INDIGO CARMINE- indigo carmine injection, solution
American Regent, 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.

INDIGO CARMINE INJECTION (Indigotindisulfonate Sodium Injection, USP)

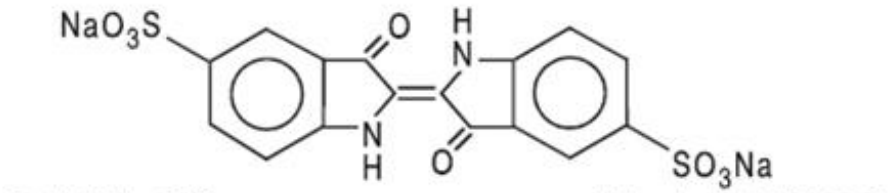
Rx Only

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:



$C_{16}H_8N_2Na_2O_8S_2$ Molecular Weight 466.35

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 LD_{50} 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 ampules[1]. 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 20º to 25º C (68º to 77º F); excursions permitted to 15º to 30º C (59º to 86º 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

PRINCIPAL DISPLAY PANEL – 5 mL Carton

INDIGO CARMINE INJECTION
(Indigotindisulfonate Sodium Injection, USP)
0.8% Solution

NDC 0517-0375-05

5 x 5 mL AMPULES

Rx Only

FOR INTRAVENOUS OR INTRAMUSCULAR USE

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

Serialization Label

INDIGO CARMINE

indigo carmine injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:0517-0375
Route of Administration	INTRAMUSCULAR, INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
INDIGOTINDISULFONATE SODIUM (UNII: D3741U8K7L) (INDIGOTINDISULFONIC ACID - UNII:X7OI7JF73P)	INDIGOTINDISULFONATE SODIUM	8 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0517-0375-05	5 in 1 BOX	09/30/1990	
1	NDC:0517-0375-01	1 mL in 1 AMPULE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		09/30/1990	

Labeler - American Regent, Inc. (002033710)

Establishment

Name	Address	ID/FEI	Business Operations
American Regent, Inc.		002033710	ANALYSIS(0517-0375) , MANUFACTURE(0517-0375)

Revised: 12/2019 American Regent, Inc.