

PATENT BLUE V WOCKHARDT

Patent Blue V 125mg/5mL 2.5%

NOW
AVAILABLE
The first Patent Blue V
prefilled syringe



125mg in 5mL (2.5%) prefilled syringe

- **First available prefilled syringe of Patent Blue V**
- **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
- **Cost effective – larger volume**
- **Made in Italy from World leading supplier**

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Patent Blue V 125mg/5mL 2.5%

Active Ingredient	Patent blue V sodium
Excipients	Water for injections, Sodium Hydroxide
Immediate Container	Polypropylene prefilled syringe
Pack Size	Presented in packs of 5 x 5mL (125mg, 2.5%) prefilled syringes in a sterile outer wrap
Stability Unopened	2 years, store in original packaging. Do not freeze.

MINIMUM PRODUCT INFORMATION:

PATENT BLUE V 2.5% STERILE PYROGEN-FREE SOLUTION - MARKER FOR SURGERY

NAME OF MEDICAL DEVICE: Patent Blue V 2.5% marker for surgery. **QUALITATIVE AND QUANTITATIVE COMPOSITION:** Patent blue V sodium salt 25 g - Sodium hydroxide q.s. pH 9.5 - Water for injections q.s. to 1000 mL. **TYPE OF DEVICE:** Sterile pyrogen-free solution - Class IIa. **USE:** A vital dye suitable for the marking of the sentinel lymph node in breast cancer and the intraoperative research of the sentinel lymph node in patients with colon cancer. It is also used in preoperative lymphoscintigraphy for sentinel lymph node biopsy in melanoma. **CONTRAINDICATIONS:** Hypersensitivity to Patent Blue V sodium salt. The device should not be administered during pregnancy, as there are insufficient data to assess the effects of Patent Blue V during pregnancy. **SIDE EFFECTS:** Patent Blue V sodium salt can cause what follows: • hives, itch, rash; • transient hypotension, bronchospasm / laryngospasm; • rare cases of anaphylaxis, anaphylactic shock and angioneurotic edema. **WARNINGS AND PRECAUTIONS FOR USE: PATENT BLUE V MUST NOT BE TAKEN ORALLY OR BE INJECTED INTRAVENOUSLY, INTRATHECALLY OR INTRA-AMNIOTICALLY.** Patent Blue V can also cause severe allergic reactions. Before use, check the patient's allergies and intolerances. Anesthesiologists and surgeons should carefully consider the onset of the first symptoms of an allergic reaction. They should also ensure the availability of personnel and equipment necessary to treat a possible allergic reaction, supervising for at least 1 hour from the time of administration, as there could be a possible delay of the onset of an adverse reaction. After the injection a bluish discoloration on the surrounding skin, that normally disappears within 24-48 hours, may occur. In the case of an intradermal injection the staining skin may persist for a long time. The dye is eliminated in 24-48 hours after the injection through the urine, strongly colored, but also through the bile. **INTERACTIONS:** After an administration of Patent Blue V, the measurement of O₂ in the blood, carried out by spectrophotometric method, can lead to false results and, for a short period, to values of approximately 5-10 % below the baseline value. In case of doubt, it is recommended to check the levels of gases in the blood. **INSTRUCTIONS FOR USE: Intraoperative sentinel lymph nodes mapping in patients with breast cancer.** The vital dye may be injected by subdermal, intradermal, periareolar, peritumoral or intratumor-al route, although this last route is rarely used, because it requires the administration of high volumes of dye, given the paucity of lymphatics within the tumor mass. The amount to be used depends on the route of administration. • By subdermal route you should inject 0.2-0.4 mL of Patent Blue V. • By peritumoral route you should inject larger volumes in two or more peritumoral points: 1-2 mL for tumors in the upper-outer quadrant; 2-3 mL for tumors at the confluence of external or internal quadrants; 3-4 mL for tumors in lower quadrants. *Intraoperative sentinel lymph nodes mapping in colon cancer in early stage.* A total amount of less than 2 mL of vital dye Patent Blue V is injected into the peritumoral region, at the four cardinal points, in the subserosal area so as to allow the identification of the first 4 sentinel nodes. *Preoperative identification of sentinel lymph nodes in melanoma.* Make peri-lesional intradermal injections of 0.5-1 mL of Patent Blue V 20 minutes prior to skin incision. **EXPIRY DATE:** Check the expiry date printed on the container. The expiry date refers to the product properly stored in an unopened package. Caution: Do not use the product after the expiry date. **SPECIAL PRECAUTIONS FOR STORAGE:** Store in its original packaging to protect the product from light. No special storage conditions as regards temperature. Do not freeze. Do not use if the container is damaged. The solution should be used for a single, uninterrupted administration only and any residue should be discarded to prevent the risk of contamination due to loss of sterility. **KEEP OUT OF THE REACH AND SIGHT OF CHILDREN. 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. **MEDICAL DEVICE FORM AND CONTENT:** Glass ampoule of 2 mL and 5 mL. Prefilled syringe of 2 mL and 5 mL. **MANUFACTURER:** S.A.L.F. S.p.A. LABORATORIO FARMACOLOGICO Via Marconi, 2 - 24069 Cenate Sotto (BG) Italy

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Date Of Revision: April 2020