Bludigo®
indigotindisulfonate sodium Injection, USP

FOR RELIABLE CYSTOSCOPIC ASSESSMENT OF URETER PATENCY[1]

SETTING THE BLUE STANDARD

The trusted performance of indigo carmine injection continues – as Bludigo®[a]

[a]When available, indigo carmine was considered the standard of care[2]

Study design: Bludigo® was studied in a phase 3, open-label, randomized, multicenter, parallel-group study of 118 patients. The study was composed of 3 periods: Screening (up to 30 days prior to surgery), Randomization/Dosing (Day 1), and a 30-day Safety Follow-up Period. Patients served as their own control by receiving a dose of normal saline prior to randomization, at which point patients were randomized 1:1 to receive 2.5 mL or 5 mL indigo carmine. The primary endpoint was efficacy based on a visualization conspicuity score. Efficacy was assessed using a 5-point ordinal scale measuring contrast flow. Secondary endpoints were physician satisfaction, time to visualization, and proportion of responders. No significant statistical difference was found between doses, and the 2.5 mL dose of Bludigo® is not approved or available in the United States.[3]

BLUDIGO® (indigotindisulfonate sodium injection, USP)

INDICATIONS 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.

IMPORTANT SAFETY INFORMATION

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®.

Please see the full Important Safety Information.

Don't Skip a Step: Make Detection Part of The Surgical Routine to Avoid Undiagnosed Ureteral Injuries

0.5% TO 10% OF PATIENTS UNDERGOING URETERAL PROCEDURES WILL EXPERIENCE A URETERAL INJURY[4-6]

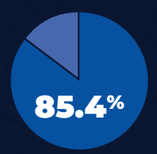
The most common injury is **iatrogenic ureteral trauma**[7]

AAGL, AUGS and AUA guidelines recommend cystoscopies to improve intraoperative identification of ureteral injury[8-11]

Proactively detecting ureteral injury by using intraoperative cystoscopy with visualization agents is a critical — yet underused — step in patient care.

Bludigo® Demonstrated Fast and Reliable Visualization of Ureter Flow

Using a five-point ordinal urine jet conspicuity score, indigo carmine was found to be significantly* superior to saline in its capacity to aid visualization[3]



85.4% of ureter patency assessments reported color contrasts in jet stream ranging from significant **3** to striking **5** [3]

89.6% of patients were defined as a responder[12,a]

FAST DETECTION
Within **4-9 minutes** post-IV injection[1]

AAGL=American Association of Gynecologic Laparoscopists; AUA=American Urological Associations; AUGS=American Urogynecologic Society; IV=intravenous.
Urine jet conspicuity score by the blinded central review process was assessed using the following 5-point ordinal scale: 1 = No jet observed; 2 = Weak jet, little color contrast; 3 = Color contrast or significant jet flow; 4 = Strong jet flow with good color contrast; 5 = Strong jet flow with striking contrast color.[3]

*An exploratory analysis showed no statistically significant difference between the 2 doses of indigo carmine in providing visualization of urine efflux.[3]
[a]A patient was considered a responder when the Bludigo® conspicuity score was ≥3 and a ≥1 increase compared with placebo.[3]

Well-Established Safety Profile

In the Bludigo® clinical trial, adverse reactions reported at ≥1% of patients receiving Bludigo® 5 mL intravenously[1a]

Adverse Reactions	Bludigo® 5 mL (N=60)
Constipation	3 (5.0%)
Nausea	2 (3.3%)
Vomiting	2 (3.3%)
Abdominal Pain	2 (3.3%)
Pyrexia	2 (3.3%)
ALT Increase	2 (3.3%)
Dysuria	1 (1.7%)

[a]At least 1 TEAE was reported for 30.0% of subjects administered the indigo carmine high dose and 43.1% of subjects administered the low dose. No TEAE was reported following saline injection but prior to indigo carmine injection. Four subjects (3.4%) experienced SAEs, none of which were considered related to indigo carmine. No deaths or TEAEs leading to discontinuation of the study or study drug were reported.[3]

ALT=alanine aminotransferase; SAE=serious adverse event; TEAE=treatment-emergent adverse event.

Provepharm is Committed to Providing a Continuous Supply of Bludigo®

Bludigo® (indigotindisulfonate sodium Injection, USP)
(40 mg/5 mL) Ampule

The recommended dose of Bludigo® is 5 mL given as an intravenous injection over 1 minute[1]

EXTENDED SHELF LIFE: 4-year stability may support efficient inventory management[13]

IMPORTANT SAFETY INFORMATION (CONT.)

