GB

# INDIGO CARMINE 1% - 10ml

5°C 45°C

## 1- NAME AND ADDRESS OF THE MANUFACTURER

***DERM TECH FRANCE***
210 avenue Aristide Briand, 93320 Les Pavillons-sous-Bois
France
Tel.: +33 (0) 1 48 02 61 63 - Fax: +33 (0) 1 48 02 61 71
*www.derm-tech.com*

## 2- IDENTIFICATION OF THE PRODUCT

**a- Name**
Indigo carmine, marking ink
REF **J2F/810160/4**

**b- Composition**
Water for Injections, Indigotine CI 73015, Butylene glycol, Ethylparaben, Methylparaben, Propylparaben, Polysorbate 20.

**c- Package Contents**
1% indigo solution prepared with water for a sprayable preparation for marking, in a vial containing 10 ml; box containing 10 units.

**d- Name and address of the manufacturer**
***DERM TECH FRANCE***
210 Av Aristide Briand – 93320 Pavillon-sous-Bois - France
Tel.: +33 (0) 1 48 02 61 63 - Fax: +33 (0) 1 48 02 61 71

**e- Device classification**
Class I medical device (in accordance with rule 5 of Annex IX of EEC Directive 93/42)

**f- Method of sterilisation**
REF **J2F/810160/4**: Not sterile

## 3- INTENDED USE

**When to use this device (indications for use)**
Indigo carmine enables mucosal anomalies (ulcerations, fissures, surface irregularities) to be detected in more detail, therefore allowing tumour margins to be marked when the borders are imprecise.

## 4- WARNING!

**a- When not to use this device: known contraindications**
**This device SHOULD NOT BE USED:**
In allergic subjects, a test dose should be administered before using the product.

**b - Contraindications:**
- Hypersensitivity to indigo carmine
- Severe hypertension
- Cardiac ischaemia
- Heart failure

**c - Precautions for use**
Handle the vial carefully to avoid injury.
Check the physical appearance of the suspension before using the device (packaging has no visible defect; colour and texture of liquid and homogeneity after shaking).

**d- Warnings and Precautions**
Product quality and safety cannot be guaranteed if the product has been altered.
This solution is for single use only. Any open product must be disposed of after use.
IF YOU HAVE ANY FURTHER QUESTIONS, CONTACT YOUR DOCTOR OR PHARMACIST FOR ADVICE.

## 5- HOW TO USE THIS DEVICE

**a- Instructions for use**
Spray the indigo carmine solution on the area to be examined. This may be repeated if necessary. If the dye is too dark, it can be lightened by rinsing.
The recommended dilution for use in gastrointestinal endoscopy is 0.2%. The dilution is done with saline.

## 6- UNDESIRABLE EFFECTS

REPORT ANY UNDESIRABLE EFFECT NOT MENTIONED IN THIS LEAFLET TO DERM TECH FRANCE

The administration of indigo carmine may cause nausea, vomiting, hypertension and bradycardia. Symptoms which can be attributed to an arterial vasoconstrictive effect have been described. The use of the dye can cause increased peripheral resistance and secondary cardiovascular changes, including reduced cardiac output and increased blood pressure.
Reactions such as skin rash, pruritus and bronchospasm have also been reported. Idiosyncratic reactions are corrected by the administration of antihistamines.
A test dose should be administered to patients with a history of allergy.
A reversible skin colouration may be observed with doses exceeding 100 mg.

## 7- STORAGE AND SHELF LIFE

**a- Shelf life**
DO NOT USE AFTER THE EXPIRY DATE PRINTED ON THE PACKAGING. SOLUTION FOR SINGLE USE ONLY. ANY OPENED PRODUCT MUST BE DISPOSED OF AFTER USE.

**b- Special precautions for storage**
Store at a temperature between 5°C and 45°C in a clean, dry place protected from light.
This is a light-sensitive product which must be stored protected from light.

**c- Single use product**
This product is for single use only.
Do not reuse, re-sterilise or repackage.

**d- Storage after opening**
This product is for single use only. Any opened product must be discarded after use and may not be stored for later use.

**e- Warning in case of visible signs of deterioration**
In case of deterioration of the vial, product quality and safety cannot be ensured.
Before using, check the integrity of the vial.

## 8- GENERAL CONDITIONS

This device is for single use only.
Any use not indicated in the leaflet is not guaranteed by the manufacturer.

## 9- LEGEND OF SYMBOLS USED

The symbols are those used in the EEC EN 980 standard.

**DATE OF REVISION: 06/07/2012**