Mentions légales abrégées corporate / Key words

Patent Blue V

(Patent Blue V)

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PATENT BLUE V. Composition: PATENT BLUE V SODIUM 2.50 g per 100 ml of solution for injection. List of excipients: Sodium chloride, disodium phosphate dodecahydrate, water for injection. **Indications (**):** diagnostic use only - Marking lymph vessels; Marking arterial regions; Marking sentinel nodes before biopsy in patients with operable breast cancer **Posology and method of administration (*)**: Posology - Marking arterial regions: not more than 10 ml intra-arterially, marking lymph vessels: 0.5 to 2 ml subcutaneously, marking the sentinel node: 0.5 to 2 ml subcutaneously around the tumor or areola. **Contraindications (*):** Hypersensitivity to Patent Blue V, tryphenylmethane dyes or any of the excipients. **Special warnings and special precautions for use (*):** There is a risk of allergic reactions whatever the administration route or dose. Patent Blue V may cause minor or major immediate allergic reactions that may be life-threatening or even fatal (anaphylactic shock). They are often unpredictable but they occur more frequently in patients with a history of hypersensitivity reactions to Patent Blue V or related triphenylmethane dyes contained in drugs, food and cosmetics. The indication should be very carefully assessed in these predisposed patients. Corticosteroids and H1-type antihistamines have been suggested as premedication in patients at risk for intolerance reactions (history of intolerance to Patent Blue V or related triphenylmethane dyes). However, they do not prevent the occurrence of serious or fatal anaphylactic shock. The risk of a major reaction implies that emergency measures must be immediately available especially in patients on beta blockers in whom adrenaline and vascular perfusion would be insufficiently effective. Therefore, Patent Blue V must only be administered in an establishment capable of adequate treatment. Before the administration of Patent Blue V: 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 V, the patient must be monitored for at least 30 minutes. Warnings and precautions specific to the sentinel node marking: In the event of an allergic reaction, an investigation must be carried out to determine whether, among all the medicinal products used during the operation and general anaesthesia, Patent Blue V is actually responsible. This result is important in the event of subsequent surgery (for contralateral cancer, for example). When marking the sentinel node, all staff caring for the patient must be trained in the technique. Data in the literature show that the rate of identification is improved by carrying out double detection with a radiopharmaceutical and a dye. **Interaction with other medicinal products and other forms of interactions (*):** Medicinal products - **Beta blockers, vasoactive substances, angiotensin-converting enzyme inhibitors, angiotensin receptor antagonists.** These medicinal products reduce the efficacy of cardiovascular compensation mechanisms for haemodynamic disorders. The physician must be aware of this before injecting Patent Blue V and emergency measures must be available. Other forms of interaction - 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. 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. **Fertility, pregnancy and lactation (*):** Pregnancy The use of this medicinal product is not recommended during pregnancy. Lactation - It is not known whether Patent Blue V is excreted in breast milk. **Effects on ability to drive and use machines (*)** The effects on the ability to drive and use machines have not been investigated**. – Undesirable effects (*)** immediate hypersensitivity reactions are possible. These reactions may involve one or more effects, occurring concomitantly or successively, and usually including cutaneous, respiratory and/or cardiovascular manifestations, each of which can be a warning sign of incipient shock and, in very rare instances, can even prove fatal. The most frequently reported effects in a context of hypersensitivity reaction include rash, pruritus, erythema, urticaria, angioedema (such as face oedema or laryngeal oedema), bronchospasm, tachycardia, blood pressure decreased, and circulatory collapse. A bluish coloring of the integuments is observed after the injection, which disappears within 24 to 48 hours. In patients with lymph stasis or circulatory disorders, the coloring may last longer. **Overdose (*)** No cases of overdose have been reported. **– Pharmacodynamic properties (*)** Pharmacotherapeutic group: Diagnostic agents, other diagnostic agents, ATC code: V04CX09. **Pharmacokinetic properties (*)** the dye is eliminated in 24 to 48 hours, mainly in urine (which is highly colored) but also in bile. **Nature and content of container:** colorless type I glass ampoule containing 2 ml. Date of revision: June 2021.

Information may vary depending on the country.
(*) For complete information please refer to the local Summary of Product Characteristics
(**) Indications may differ from country to country.

Reporting of suspected adverse reactions is important as it helps to continuously assess the benefit-risk balance. Therefore, Guerbet encourages you to report any adverse reactions to your health authorities or to our local Guerbet representative.