

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

The PROVENDO® solution 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.

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

Do not use for intravenous 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

36 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.

VERSION AND PUBLICATION DATE

IFU Version 06 - Last revision: 01/2024



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