

**CARMINDY  
INDIGO CARMINE 0.4%**

STERILE PYROGEN-FREE SOLUTION  
CONTRAST DYE

**CE** 0477

**QUALITATIVE AND QUANTITATIVE COMPOSITION**

Indigotindisulfonate Sodium (Indigo Carmine) 4 g - Sodium citrate dihydrate 1.64 g - Citric acid monohydrate 0.93 g - Water for injections q.s. to 1000 mL.

**TYPE OF DEVICE**

Sterile pyrogen-free solution - Class IIa.  
Sterile by steam.

**USE**

Indigo carmine is a contrast dye for the endoscopic tattoo. It is indicated to delineate the margins and the surface of pathological lesions of the gastro-intestinal mucosa by chromoendoscopy.

The indigo carmine solution is applied directly on the mucosa to highlight the microarchitecture of neoplastic lesions present on the gastrointestinal mucosa of the internal organs of the digestive apparatus: esophagus, stomach, duodenum, colon and rectum.

**MECHANISM OF ACTION**

The dye is not absorbed by the epithelial cells of the mucosa but spreads simply in the glandular dimples, in the interstices and in the furrows of the mucosa making the micro-architecture of the tissue under examination more visible. The use of this marker for gastrointestinal endoscopy allows to stain the area of irregularity of the mucous surface (protruding or depressed). The endoscopist can mark the area, take fragments to send to the clinical laboratory and remove the pathological lesion area.

**CONTRAINDICATIONS**

The device is contraindicated in patients with known hypersensitivity to its components or in general to synthetic dyes.

It is also contraindicated in patients suffering from severe hypertension or patients suffering from heart problems such as heart failure or cardiac ischemia.

Caution: Not indicated for use on pregnant and nursing patients and in pediatric patients.

**INTERACTIONS**

Indigo Carmine solution must not be mixed with medicines.

**METHOD OF ADMINISTRATION**

Marking of mucosal anomalies (ulcerations, fistula, irregular surfaces) - marking of tumour margins when the limits are not clearly visible Indigo carmine 0.4% solution is sprayed directly onto the mucosa of the gastrointestinal tract with a spray catheter introduced through an orifice (mouth or anus).

Fit the backstop onto the syringe barrel before connecting it to the spray catheter.

The syringe is equipped with Luer-Lock connection compatible with common catheters.

Select a suitable endoscopic spray catheter and connect the syringe to the Luer-Lock adapter.

Prime the catheter before use.

The volume to be administered depend on the intensity of the coloration needed for the visualisation purposes and the extent of the area to be stained. If necessary, the operation can be repeated. Too intense colors can be diluted by washing and excessive product can also be removed by suction.

#### **WARNINGS**

- Not for intravenous administration
- Do not use if the container is damaged;
- Do not reuse. The solution should be used for a single, uninterrupted administration and any residue should be discarded to prevent the risk of contamination due to loss of sterility;
- Remove completely the product by suction at the end of the procedure.
- **KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.**

#### **EXPIRY DATE**

Check the expiry date printed on the container. The expiry date refers to the product properly stored in an unopened package. Caution: Do not use the product after the expiry date.

#### **SPECIAL PRECAUTIONS FOR STORAGE**

Store in its original packaging to protect the product from light. No special storage conditions as regards temperature. Do not freeze.

#### **SPECIAL PRECAUTIONS FOR DISPOSAL AND OTHER HANDLING OF THE DEVICE**

Any unused part of the device and waste material deriving from it should be disposed of in accordance with local legislation in force.

**SERIOUS INCIDENT REPORTING:** the user and/or patient are recommended to report any serious incident that has occurred in relation to the device to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

#### **MEDICAL DEVICE FORM AND CONTENT**

Amber glass ampoules 5x10 mL.

Glass syringes 5x10 mL.

#### **MANUFACTURER**

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DATE OF TEXT REVISION: MAY 2025