

COMPOSITION

Each ampoule of PROVENDO® contains 40 mg of indigo carmine diluted in 5 ml of water for injections. PROVENDO® may also contain citric acid monohydrate and/or sodium citrate in case of pH adjustment by the manufacturer.

INDICATION

Marker for gastrointestinal endoscopy, as an aid in visualisation of topographic irregularities and in delineation of polypoid or flat lesions, including adenomas.

CONTRAINDICATIONS

Known hypersensitivity (allergy) to indigo carmine or any of the excipients.

METHOD OF ADMINISTRATION AND DOSAGE

PROVENDO® has to be sprayed onto the gastrointestinal mucosa or on a specific targeted lesion.

PROVENDO® can be used diluted up to 0.1% in water for injections immediately before administration. The dilution and 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.

Several sprays may be necessary, depending on the duration of observation and the extent of the lesions.

PROVENDO® must be used immediately after opening or dilution. PROVENDO® is for single patient use only.

Do not use for intravenous injection.

Table 1. Proposition of dilution

		0.16% dilution	0.24% dilution	0.32% dilution
Spray catheter	25 mL	1 ampoule diluted in 20 mL of water for injection	1.5 ampoules diluted in 17.5 mL of water for injection	2 ampoules diluted in 15 mL of water for injection
	50 mL	2 ampoules diluted in 40 mL of water for injection	3 ampoules diluted in 35 mL of water for injection	4 ampoules diluted in 30 mL of water for injection
Water Jet pump	100 mL	4 ampoules diluted in 80 mL of water for injection	6 ampoules diluted in 70 mL of water for injection	8 ampoules diluted in 60 mL of water for injection

WARNINGS AND PRECAUTIONS

- > PROVENDO® must be administered by a healthcare professional.
- > The wearing of gloves is recommended for users.
- > Do not use a damaged ampoule of PROVENDO®. Do not use PROVENDO® if the solution is not blue or blueish-purple.
- > Do not inject PROVENDO® intravenously.
- > PROVENDO® is for single use only: discard any remaining solution after opening.
- > Do not re-use or re-sterilise PROVENDO® due to the risk of contamination and the loss of technical performances of the device.
- > PROVENDO® should be disposed of in clinical waste.

ADVERSE EFFECTS

No adverse effects were reported when using indigo carmine solution as a marker for gastrointestinal endoscopy. However, allergic reactions may occur in patients with hypersensitivity to indigo carmine or any of the excipients.

Note to the user

Any serious incident that has occurred in relation to the device should be reported to the manufacturer at safety@provepharm.com and the Competent Authority of the Member State in which the user is established.

SHELF-LIFE

60 months

STORAGE

Do not refrigerate PROVENDO® under 8°C. Do not freeze.
After opening the ampoule: PROVENDO® must be used immediately.

PACKAGING

5 ml ampoules, in packs of 5 ampoules.

SYMBOLS GLOSSARY

	Manufacturer		Medical Device Code
	Lower limit of temperature		CE marking – Notified Body 2797
	Do not re-sterilize		Expiry date
	Do not reuse / Single use only		Batch code
	Caution		Unique device ID
	Sterilized by steam sterilization		Sterilized by steam sterilization - Unique sterile barrier system
	Pay attention to the instructions for use before using it		

VERSION AND PUBLICATION DATE

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