

METHYLENE BLUE 1%
SURGICAL DYE
 NOT FOR ORAL, INTRAVENOUS, INTRATHECAL
 OR INTRA-AMNIOTIC INJECTION

CE 0373

QUALITATIVE AND QUANTITATIVE COMPOSITION

Methylthionium chloride trihydrate (methylene blue trihydrate) 0.1 g - Hydrochloric acid or sodium hydroxide to adjust pH as needed - Water for injections q.s. to 10 mL.

TYPE OF DEVICE: Sterile pyrogen-free solution – Class IIa.

USE: The device is intended to be used in surgery for the marking of tissues and surgical findings and to test the tightness of urinary tract sutures and colorectal sutures.

CONTRAINDICATIONS: Known hypersensitivity to methylthionium chloride trihydrate (methylene blue). Do not use during pregnancy.

WARNINGS AND PRECAUTIONS FOR USE

METHYLENE BLUE MUST NOT BE TAKEN ORALLY OR INJECTED INTRAVENOUSLY, INTRATHECALLY OR INTRA-AMNIOTICALLY.

For the described indications, methylene blue is not a specific stain. It is therefore not to be used for diagnostic purposes in humans, for example in screening for precancerous lesions.

When methylene blue is administered by subcutaneous injection, it can cause vasoconstriction or skin necrosis.

In case of contact with mucous membranes in the eyes, flush thoroughly with plenty of water. The use of methylene blue may cause staining of urine and faeces.

INSTRUCTIONS FOR USE

MARKING OF TISSUES FOR SURGICAL FINDINGS

IN THE VISUALISATION OF SENTINEL LYMPH NODES TO ENABLE THE EXCISION OF POTENTIALLY MALIGNANT LYMPH NODES DURING SURGERY ON THE BREAST

Administer by periareolar injection a quantity between 2 mL and 5 mL methylene blue solution with a concentration of 1%.

For all other indications listed below, use a methylene blue solution with a concentration of 0.01%. Therefore, before use, dilute 1 part of methylene blue 1% with 100 parts of sterile 0.9% sodium chloride.

IN THE IDENTIFICATION OF THE RENAL CAVITY DURING SURGERY OR PERCUTANEOUS NEPHROLITHOTOMY
 Administer intravesically a quantity of diluted solution of between 100 mL and 250 mL.

IN THE IDENTIFICATION OF THE URINARY OR COLONIC FISTULA BEFORE SURGICAL EXCISION

Administer intravesically a quantity of diluted solution, generally of between 10 mL and 100 mL.

IN THE MARKING OF THE PILONIDAL SINUS BEFORE SURGICAL REMOVAL

Administer with a syringe directly into the pilonidal sinus a quantity of diluted solution, generally between 1 mL and 5 mL according to the size of the cyst.

IN THE PREOPERATIVE MARKING OF STOMA PRIOR TO EXCISION

The volume of diluted solution to inject subcutaneously is at the physician's discretion (generally between 2 mL and 5 mL).

CHECKING THE TIGHTNESS OF URINARY TRACT AND COLORECTAL SUTURES

Use a methylene blue solution with a concentration of 0.01%. Therefore, before use, dilute 1 part of methylene blue 1% with 100 parts of sterile 0.9% sodium chloride.

Intravesically or rectally, administer a quantity of diluted solution of between 25 mL and 250 mL according to the position of the suture. If no blue staining can be detected in the suture area, then this is proof that the suture is properly sealed.

SHELF LIFE: Three years in an unopened pack.

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

SPECIAL PRECAUTIONS FOR STORAGE: Store in original packaging to protect the product from light. No special temperature storage conditions. Do not freeze. Do not use if the container is damaged. The solution must be used for a single, uninterrupted administration and any residue must be discarded to prevent the risk of contamination due to loss of sterility.

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN

PRIMARY CONTAINER

Glass ampoules and prefilled syringes with a protective wrapping.

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.

MANUFACTURER:  S.A.L.F. S.p.A. LABORATORIO FARMACOLOGICO
 Via Marconi, 2 - 24069 Cenate Sotto (BG) Italy

DATE OF REVISION: April 2020