

NEW

Indigo carmine/ Provingo® 40 mg/5 mL

Ενέσιμο διάλυμα

Here, there is
no room for doubt

Detecting iatrogenic urinary tract injury during abdominal and pelvic surgery is key to limiting the risk of complications.⁽¹⁾

In case of suspicion, confirm your diagnosis intraoperatively with Indigo carmine Provingo®.⁽²⁾



This medicinal product is for diagnostic use only. Indigo carmine Provingo® is indicated for the intra-operative detection of suspected ureteral injuries during abdominal and pelvic surgery.⁽²⁾

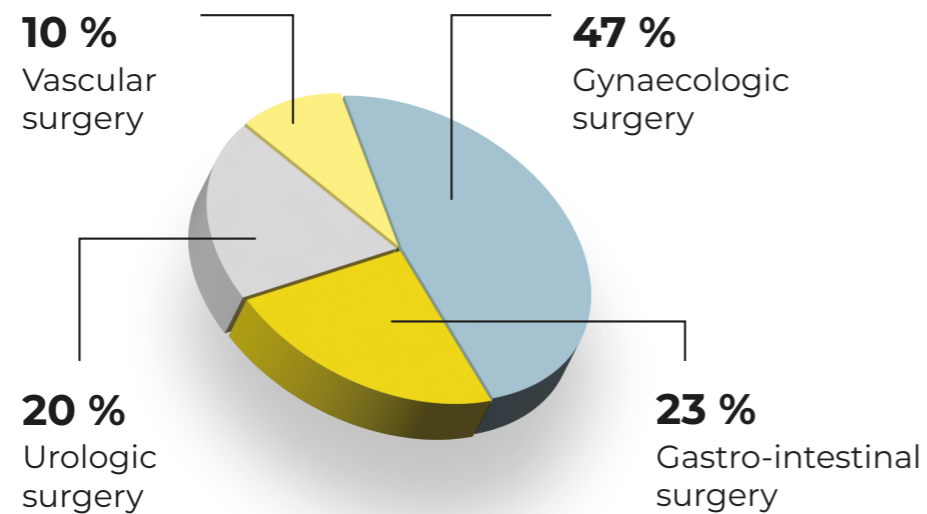


ACT TO IMPROVE LIFE
PROVEPHARM

> Iatrogenic ureteral injuries

IATROGENIC URETERAL INJURIES USUALLY OCCUR DURING ABDOMINAL AND PELVIC SURGERY ^(1,3)

High-risk surgeries* ^(4,5)



MANY POSSIBLE CAUSES ⁽³⁾

- > Ligation or kinking with a suture
- > Crushing from a clamp
- > Partial or complete transection
- > Thermal injury
- > Ischaemia from devascularisation

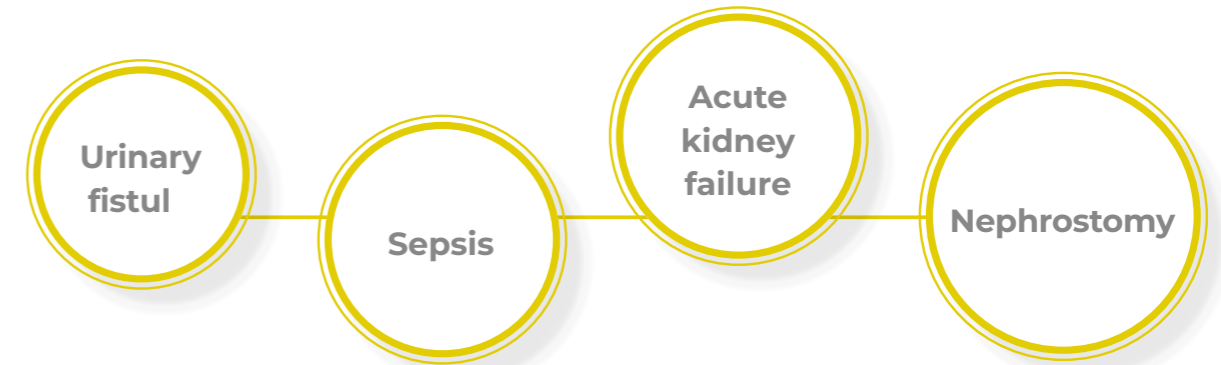


MORE THAN 65 % OF IATROGENIC URETERAL INJURIES ARE NOT DETECTED DURING SURGERY ⁽⁶⁾

* Breakdown of ureteral injuries by surgical speciality ⁽⁵⁾

EARLY DIAGNOSIS OF URETERAL INJURIES IS ESSENTIAL TO PROVIDE BETTER OUTCOMES TO THE PATIENTS. ^(3,6)

Serious complications of ureteral injuries ^(3,7)



> Diagnostic colouration with indigo carmine

Iatrogenic injury may be noticed during the primary procedure, when intravenous dye (e.g. indigo carmine) is injected to exclude ureteral injury ⁽³⁾



