הודעה על החמרה (מידע בטיחות)

תאריך: 1.1.13

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		
פרק בעלון	טקסט נוכחי	טקסט חדש

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.	Marking lymph vessels and arterial regions. Marking sentinel nodes before biopsy in patients with operable breast cancer.	**4.1 Therapeutic indications**
Pregnancy No reliable animal teratogenesis data are available. Currently, there are no, or limited data, to evaluate a possible malformative or foetotoxic effect of Patent Blue V when it is administered during pregnancy. Consequently, the use of this medicinal product is not recommended during pregnancy. Lactation There are no data concerning excretion of Patent Blue V into breast milk.	Consequently, the use of this medicinal product is not recommended during pregnancy. 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.	**4.6 pregnancy and lactation**
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. A bluish discolouration of the integuments is observed after injection, which resolves over the following 24 to 48 hours. The discolouration can persist for longer in the event of lymph stasis or circulatory disorders. Undesirable effects are given in the table below by System Organ Class and by frequency, using the following classifications: very commom (≥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 (cannot be estimated from available data).	Immediate hypersensitivity reactions (several minutes to several hours): urticaria is common, angioneurotic oedema and anaphylactic shock are uncommon. A bluish colouring of the integuments is observed after the injection, which disappears within 24 to 48 hours. In patients with lymph stasis or circulatory disorders, the colouring may last longer.	**4.8 Undesirable effects**

<table><tr><td>System Organ Class</td><td>Frequency: adverse event</td></tr><tr><td>Immune system disorders</td><td>Unknown frequency: anaphylactic shock, hypersensitivity</td></tr><tr><td>Skin and subcutaneous tissue disorders</td><td>Unkown frequency: angio-oedema, 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>			
Preclinical data derived from conventional single-dose and repeated-dose safety pharmacology and toxicology studies have not revealed any particular risk for humans. A mutagenic effect was observed *in vitro*, at high concentrations, on a bacterial gene mutation test after metabolic activation. This effect was not confirmed on an *in vitro* gene mutation test on mammalian cells (L5178Y murine lymphoma cells), or on a micronucleus test in rats by intravenous injection of doses significantly higher than the maximum dose in humans, and therefore has limited clinical significance.		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**

בעלון לצרכן

פרטים על השינוי/ים המבוקש/ים		
פרק בעלון	טקסט נוכחי	טקסט חדש

לא רלוונטי

העלון, שבו מסומנים השינויים המבוקשים על רקע צהוב הועבר בדואר אלקטרוני בתאריך 19.11.2012

- ☐ קיים עלון לצרכן והוא מעודכן בהתאם.
- ☑ אסמכתא לבקשה: SPC של היצרן
- ☑ השינוי הנ"ל הוגש לרשויות הבריאות בצרפת
- ☑ אני, הרוקח הממונה של חברת Promedico LTD מצהיר בזה כי אין שינויים **נוספים** בעלון.

שרון פלדמן
רוקחת ממונה
מ.ר. 31303

חתימת הרוקח הממונה