BLUDIGO® PRODUCT FACT SHEET AND ORDERING GUIDE

Bludigo®
indigotindisulfonate sodium Injection, USP

INDICATION[1]

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.

DESCRIPTION[1]

Bludigo® is a sterile deep blue or bluish-purple diagnostic dye for intravenous use.

Each mL contains 8 mg indigotindisulfonate sodium (equivalent to 7.2 mg indigotindisulfonate) and may also contain citric acid and sodium citrate to adjust pH value between 3 and 6.5 and has an osmolality ≤ 0.05 osmol/kg.

Indigotindisulfonate sodium is also known as indigo carmine.

STORAGE REQUIREMENTS[1]

Store at 20°C to 25°C (68°F to 77°F); excursions permitted to 15°C to 30°C (59°F to 86°F).
[See USP Controlled Room Temperature]

- Store in original carton to protect from light
- Do not refrigerate or freeze
- Use immediately after opening ampule. Discard unused portion

PRODUCT INFORMATION

Product Name	Strength	Pack Size	Therapeutic Class	NDC or UPC Number	GTIN
Bludigo®	5 mL	5 Ampules	Diagnostic Dye	81284-315-05	00381284315050

WHOLESALER INFORMATION

Wholesaler Name	Product Number	Phone Number	Website
Cencora (ABC)	10273555	610-727-7000	www.amerisourcebergen.com
Cardinal	5807821	800-926-3161	www.cardinalhealth.com
McKesson	2644276	855-625-6285	www.mckesson.com
Morris & Dickson	246223	800-388-3833	www.morrisdickson.com

Available through GPO partnerships

IMPORTANT ORDERING INFORMATION: Search for and order Bludigo® specifically. Do not search for "indigo carmine" as this will show as unavailable. Bludigo® is the current brand name.

Contact customer support at us-info@provepharm or 1-833-727-6556.

Please see the full Important Safety Information.

GPO=group purchasing organization.

Supplied and marketed by ProvePharm, Inc. | Bludigo.com

BLUDIGO® (indigotindisulfonate sodium injection, USP)

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®.

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 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.

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.

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; 2024.

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