הודעה על החמרה (מידע בטיחות)

תאריך: 02/01/2012

שם תכשיר באנגלית: Patent Blue V

מספר רישום: 060-28-27291-05

שם בעל הרישום: Promedico LTD

השינויים בעלון מסומנים על רקע צהוב

בעלון לרופא

פרטים על השינוי/ים המבוקש/ים

טקסט חדש	טקסט נוכחי	פרק בעלון
This medicinal product is for diagnostic use only. Marking lymph vessels and arterial regions. Marking sentinel nodes before biopsy in patients with operable breast cancer.	Identification of lymph vessels and arterial territories.	**4.1. Therapeutic indications**
Marking arterial regions: not more than 10 ml intra-arterially Marking lymph vessels and the sentinel node: 1 to 2 ml subcutaneously around the tumour or areola. There is no specific indication for using Patent Blue in children.	The dosage by subcutaneous or intravascular injection is 1 to 10 ml.	**4.2. Posology and method of administration**
Known hypersensitivity to the active substance (Patent Blue V), triphenylmethane dyes or any of excipients indicated in section 6.1.	This medicinal product is contraindicated in patients with a history of	**4.3 Contraindications**

	hypersensitivity to patent blue. This medicinal product is generally not recommended for use during pregnancy.	
There is always a risk of hypersensitivity regardless of the route of administration and the dose administered. Patent Blue V 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 V or triphenylmethane dyes contained in medicinal products, foods and cosmetics. The indication for use of Patent Blue V must therefore be carefully evaluated in these predisposed patients. Corticosteroids and H1 antihistamines have been proposed as premedication in patients at greatest risk of hypersensitivity reactions (history of hypersensitivity to Patent Blue V or other triphenylmethane dyes). However, this premedication does not exclude the possibility of serious or fatal anaphylactic shock. 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 V must be administered only in a setting able to adequately treat these major hypersensitivity reactions. Before administering Patent Blue V: Identify high-risk subjects by means of a detailed clinical interview concerning the patient's history; Insert a venous catheter. During the examination, ensure: Medical surveillance; Maintenance of a venous line; That resuscitation equipment and medications are immediately at hand. After administration of Patent Blue V, the patient must be kept under observation for at least 30 minutes. In the event of an allergic reaction, an investigation must be conducted to determine whether, among all of the medicinal products used during a surgical procedure with general anaesthesia, this reaction can be truly attributed to Patent Blue V. The result of this investigation is important when another surgical procedure is required (e.g. contralateral cancer).	Before any injection, it is essential to question the patient about a history of allergy or intolerance.	**4.4. Special warnings and precautions for use**

All of the team managing the patient must be trained in the sentinel node identification technique. Data of the literature demonstrate improvement of the sentinel node identification rate by performing double detection with a radiopharmaceutical and a dye.		
Medicinal products **Beta-blockers, vasoactive substances, angiotensin-converting enzyme inhibitors, angiotensin receptor antagonists.** These medicinal products decrease the efficacy of cardiovascular mechanisms of compensation of blood pressure disorders: the physician must be informed before injecting Patent Blue and resuscitation equipment must be immediately at hand. Other forms of interaction The partial pressure of oxygen measured by spectrophotometry can be transiently and falsely lowered by about 5 to 10% of baseline values, following an examination with Patent Blue V. When in doubt, arterial blood gases should be checked. Methaemoglobinaemia, measured by the same spectrophotometric method, can be falsely raised.	The measurement of blood O_2 by a spectrophotometric method may yield results which are, falsely and for a short time, about 5 to 10 % under the baseline value during an examination with Patent Blue. In case of doubt it is recommended to verify blood gases .	**4.5. Interaction with other medicinal products** **and other forms of interaction**
Pregnancy No reliable animal teratogenesis data are available. There are no or limited amount of data from the use of Patent Blue V in pregnant women Consequently, the use of Patent Blue V is not recommended during pregnancy. Lactation It is unknown whether Patent Blue V is excreted in human milk	No reliable animal teratogenesis data are available. The currently available relevant data are not sufficient to evaluate a possible malformative or foetotoxic effect of patent blue, when it is administered during pregnancy. Consequently, the use of this medicinal product is not recommended during pregnancy.	**4.6.** Pregnancy **and lactation**

<table>
<tr><td>The potential effects of Patent Blue V on the ability to drive and use machines have not been studied.</td><td></td><td>4.7. Effects on ability to drive and use machines</td></tr>
<tr><td>Immediate hypersensitivity reactions can occur. These reactions may comprise one or more of the following effects, either concomitantly or successively: skin, respiratory and/or cardiovascular reactions. Each of these effects can be a precursor sign of anaphylactic shock, which, in very rare cases, can be fatal.

A bluish discolouration of the integument is observed after injection, which resolves over the following 24 to 48 hours. This discolouration can persist for a longer time in the presence of lymphatic stasis or circulatory disorders.

Adverse events are presented in the following table by System Organ Class and by frequency using the following categories: very common ((1/10), common ((1/100 to 1< 1/10), uncommon ((1/1,000 to 1< 1/100), rare ((1/10,000 to< 1/1,000), very rare (< 1/10,000), unknown frequency (cannot be estimated on the basis of available data).
<table>
<tr><th>System Organ Class</th><th>Frequency: adverse event</th></tr>
<tr><td>Immune system disorders</td><td>Unknown frequency: anaphylactic shock, hypersensitivity</td></tr>
<tr><td>Respiratory, thoracic and mediastinal disorders</td><td>Unknown frequency: bronchospasm</td></tr>
<tr><td>Skin and subcutaneous tissue disorders</td><td>Unknown frequency: angioedema, urticaria, blue discolouration of the skin</td></tr>
<tr><td>General disorders and administration site conditions</td><td>Unknown frequency: discolouration of the administration site</td></tr>
</table>
</td><td>Possibility of hypersensitivity reaction with urticaria, exceptionally angioneurotic oedema, anaphylactic shock.
Bluish staining of the integumant is observed after injection, which resolves over the following 24 or 48 hours. This staining can exceptionally persist for a longer time in the case of lymph stasis or circulatory disorders.</td><td>4.8. Undesirable effects</td></tr>
<tr><td>No cases of overdose have been reported.</td><td></td><td>4.9. Overdose</td></tr>
<tr><td>The dye is eliminated in 24 to 48 hours, mainly in urine (which is highly coloured) but also in bile.</td><td>This dye is eliminated within 24 to 48 hours, mainly in the urine which is intensely stained, but also in the bile.</td><td>5.2. Pharmacokinetic</td></tr>
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Preclinical data derived from conventional single-dose and repeated-dose safety pharmacology and toxicology studies have not revealed any particular risk for humans.		**5.3. Preclinical safety data**
In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.		**6.2. Incompatibilities**

*מבוסס על עלון spc מאושר בצרפת ועל עדכוני בטיחות PV expert Report.

בעלון לצרכן -NA-

פרטים על השינוי/ים המבוקש/ים		
פרק בעלון	טקסט נוכחי	טקסט חדש
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שרה פלזמן – רוקחת
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