

# הודעה על החומרה ( מידע בטיחות) בעלון לרופא

(מספרן 3102.50)

תאריך 16/06/2014

שם תכשיר באנגלית ומספר הרישום **MabThera® 112.51.29472.00**

שם בעל הרישום **רוש פרמצטטיקה (ישראל) בע"מ**

טופס זה מיועד **לפרוטה החומרה בלבד!**

ההומרות המבוקשות		
טקסט חדש	טקסט הנוכחי	פרק בעלון
<p><u>Non-Hodgkin's lymphoma and chronic lymphocytic leukaemia</u></p> <p><i>Infusion related reactions</i></p> <p>Severe infusion related reactions with fatal outcome have been reported during post-marketing use of the MabThera intravenous formulation, with an onset ranging within 30 minutes to 2 hours after starting the first MabThera IV infusion. They were characterized by pulmonary events and in some cases included rapid tumour lysis and features of tumour lysis syndrome in addition to fever, chills, rigors, hypotension, urticaria, angioedema and other symptoms (see section 4.8).</p>		<b>4.4 Special warnings and precautions for use</b>
<p><u>Experience from rheumatoid arthritis</u></p> <p><i>Neurologic events</i></p> <p>Cases of posterior reversible encephalopathy syndrome (PRES) / reversible posterior leukoencephalopathy syndrome (RPLS) have been reported. Signs and symptoms included visual disturbance, headache, seizures and altered mental status, with or without associated hypertension. A diagnosis of PRES/RPLS requires confirmation by brain imaging. The reported cases had recognised risk factors for PRES/RPLS, including the patients' underlying disease, hypertension, immunosuppressive therapy and/or chemotherapy.</p> <p><u>Experience from granulomatosis with polyangiitis and microscopic polyangiitis</u></p>		<b>4.8 Undesirable effects</b>

<p><b>Neurologic events</b></p> <p>Cases of posterior reversible encephalopathy syndrome (PRES) / reversible posterior leukoencephalopathy syndrome (RPLS) have been reported in autoimmune conditions. Signs and symptoms included visual disturbance, headache, seizures and altered mental status, with or without associated hypertension. A diagnosis of PRES/RPLS requires confirmation by brain imaging. The reported cases had recognised risk factors for PRES/RPLS, including the patients' underlying disease, hypertension, immunosuppressive therapy and/or chemotherapy.</p>		
<p>Patients who experience overdose should have immediate interruption of their infusion and be closely monitored.</p>		<p><b>4.9 Overdose</b></p>

**מצ"ב העלון, שבו מסומנת החומרה המבוקשת על רקע צהוב.**  
 שינויים שאינם בגדיר החומרות סומנו (עלון) בצבע שונה. יש לסמן רק תוכן מהותי ולא שינויים במיקום הטקסט.

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