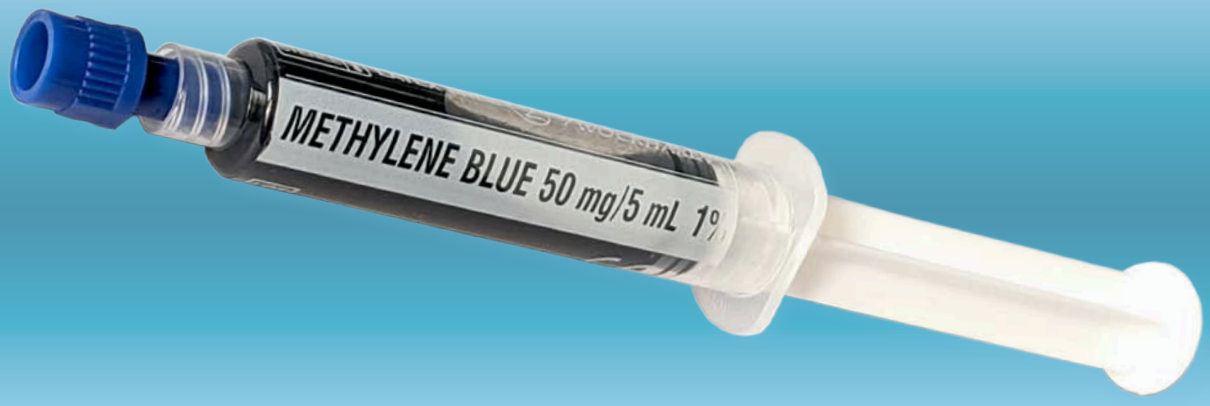
METHYLENE BLUE WOCKHARDT

Methylene Blue 50mg/5mL 1%

NOW AVAILABLE
The first Methylene Blue prefilled syringe



50mg in 5mL (1%) prefilled syringe

- First specialised Methylene Blue surgical dye approved in Australia
  - wide range of indications
  - detailed volume/concentration recommendations
- Improved convenience and simplicity of use
- Reducing risk of spillage versus glass ampoules
- Sterile outer wrap:
  - enabling direct use in a sterile field
  - reducing risk of microbial contamination
- Made in Italy from World leading supplier

InterPharma

Distributed in Australia by:
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Methylene Blue 50mg/5mL 1%

Active Ingredient	Methylene Blue Trihydrate
Excipients	Water for injections, Sodium Hydroxide / HCl (pH adjustment)
Immediate Container	Polypropylene prefilled syringe
Pack Size	Presented in packs of 5 x 5mL (50mg, 1%) prefilled syringes in a sterile outer wrap
Stability Unopened	3 years, store in original packaging. Do not freeze.

MINIMUM PRODUCT INFORMATION:

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

QUALITATIVE AND QUANTITATIVE COMPOSITION Methylthioninium 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 fi ndings and to test the tightness of urinary tract sutures 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 TAKEN ORALLY OR INJECTED INTRAVENOUSLY, INTRATHECALLY OR INTRA-AMNIOTICALLY. For the described indications, methylene blue is not a specifi c 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, fl ush 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 prefi lled 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

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