Bludigo™
(indigotindisulfonate sodium injection, USP)

The first and only FDA-approved injectable indigo carmine diagnostic dye.

Bludigo™ (indigotindisulfonate sodium injection) is a diagnostic dye indicated for use as a visualization aid in the cystoscopic assessment of the integrity of the ureters in adults following urological and gynecological open, robotic, or endoscopic surgical procedures.

Please see Important Safety Information on reverse side.

PRODUCT NAME	PACK SIZE	THERAPEUTIC CLASS	NDC OR UPC NUMBER	ANDA/NDA#	GTIN
Bludigo™ (Indigotindisulfonate Sodium) Injection USP 0.8% (40 mg/5ml) Ampule	5 Ampules	Diagnostic Dye	81284-0315-05	216264	00381284315050

PRODUCT NAME	ABC PRODUCT NUMBER	CARDINAL PRODUCT NUMBER	MCKESSON PRODUCT NUMBER	MORRIS & DICKSON PRODUCT NUMBER
Bludigo™ (Indigotindisulfonate Sodium) Injection USP 0.8% (40 mg/5ml) Ampule	10273555	5807821	2644276	246223

PROVEPHARM

For more information or to purchase Bludigo,™ contact customer service at us-info@provepharm.com or 1-833-727-6556

provepharmusa.com

BLUDIGO™ (indigotindisulfonate sodium injection, USP)

INDICATION AND IMPORTANT SAFETY INFORMATION

INDICATION AND USAGE

BLUDIGO™ is a diagnostic dye indicated for use as a visualization aid in the cystoscopic assessment of the integrity of the ureters in adults following urological and gynecological open, robotic, or endoscopic surgical procedures.

CONTRAINDICATIONS

BLUDIGO™ is contraindicated in patients with known hypersensitivity to indigotindisulfonate or any of its components.

WARNINGS AND PRECAUTIONS

Cardiovascular Reactions: Severe or life-threatening cardiovascular reactions including cardiac arrest, arrhythmia, asystole, atrioventricular block second degree, hypotension, elevation in blood pressure, bradycardia, and tachycardia have been reported. Closely monitor blood pressure and cardiac rhythm during and following the BLUDIGO™ injection. Interrupt administration if reactions are observed.

Hypersensitivity Reactions: Serious anaphylactic reactions with hypotension, dyspnea, bronchospasm, urticaria, or erythema have been reported. Monitor patients for anaphylactic reactions and have emergency equipment and trained personnel readily available.

Interference with Oximetry Measurements: Anesthesiologists should be aware of the potential for artifactual reduction in SpO2 when anesthetized patients are administered BLUDIGO™.

USE IN SPECIFIC POPULATIONS

Renal Impairment: BLUDIGO™ is not recommended for use in patients with eGFR<30 mL/min.

Pediatric Use: The safety and effectiveness of BLUDIGO™ have not been established in pediatric patients.

Pregnancy and Lactation: Please consult the Full Prescribing Information before using BLUDIGO™ in a patient that is lactating, pregnant, or may be pregnant.

RECOMMENDED DOSAGE

The recommended dose for BLUDIGO™ is 5 mL given intravenously over 1 minute.

IMPORTANT ADMINISTRATION INSTRUCTIONS

- Monitor blood pressure and cardiac rhythm during and following the injection.
- Use immediately after opening ampoule.
- Withdraw the contents of the ampoule through a 5 micron or smaller filter straw/filter needle to ensure that the withdrawn solution contains no particulates. The withdrawn solution should be inspected visually for particulate matter and discoloration prior to administration.
- Do not administer with infusion assemblies used with other diluents or drugs.
- Discard any unused portion.

ADVERSE REACTIONS

Clinical Trial Experience: The most common adverse reactions (≥ 1%) associated with BLUDIGO™ in clincal trials were: constipation, nausea, vomiting, abdominal pain, pyrexia, ALT increase, and dysuria.

Postmarketing Experience: The following adverse reactions have been identified following the use of indigotindisulfonate sodium injection products:

- *Cardiovascular disorders:* cardiac arrest, arrhythmia, asystole, atrioventricular block second degree, hypotension, elevation in blood pressure, bradycardia, tachycardia
- *General disorders and administration site conditions:* injection site discoloration
- *Immune system disorders:* anaphylactic reactions with hypotension, dyspnea, bronchospasm, urticaria, erythema

Please see the full **Prescribing Information** for additional important safety information.

To report SUSPECTED ADVERSE REACTIONS, contact PROVEPHARM Inc at 1–833-727-6556 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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100 Springhouse Drive, Suite 105, Collegeville, PA 19426

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