile, nonpyrogenic solution

NOVAPLUS® 10 Ampules (5 mL each)


# INDIGO CARMINE

indigotindisulfonate sodium injection, solution

## Product Information

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN PRESCRIPTION DRUG LABEL | **Item Code (Source)** | NDC:17478-808 |
| **Route of Administration** | INTRAMUSCULAR, INTRAVENOUS | **DEA Schedule** | |

## Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **Indigotindisulfonate Sodium** (INDIGOTINDISULFONIC ACID) | Indigotindisulfonate Sodium | 8 mg in 1 mL |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **Water** | |
| **Citric Acid Monohydrate** | |
| **Sodium Citrate** | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:17478-808-01 | 10 in 1 BOX | | |
| **1** | | 5 mL in 1 AMPULE | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| unapproved drug other | | 03/22/2013 | |

## Labeler - Akorn, Inc. (062649876)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Akorn, Inc | | 063434679 | PACK(17478-808), LABEL(17478-808) |

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Akorn, Inc. | | 155135783 | MANUFACTURE(17478-808), ANALYSIS(17478-808), STERILIZE(17478-808) |

Revised: 3/2013 Akorn, Inc.