METHYBLUE
METHYLENE BLUE 1%

CE 0477

SURGICAL DYE STERILE
NOT FOR ORAL, INTRAVENOUS, INTRATHECAL OR INTRA-AMNIOTIC INJECTION

NAME OF MEDICAL DEVICE:
Methyblue – Methylene Blue 1% marker for surgery.

QUALITATIVE AND QUANTITATIVE COMPOSITION:
Methylthioninium Chloride Trihydrate (Methylene Blue Trihydrate) 10 g – Hydrochloric Acid or Sodium Hydroxide to adjust pH as needed - Water for injections q.s. to 1000 mL.

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

USE:
This product was designed to be used in surgery as a way of marking tissues and operative findings and to check the tightness of urinary tract and colorectal sutures.

CONTRAINDICATIONS:
Known hypersensitivity to Methylthioninium Chloride Trihydrate (Methylene Blue). Do not use during pregnancy.

WARNINGS AND PRECAUTIONS FOR USE:
METHYLENE BLUE MUST NOT BE USED ORALLY AND INJECTED INTRAVENOUSLY, INTRATHECALLY OR INTRAAMNIOTICALLY.
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:
According to its intended use, the device MethyBlue can be connected with either a needle or a catheter. Both of them must be equipped with a standard Luer Lock connection to ensure compatibility.

MARKING OF TISSUES AND OPERATIVE 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 (approximately) 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

SERIOUS INCIDENT REPORTING:
The user and/or patient are recommended to report any serious incident that has occurred in relation to the device to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

PRIMARY CONTAINER:
Prefilled syringes 5mL 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
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Cenate Sotto (BG) – Italy

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18-01-2023