



## **Previous Versions Product Information**



### COMPOSITION

Each ampoule of ProvEndo® contains 40 mg of indigo carmine diluted in 5 ml of water for injections. Citric acid monohydrate and/or sodium citrate may be added to the solution as pH adjusters.

### 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

Do not use for intravenous injection.

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.

The ProvEndo® solution can be sprayed onto the gastrointestinal mucosa or on a specific targeted lesion.

### WARNINGS AND PRECAUTIONS

- > ProvEndo® must be used 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 performance of the device and could expose the patient to post-operative complications.
- > 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 and the competent authority of the Member State in which the user is established.

### SHELF-LIFE

24 months

### STORAGE

Before opening: ProvEndo® does not require any special storage conditions.

After opening the ampoule: ProvEndo® must be used immediately.

### PACKAGING

5 ml ampoules, in packs of 5 ampoules.

### VERSION AND PUBLICATION DATE

IFU Version 03 - Last revision: 11/2020



**Provepharm S.A.S.**  
 22 Rue Marc Donadille 13013 Marseille, France  
[www.provepharm.com](http://www.provepharm.com)



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**COMPOSITION**

Each ampoule of ProvEndo™ contains 40 mg of indigo carmine diluted in 5 ml of water for injection. Citric acid monohydrate and/or sodium citrate may be added to the solution as pH adjusters.

**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 one of the excipients

**METHOD OF ADMINISTRATION AND DOSAGE**

Do not use for intravenous injection.

ProvEndo™ can be used diluted up to 0.1% in water for injection right before administration. The dilution and volume to be administered depend on the intensity of the coloration needed for the visualisation purposes and the extend of the area to be stained.

ProvEndo™ must be used immediately after opening or dilution, for a single patient only.

The ProvEndo™ solution can be sprayed onto the gastrointestinal mucosa or on a specific targeted lesion.

**WARNINGS AND PRECAUTIONS**

- > ProvEndo™ must be used 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™ because it may create a risk of contamination, decrease the technical performances of the device and lead to patient post-operative complications.
- > 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 the excipients.

Note to the user

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user is established.

**SHELF-LIFE**

24 months

**STORAGE**

Keep the ampoules in the original packaging to protect it from light.  
Do not freeze or refrigerate. Do not store above 25°C.

**PACKAGING**

5 ml ampoules, in packs of 5 ampoules.

**VERSION AND PUBLICATION DATE**

IFU Version 02 - Last revision: 09/2020



Provepharm S.A.S.  
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**COMPOSITION**

Each ampoule of ProvEndo™ contains 40 mg of indigo carmine diluted in 5 ml of water for injection. Citric acid monohydrate and/or sodium citrate may be added to the solution as pH adjusters.

**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 one of the excipients

**METHOD OF ADMINISTRATION AND DOSAGE**

Do not use for intravenous injection.

ProvEndo™ can be used diluted up to 0.1% in water for injection right before administration. The dilution and volume to be administered depend on the intensity of the coloration needed for the visualisation purposes and the extend of the area to be stained.

ProvEndo™ must be used immediately after opening or dilution, for a single patient only.

The ProvEndo™ solution can be sprayed onto the gastrointestinal mucosa or on a specific targeted lesion.

**WARNINGS AND PRECAUTIONS**

- > ProvEndo™ must be used 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™ because it may create a risk of contamination, decrease the technical performances of the device and lead to patient post-operative complications.
- > 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 the excipients.

Note to the user

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user is established.

**SHELF-LIFE**

18 months

**STORAGE**

Keep the ampoules in the original packaging to protect it from light.  
Do not freeze or refrigerate. Do not store above 25°C.

**PACKAGING**

5 ml ampoules, in packs of 5 ampoules.

**VERSION AND PUBLICATION DATE**

IFU Version 01 - Last revision: 06/2020



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## Instructions for use



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### 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 ([safety@provepharm.com](mailto:safety@provepharm.com)) and the competent authority of the Member State in which the user is established.

### SHELF-LIFE

24 months

### STORAGE

Before opening: ProvEndo® does not require any special storage conditions.  
After opening the ampoule: ProvEndo® must be used immediately.

### PACKAGING

5 ml ampoules, in packs of 5 ampoules.

### VERSION AND PUBLICATION DATE

IFU Version 04 - Last revision: 09/2021



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