

PRESCRIBING INFORMATION

PATENT BLUE SODIUM INJECTION

Patent Blue Sodium

2.5% (25mg/mL)

Diagnostic Aid

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**Patent Blue
Sodium Injection
2.5% (25 mg/mL)**

FORMULA

PATENT BLUE Na is a solution of sodium salt of anhydride bis-(diethylamino-4- phenyl) (hydroxy-5 disulfo-2, 4 phenyl) methanol. $C_{27}H_{31}N_2O_7S_2Na$. Wt. 582.

PHYSICAL AND CHEMICAL PROPERTIES

PATENT BLUE Na is an aqueous solution of 2.5% sodium salt. Its composition is:

2 mL ampoule

Patent Blue Na.....	0.05g
Sodium Chloride.....	0.012g
Disodium Phosphate 12 H ₂ O (buffer)	0.001g
Water for injection to	2 mL

INDICATIONS AND DOSAGE

For marking:

- lymphatic vessels and arterial territories, and
- sentinel lymph node prior to biopsy in patients with operable breast cancer and clinically negative lymph nodes in combination with a radiotracer.

For marking lymphatic vessels and arterial territories. Subcutaneous and intravascular dosage is 1 to 10 mL.

Marking of Lymphatic Vessels:

Approximately 1 mL of PATENT BLUE Na is injected into the subcutaneous tissue:

- In the foot at the base of the large toe
- In the upper limb either between the metacarpus or at the level of the thenar or hypothenar prominences, or at the elbow.

Marking of Arterial Territories:

Intra-arterial injection of PATENT BLUE Na results in a coloring of the tissues vascularized by the vessels. This allows one to determine the areas involved by an antimitotic medication. To control the correct position of the catheter intended for intra-arterial chemotherapy, we infuse 50 mL of the solution comprising of:

- 80 mL of an isotonic solution in water solution
- 40 mL of a 2.5% PATENT BLUE Na solution
- 20 mL of a 1% Xylocaine Solution

For marking the sentinel lymph node:

Users should be familiar with the sentinel lymph node marking technique. Literature data indicate an improved detection rate when using a double marking technique with radioactive tracer combined with a dye. Pre-operatively, PATENT BLUE Na is injected subcutaneously around the tumour or around the nipple.

CONTRAINDICATIONS

PATENT BLUE Na Injection is contraindicated in patients who are hypersensitive to this drug, or any of the excipients or triphenylmethane dyes.

WARNINGS AND PRECAUTIONS

Hypersensitivity

There is always a risk of hypersensitivity regardless of the route of administration and the dose administered.

PATENT BLUE Na can induce minor or major, possibly life-threatening immediate hypersensitivity reactions that can sometimes be fatal (anaphylactic shock). These reactions are often unpredictable, but occur more frequently in patients with a history of hypersensitivity reaction to PATENT BLUE Na or triphenylmethane dyes contained in medicinal products, foods and cosmetics.

Due to the risk of major hypersensitivity reactions, resuscitation equipment must be immediately at hand, especially for patients on beta-blockers, in whom adrenaline and intravascular infusions may be less effective. Consequently, PATENT BLUE Na must be administered only in a setting able to adequately treat these major hypersensitivity reactions.

Before the administration of PATENT BLUE Na:

- Identify subjects at risk by a precise interview on their history.
- Insert an indwelling venous catheter.

Throughout the examination, maintain:

- Medical monitoring.
- An indwelling intravenous catheter.
- Drugs and equipment for resuscitation readily available.

After the administration of PATENT BLUE Na, the patient must be monitored for at least 30 minutes.

Interaction with Other Diagnostic Measurements

The value of partial oxygen pressure measured by spectrophotometry may show a transient false decrease of 5 to 10% below baseline values during examinations with PATENT BLUE Na. When in doubt, it is advisable to check by arterial blood gas analysis. The value of serum methaemoglobin measured by the same spectrophotometric method may be falsely increased.

Pregnancy

Safety during pregnancy has not been determined. Consequently, the use of this drug is discouraged during pregnancy.

Lactation

No study has been carried out regarding the passage of PATENT BLUE Na in breast milk.

Non clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology and single- and repeated-dose toxicology. A mutagenic effect was observed in vitro, at high concentrations, in a gene mutation test on bacteria, after metabolic activation. This finding was neither confirmed in an in vitro mammalian cell gene mutation test on L5178Y mouse lymphoma cells nor in vivo in a micronucleus test in rats at dose levels significantly greater than the maximum human dose level, indicating little relevance to clinical use.

After injection of PATENT BLUE Na, skin structures may become blueish but this colouration disappears within 24 to 48 hours. In patients with lymph stasis or circulatory disorders, the colouring may last longer.

ADVERSE REACTIONS

PATENT BLUE Na may produce allergic adverse reactions. Allergic manifestations, although quite rare, should be recognized since their clinical expression is often quite spectacular. These reactions occur shortly after the injection of the dye.

These reactions may comprise one or more of the following, either concomitantly or successively: skin, respiratory and/or cardiovascular reactions. Each of these reactions can be a precursor sign of anaphylactic shock. Most often, it is erythematous reaction, very pruriginous followed by the appearance of areas of urticaria and occasional edema of the lips and the eyelids. The unique character is the pale green or blue coloration of the papulas and the edema which is explained by fixation of the dye at the level of the local exsudate due to the liberation of histamine. The reactions may be more severe with hypotension, nausea, laryngeal edema and even cardiovascular failure.

The adverse reactions are given in the table below, by system organ class and by frequency using the following categories: very common ($\geq 1/10$), common ($\geq 1/100$ to $< 1/10$), uncommon ($\geq 1/1000$ to $< 1/100$), rare ($\geq 1/10,000$ to $< 1/1000$), very rare ($< 1/10,000$), not known (cannot be estimated from the available data).

Organ Class System	Frequency: Adverse Reaction
Immune system disorders	Unknown: Anaphylactic shock, hypersensitivity
Skin and subcutaneous tissue disorders	Unknown: Angio-edema, urticaria, blue discolouration of the skin
General disorders and administration site conditions	Unknown: discolouration of the administration side
Respiratory, thoracic and mediastinal disorders	Unknown: Bronchospasm

PRESENTATION

Box containing 5 x 2 mL ampoules

DIN 00405396

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