Arzerra 100 mg; Arzerra 1000 mg
ארזרה 100 מ"ג; ארזרה 1000 מ"ג

התוויה:
Treatment of chronic lymphocytic leukaemia (CLL) in patients who are refractory to fludarabine and alemtuzumab.

הרכב וחוזק:
Each vial contains 100 mg of ofatumumab in 5 ml, or 1,000 mg of ofatumumab in 50 ml.

- **העלון לצרכן במתכונת עלון לרופא עודכן ב-נובמבר 2013**
- **בהודעה זו מצוינים השינויים המהווים החמרה. בעלון שינויים נוספים שאינם החמרה.**
- **טקסט שהתווסף מסומן בקו תחתי.**

- **העדכונים בעלון לצרכן במתכונת עלון לרופא נעשו בסעיפים הבאים:**

Special warnings and precautions for use
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
Rare - Hepatits B infection and reactivation

העלון לצרכן במתכונת של עלון לרופא ישלח למשרד הבריאות לצורך פרסומו במאגר התרופות שבאתר משרד הבריאות וניתן לקבלו מודפס על-ידי פניה לחברת http://www.health.gov.il/units/pharmacy/trufot/index.asp
גלקסוסמיתקליין רח' בזל 25 פתח תקוה בטלפון: 03-9297100.

סבינה עמית
רוקחת ממונה
Vaccines