הודעה על החמרה (מידע בטיחות) בעלון לרופא

**תאריך 13/01/2014**

**שם התכשיר באנגלית ומספר הרישום:**

**Oxaliplatin Medac 50 mg 137 24 31503**

**Oxaliplatin Medac 100 mg 137 25 31504**

**Oxaliplatin Medac 150 mg 139 57 31825**

**שם בעל הרישום: צמל ביו-פארמה בע"מ**

טופס זה מיועד לפרוט ההחמרות בלבד!

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| **ההחמרות המבוקשות** | | |
| **פרק בעלון** | **טקסט נוכחי** | **טקסט חדש** |
| **Special warnings and precautions for use** | …  Oxaliplatin rechallenge is contra-indicated.  In case of oxaliplatin extravasation, the infusion must be stopped immediately and usual local symptomatic treatment initiated.  … | ….  Cross reactions, sometimes fatal, have been reported with all platinum compounds.  ….  *Reversible Posterior Leukoencephalopathy Syndrome (RPLS)*  Cases of Reversible Posterior Leukoencephalopathy Syndrome (RPLS) have been reported in patients receiving oxaliplatin in combination chemotherapy. RPLS is a rare, reversible, rapidly evolving neurological condition, which can include seizure, hypertension, headache, confusion, blindness, and other visual and neurological disturbances (see section 4.8). Diagnosis of RPLS is based upon confirmation by brain imaging, preferably MRI (Magnetic Resonance Imaging).  … |
| **Effects on ability to drive and use machines** |  | …  Vision abnormalities, in particular transient vision loss (reversible following therapy discontinuation), may affect patients´ ability to drive and use machines. Therefore, patients should be warned of the potential effect of these events on the ability to drive or use machines. |
| **Undesirable effects** | **Rare/ Respiratory, thoracic and mediastinal disorders:**  …  - Interstitial lung disease  …  1 Extravasation may result in local pain and inflammation which may be severe and lead to complications, especially when oxaliplatin is infused through a peripheral vein (see section 4.4).  …  3 Very common fever, either from infection (with or without febrile neutropenia) or isolated fever from immunological mechanism. | **Table:**  **Rare/Nervous system disorders:**  …  - Reversible Posterior Leukoencephalopathy syndrome (RPLS) (see section 4.4)  **Rare/Eye disorders:**  …  - Transient vision loss, reversible following therapy discontinuation  **Rare/ Respiratory, thoracic and mediastinal disorders:**  …  - Interstitial lung disease, sometimes fatal  …  **Common/Gastrointestinal disorders:**  …  - Gastrointestinal haemorrhage  …  ++ Very common fever, rigors (tremors), either from infection (with or without febrile neutropenia) or possibly from immunological mechanism.  +++ Injection site reactions including local pain, redness, swelling and thrombosis have been reported.  Extravasation may also result in local pain and inflammation which may be severe and lead to complications including necrosis, especially when oxaliplatin is infused through a peripheral vein (see section 4.4).  Blood and lymphatic system disorders  Postmarketing experience with frequency unknown  Hemolytic uremic syndrome  Nervous system disorders  Postmarketing experience with frequency unknown  Convulsion |

מצ"ב העלון שבו מסומנים ההחמרות המבוקשות על רקע צהוב.

שינויים שאינם בגדר החמרות סומנו (בעלון) בטקסט ירוק. יש לסמן רק תוכן מהותי ולא שינויים במיקום הטקסט.

הועבר בדואר אלקטרוני בתאריך 13.01.2014