REDUCED RISK OF POST-OPERATIVE COMPLICATIONS FOR PATIENTS ⁽¹⁾

- > Effectiveness of the carmine indigo test, with a specificity >99% ⁽²⁾
- > Prevention of severe complications avoiding delays in diagnosis ⁽¹⁾
- > Immediate management of the identified ureteral injuries ⁽²⁾



SIMPLE TO USE FOR SURGEONS ⁽²⁾

- > Colouration of urine (in dark blue) within 4 to 9 minutes after the injection
- > Identification of the ureter tracks
- > Confirming the ureteral patency

> Product presentation

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DYE OF CHOICE ⁽²⁾

- > Sterile solution for IV injection
- > Slow intravenous injection under monitoring of arterial pressure and heart rate

DIAGNOSTIC PERFORMANCE ⁽²⁾

- > Intense colouration of urine within 4 to 9 min
- > High sensitivity and specificity of the test with indigo carmine (89.2% and 99.7% respectively)
- > Significant impact on the diagnostic process (PPV of 86.7% and NPV of 99.7% in a population with an incidence of ureteral lesions of 2.3%)



HIGH QUALITY STANDARDS ⁽⁸⁾

- > Purity of indigo carmine \geq 97.5%

PRACTICAL DETAILS ⁽²⁾

- > 5 ampoules of 5 mL
- > Shelf life: 3 years

PPV = Positive predictive value / NPV = Negative predictive value

Safety information ⁽²⁾:

- > **Contraindications:** Hypersensitivity to the active substance or to any of the excipients.
- > **Undesirable effects:** The most common adverse reactions of indigo carmine are mainly related to its alpha-adrenergic activity and are of cardiovascular origin ● Very common (\geq 1/10) : Hypertension (transient) and bradycardia, especially in patients under general anaesthesia or under spinal anaesthesia ● Other idiosyncratic reactions such as changes in blood pressure or heart rate or anaphylactoid reactions have also been described. Serious adverse reactions of indigo carmine are very rare.
- > **Special warnings and precautions for use:** The use of a filter is recommended at the time of intravenous administration. ● It is necessary to monitor heart rate and blood pressure during and a few minutes after the injection. Intravenous injection should be stopped if the following symptoms occur: bradycardia, tachycardia, hypotension, hypertension, rash or erythema, respiratory symptoms such as dyspnea or bronchospasm ● Indigo carmine Provingo should not be used in patients with clearance of creatinine < 10 mL/min (onset in urines may be delayed for several minutes) ● Indigo carmine may interfere with pulse oxymetric methods ● A discolouration of urine may be observed following administration of indigo carmine. ● Indigo carmine should be used with caution in case of: concomitant use of medicines inducing bradycardia, heart rate and conduction disorders, high blood pressure, low heart rate, coronary disorders due to its peripheral vasoconstrictor effect. ● The use of indigo carmine should be avoided in patients with: uncontrolled heart failure, history of allergic reactions, hemodynamic instability.
- > **Pregnancy:** Indigo carmine Provingo is not recommended during pregnancy and in women of childbearing potential not using contraception.
- > **Breast-feeding:** A risk to the newborns/infants cannot be excluded. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from indigo carmine therapy taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman.

For complete information, please consult the Summary of Product Characteristics.

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Indigo carmine/ Provingo® 40 mg/5 mL Ενέσιμο διάλυμα

40 mg ampoule of indigo carmine (indigotine)
diluted in 5 ml of water for injection

> In practice



Slow IV injection ⁽²⁾



Recommended initial
dose: 1 ampoule of 5 mL ⁽²⁾



A second ampoule may
be injected 20 to 30
minutes after the first
injection if necessary ⁽²⁾

> Distributor and contact



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References:

1. Siff LN, et al. Intraoperative Evaluation of Urinary Tract Injuries at the Time of Pelvic Surgery: A Systematic Review. Female Pelvic Med Reconstr Surg. 2018;26(11):655-663. **2.** Indigo carmine Provingo® 40 mg/5 ml - Summary of product characteristics -Nov 2023. **3.** Kitrey N.D. et al, EAU Guidelines. Edn. presented at the EAU Annual Congress, Amsterdam, the Netherlands. 2022. **4.** Klap J. et al, Etiologie et traitements des plaies iatrogènes de l'uretère : analyse de la littérature, AFU (French Association of Urology). Prog Urol. 2012;15(22):913-919. **5.** Karmouni T. et al, Prise en charge urologique des traumatismes iatrogènes de l'uretère. Prog Urol. 2001;11:642-646. **6.** Brandes S, Coburn M, Armenakas N, McAninch J. Diagnosis and management of ureteric injury: an evidence-based analysis. BJU Int. 2004;94(3):277-89. **7.** Blackwell RH. et al, Complications of Recognized and Unrecognized Iatrogenic Ureteral Injury at Time of Hysterectomy: A Population Based Analysis. J Urol. 2018;199(6):1540-1545. **8.** CoA Indigo carmine Provingo® API - Results analysis - Batch 4015/2/002/21.

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