

הודעה על החמרה (מידע בטיחות) בעלון לרופא
(מעודכן 3102.50)

תאריך 01/12/2013

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

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

טופס זה מיועד לפרוט ההחמרות בלבד !

ההחמרות המבוקשות		
טקסט חדש	טקסט נוכחי	פרק בעלון
<p><u>Non-Hodgkin's lymphoma and chronic lymphocytic leukaemia</u></p> <p><i>Infections</i></p> <p>Hepatitis B virus (HBV) screening should be performed in all patients before initiation of treatment with MabThera. At minimum this should include HBsAg-status and HBcAb-status. These can be complemented with other appropriate markers as per local guidelines. Patients with active hepatitis B disease should not be treated with MabThera. Patients with positive hepatitis B serology (either HBsAg or HBcAb) should consult liver disease experts before start of treatment and should be monitored and managed following local medical standards to prevent hepatitis B reactivation.</p> <p><u>Rheumatoid arthritis, Granulomatosis with polyangiitis and Microscopic polyangiitis</u></p> <p><i>Hepatitis B Infections</i></p> <p>Hepatitis B virus (HBV) screening should be performed in all patients before initiation of treatment with MabThera. At minimum this should include HBsAg-status and HBcAb-status. These can be complemented with other appropriate markers as per local guidelines. Patients with active hepatitis B disease should not</p>	<p><u>Non-Hodgkin's lymphoma and chronic lymphocytic leukaemia</u></p> <p><i>Infections</i></p> <p>Hepatitis B virus (HBV) screening should always be performed in patients at risk of infection with HBV before initiation of treatment with MabThera. Carriers of hepatitis B and patients with a history of hepatitis B should be closely monitored for clinical and laboratory signs of active HBV infection during and for several months (up to seven) following MabThera therapy.</p> <p><u>Rheumatoid arthritis, Granulomatosis with polyangiitis and Microscopic polyangiitis</u></p> <p><i>Hepatitis B Infections</i></p> <p>Hepatitis B virus (HBV) screening should always be performed in patients at risk of infection with HBV before initiation of treatment with MabThera. Carriers of hepatitis B and Patients with a history of hepatitis B should be closely monitored for clinical and laboratory signs of active HBV infection during, and for several</p>	<p>Special warnings and precautions for use</p>

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מצ"ב העלון, שבו מסומנות החמרות המבוקשות **על רקע צהוב**. שינויים שאינם בגדר החמרות סומנו (בעלון) בצבע שונה. יש לסמן רק תוכן מהותי ולא שינויים במיקום הטקסט.
