VUEBLU®

Methylene Blue 0.5%

IMPORTANT INFORMATION

Caution: Federal law restricts this device to sale by or on the order of a physician. Read all instructions carefully before use. They contain essential information on using this device safely and effectively. Keep these instructions in a safe, accessible location, as you may need to refer to them again.

If you have any questions or comments about any information in these instructions, please contact Genus Medical Technologies, LLC or Cosmo Technologies Ltd.

COMPOSITION

Methylene Blue, sterile water for injection.

INTENDED USE

VUEBLU® (Methylene Blue 0.5%) is indicated for temporary endoscopic marking of tissue in the gastrointestinal tract in patients 18 years of age and older, to aid tissue visualization. VUEBLU® (Methylene Blue 0.5%) is especially indicated in endoscopy procedures and can be used undiluted or diluted with sterile water for injection (see Section "Procedure").

CONTRAINDICATIONS

Gastrointestinal obstruction or perforation.

Known sensitivity to or any of the ingredients in the device.

Patients with known glucose-6-phosphate dehydrogenase deficiency, due to the potential risk for hemolytic anemia.

Not for use in pregnant or breastfeeding women.

Not for pediatric use.

WARNINGS AND PRECAUTIONS

The product is intended for use as a tissue marker only. The product should not be used for treating methemoglobinemia. The product has not been tested in the treatment of methemoglobinemia and, therefore, its efficacy and safety for such indication are not established.

Do not use this product for any purpose other than its intended use.

Only the internal liquid is sterile; neither the external vial nor the outer packaging are sterile.

Product can be used undiluted (as is) or can be diluted with sterile water for injection before use.

Do not dilute the product with sterile normal saline or sterile phosphate buffered saline; only dilute (as needed) with sterile water for injection.

The product is intended for single -use only; do not re-use, re-sterilize and/or re-process. Re-use, re-sterilization or re-processing may contaminate the device and/or cause patient infectious disease(s).

The product is only for patients 18 years of age and older.

The safety of VUEBLU® has not been established in pregnant or breastfeeding women, or in patients under 18 years of age.

The device is not made with natural rubber latex.

The device is intended for use under the direct supervision of a trained physician only. A thorough understanding of the technical principles, clinical applications, and associated risks is expected before usage.

Inappropriate use of the device outside what is recommended in these Instructions for Use may lead to contamination, which can pose risks to patients.

Product name: VUEBLU® 0.5%.
Concentration: Methylene Blue 0.5%; can be used undiluted or diluted with sterile water for injection.
Packaging: packaged in vials, 5 vials in each carton box.
Production date: see packaging.
Sterilization: terminal sterilization by steam.
Shelf life: 2 years.

PROCEDURE

1. Check expiration date on the carton box; if the product has not expired, open the package carefully. If the product is expired, please discard.
2. Check integrity of the vials; leakage of the product may be evidence of damage. DO NOT USE the product if damaged. The sterility is guaranteed only if the product is not damaged.
3. Reference product label and choose the appropriate device for application (for example spray catheter, not provided with VUEBLU®)
4. Use as is or dilute the solution with sterile water for injection, in accordance with your standard procedures.
   DO NOT DILUTE WITH SOLUTION CONTAINING SODIUM CHLORIDE (FOR EXAMPLE NORMAL SALINE OR PHOSPHATE BUFFERED SALINE).
5. Select a suitable spray catheter (for superficial tissue marking) or an injection needle (for submucosal marking) with a luer lock connection. Prime the catheter or injection needle prior to use.

   FOR SUPERFICIAL MARKING:
6. Carefully insert the endoscope under direct visualization.
7. Carefully spray aliquots as directed by the physician.
8. Once a segment has been sprayed, and after a dwell time of a few minutes (for example 1-3 minutes), suction excess dye.
9. Advance the endoscope to the proximal extent of the segment to commence evaluation.
10. At the end of the procedure wash the mucosa with water.

    FOR SUBMUCOSAL MARKING:

#6. With the needle retracted, carefully insert the catheter through the biopsy channel of the endoscope under direct visualization until the needle emerges into the endoscopic view.
#7. When the needle is properly positioned, advance the needle and inject into the target tissue.
CAUTION: Do not insert the needle perpendicular to the colon, as this may lead to perforation of the serosa and injection of the marker directly into the peritoneal cavity.
#8. Carefully inject aliquots as directed by the physician.
CAUTION: Observe for leakage of the marker into the lumen. If this occurs, stop the injection and reposition the needle.

CAUTION: for use as a tissue marker only.

STORAGE

The product should be stored in a dark place to protect from light, at a temperature of 20-25°C/68-77°F. Do not refrigerate or freeze.
Do not use if packaging is damaged.
Sterile product for single use only.
Do not use after expiration date.
Do not dilute with solution containing sodium chloride (for example normal saline or phosphate buffered saline). The use of these solutions leads to Methylene Blue precipitation.

PRODUCT DISPOSAL

Discard any unused product after the vials have been opened. After use, this product may be a potential biohazard. Handle and dispose of it in accordance with hospital, local and administrative laws, and regulations.

DESCRIPTION OF USED SYMBOLS

Brief description of the symbols; for the complete symbols glossary visit:
https: //www.cosmopharma.com/activities/XXX

Date of manufacture

Use by (Expiration Date)

Lot number

Sterilized using steam

Do not resterilize

Do not use if package is damaged and consult instruction for use

Fragile, handle with care

Keep away from sunlight

Storage temperature range

Consult instructions for use

Rx Only Prescription only

Non Pyrogenic

REF Catalogue or model number

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