# הודעה על החמרה ( מידע בטיחות) בעלון לרופא

# (מעודכן 05.2013)

**תאריך 10/2013**

**שם תכשיר באנגלית ArzerraTM 1000mg ArzerraTM 100mg**

**מספר הרישום 148-72-33501 148-71-33508**

**שם בעל הרישום GlaxoSmithKline (ISRAEL) Ltd :**

טופס זה מיועד לפרוט ההחמרות בלבד !

בעלון לרופא

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| **ההחמרות המבוקשות** | | |
| **פרק בעלון** | **טקסט נוכחי** | **טקסט חדש** |
| **Special Warnings and Precautions for Use** | Hepatitis B  Hepatitis B (HBV) infection and reactivation, including fatal cases, can occur in patients taking ofatumumab. Patients at high risk of HBV infection should be screened before initiation of Arzerra. Carriers of hepatitis B should be closely monitored for clinical and laboratory signs of active HBV infection during treatment with ofatumumab and for 6-12 months following the last infusion of Arzerra. Arzerra should be discontinued in patients who develop viral hepatitis, and appropriate treatment should be instituted. Insufficient data exist regarding the safety of administration of ofatumumab in patients with active hepatitis. | Hepatitis B  Hepatitis B virus (HBV) infection and reactivation, in some cases resulting in fulminant hepatitis, hepatic failure and death, has occurred in patients treated with drugs classified as CD20-directed cytolytic antibodies, including Arzerra. Cases have been reported in patients who are hepatitis B surface antigen (HBsAg) positive and also in those who are hepatitis B core antibody (anti-HBc) positive but HBsAg negative. Reactivation has also occurred in patients who appear to have resolved hepatitis B infection (i.e. HBsAg negative, anti-HBc positive, and hepatitis B surface antibody [anti-HBs] positive).  HBV reactivation is defined as an abrupt increase in HBV replication manifesting as a rapid increase in serum HBV DNA level or detection of HBsAg in a person who was previously HBsAg negative and anti-HBc positive. Reactivation of HBV replication is often followed by hepatitis, i.e., increase in transaminase levels and, in severe cases, increase in bilirubin levels, liver failure, and death.  All patients should be screened for HBV infection by measuring HBsAg and anti-HBc before initiation of Arzerra treatment. For patients who show evidence of prior (HBsAg negative, anti-HBc positive) hepatitis B infection, physicians with expertise in managing hepatitis B should be consulted regarding monitoring and initiation of HBV antiviral therapy. Arzerra treatment should not be initiated in patients with evidence of current hepatitis B infection (HBsAg positive) until the infection has been adequately treated.  Patients with evidence of prior HBV infection should be monitored for clinical and laboratory signs of hepatitis or HBV reactivation during treatment with and for 6-12 months following the last infusion of Arzerra. HBV reactivation has been reported up to 12 months following completion of therapy. Discontinuation of HBV antiviral therapy should be discussed with physicians with expertise in managing hepatitis B.  In patients who develop reactivation of HBV while receiving Arzerra, Arzerra and any concomitant chemotherapy should be interrupted immediately, and appropriate treatment instituted. Insufficient data exist regarding the safety of resuming Arzerra in patients who develop HBV reactivation. Resumption of Arzerra in patients whose HBV reactivation resolves should be discussed with physicians with expertise in managing hepatitis B. |
| **Undesirable Effects** | Infections and Infestations  Very common  Lower respiratory tract infection, including pneumonia, upper respiratory tract infection  Common  Sepsis, including neutropenic sepsis and septic shock, herpes virus infection, urinary tract infection | Infections and Infestations  Very common  Lower respiratory tract infection, including pneumonia, upper respiratory tract infection  Common  Sepsis, including neutropenic sepsis and septic shock, herpes virus infection, urinary tract infection  Rare  Hepatits B infection and reactivation |