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LAZULYMPH
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:
Patent Blue V is a vital dye suitable for the marking of sentinel lymph nodes in the breast cancer and in the intraoperative sentinel lymph nodes mapping in patients with colon cancer. It is also used in the preoperative lymphoscintigraphy for the biopsy of sentinel lymph nodes in the melanoma.

CONTRAINDICATIONS:
Hypersensitivity to Patent Blue V Sodium Salt.
WARNING: The device should not be administered during pregnancy. Avoid the use during the lactation and in pediatric patients, because the related studies are not available.

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 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.

INSTRUCTIONS FOR USE:
To be used with needle with Luer Lock connection:
Intraoperative sentinel lymph nodes mapping in patients with breast cancer
The vital dye may be injected by subdermal, intradermal, periareolar, peritumoral or intratumoral 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 (approximately) 0.2-0.4 ml of Patent Blue V.
• By peritumoral route you should inject larger volumes in two or more peritumoral points: (approximately) 1-2 ml for tumors in the upperouter quadrant; (approximately) 2-3 ml for tumors at the confluence of external or internal quadrants; (approximately) 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 (approximately) 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.

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.

MEDICAL DEVICE FORM AND CONTENT:
Prefilled syringe of 2 mL with a protective wrapping.

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

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