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.

Please see the full Important Safety Information.

IMPORTANT SAFETY INFORMATION (CONT.)

IMPORTANT ADMINISTRATION INSTRUCTIONS

- Monitor blood pressure and cardiac rhythm during and following the injection.
- Use immediately after opening ampule.
- Withdraw the contents of the ampule 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.

Please see the full Important Safety Information.

The Bludigo® Difference

FAST DETECTION[1]
Within 4-9 minutes post-IV injection[1]

RELIABLE VISUALIZATION[10]
Deep blue color with **enhanced visualization of ureter flow**[3]

WELL-ESTABLISHED SAFETY PROFILE[1]

FDA-APPROVED INJECTABLE INDIGO CARMINE[1]
The **first and only FDA-approved** injectable indigo carmine diagnostic dye

Choose Bludigo® as your primary diagnostic dye for assessing ureter patency. Scan the QR code or visit Bludigo.com to learn more

IMPORTANT SAFETY INFORMATION (CONT.)

ADVERSE REACTIONS

Clinical Trial Experience: The most common adverse reactions (≥ 1%) associated with BLUDIGO® in clinical 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 Important Safety Information and full Prescribing Information at www.Bludigo.com.

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.

References: 1. Bludigo. Prescribing Information. Provepharm, Inc.; 2025. **2.** Doyle PJ, Duecy E, Wood R. Sodium fluorescein as an alternative to indigo carmine during intraoperative cystoscopy. *JMIG.*2015;22(3):S65.doi:10.1016/j.jmig.2014.12.147. **3.** Data on file. PVP-10ICO1 clinical study report. Newark, NJ: Provepharm, Inc.; 2025. **4.** Chalya PL, Massinde AN, Kihunrwa A, Simbila S. Iatrogenic ureteric injuries following abdomino-pelvic operations: a 10-year tertiary care hospital experience in Tanzania. *World J Emerg Surg.* 2015;10:17. Published 2015 Mar 12. doi:10.1186/s13017-015-0011-z. **5.** Vakili B, Zheng YT, Loesch H, Echols KT, Franco N, Chesson RR. Levator contraction strength and genital hiatus as risk factors for recurrent pelvic organ prolapse. *Am J Obstet Gynecol.* 2005;192(5):1592-1598. doi:10.1016/j.ajog.2004.11.022. **6.** Gilmour DT, Das S, Flowerdew G. Rates of urinary tract injury from gynecologic surgery and the role of intraoperative cystoscopy. *Obstet Gynecol.* 2006;107(6):1366-1372. doi:10.1097/01.AOG.0000220500.83528.6e. **7.** Cohen SA, Carberry CL, Smilen SW. American Urogynecologic Society Consensus Statement: Cystoscopy at the Time of Prolapse Repair. *Female Pelvic Med Reconstr Surg.* 2018;24(4):258-259. doi:10.1097/SPV.0000000000000529. **8.** Jacob GP, Vilos GA, Al Turki, et al. F. Ureteric injury during gynaecological surgery – lessons from 20 cases in Canada. *Facts Views Vis Obgyn.* 2020;12(1):31-42. **9.** Ibeanu OA, Chesson RR, Echols KT, Nieves M, Busangu F, Nolan TE. Urinary tract injury during hysterectomy based on universal cystoscopy. *Obstet Gynecol.* 2009;113(1):6-10. doi:10.1097/AOG.0b013e31818f6219. **10.** Pickett CM, Seeratan DD, Mol BWJ, et al. Surgical approach to hysterectomy for benign gynaecological disease. *Cochrane Database System Rev.* 2023;8(8):CD003677. doi:10.1002/14651858.CD003677.pub6. **11.** Vree FEM, Cohen SL, Chavan N, et al. The impact of surgeon volume on perioperative outcomes in hysterectomy. *JSLS.* 2014;18(2):174-181. doi:10.4293/108680813X13753907291594. **12.** Lepor H, Weigand L, Patel K, Du W, Gagnon S; 19IC01 Investigators. A randomized clinical trial evaluating indigo carmine as a visualization aid for evaluating ureteral patency. *Urology.* 2024;184:105-111. **13.** Data on file. Newark, NJ: Provepharm, Inc.; 2025.

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