Not just any blue dye.

Introducing Bludigo™ (indigotindisulfonate sodium injection, USP) the first and only FDA-approved injectable indigo carmine diagnostic dye.

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.

Its color and contrast significantly aids visualization when assessing ureter patency.

Learn more about Bludigo™ (indigotindisulfonate sodium injection, USP) at **provepharmusa.com**.

PROVEPHARM

Bludigo™
(indigotindisulfonate sodium injection, USP)

See the difference.

BLUDIGO™ (indigotindisulfonate sodium injection)
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.

Why Bludigo™?

Bludigo™ has a deep blue color that significantly aids visualization when assessing ureter patency.

In 83%

of ureter patency assessments in the Bludigo™ clinical trial, investigators reported visualizing good or striking color contrast in the jet stream.

Summary of Proportion of Responders by Ureter and Reviewer or Surgeon in Patients Receiving Bludigo™ 5 mL

The conspicuity of the urine flow from the ureteral orifices was assessed in a randomized, blinded fashion by two independent central reviewers using a 5-point scale (1 = no urine flow observed; 2 = weak urine flow, little color contrast; 3 = color contrast or significant urine flow; 4 = strong urine flow with good color contrast; and 5 = strong jet flow with striking contrast in color.)

% RESPONDER* 95% CL**	LEFT URETER (N=49)	RIGHT URETER (N=49)
Reviewer 1	63% (48%, 77%)	76% (61%, 87%)
Reviewer 2	78% (63%, 88%)	82% (68%, 91%)
Reviewer 3	71% (57%, 83%)	82% (68%, 91%)

*responder: IC conspicuity score ≥3 and difference (IC – Saline) in conspicuity score ≥1, missing data is imputed as non-responder.
** two-sided 95% confidence limits for the proportion of responder, calculated using the Clopper-Pearson (exact) method.

In 90%

of urologic and gynecologic surgical procedures (N=49) in the Bludigo™ clinical trial physicians agreed that their ability to assess ureteral patency was improved following the use of Bludigo™ compared to saline.†

†Data on file PVP-19ICO1 clinical study report.

Fast detection.

Bludigo™ is excreted in the urine quickly.

After injection, the blue color at the ureteral orifices is detectable within

4–9 minutes

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