

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

תאריך 30/06/2015

שם תכשיר באנגלית ומספר הרישום [153-41-34195-00] Gazyva

שם בעל הרישום רוש פרמצבטיקה (ישראל) בע"מ

טופס זה מיועד לפרוט ההחמרות בלבד !

ההחמרות המבוקשות - עלון לרופא		
טקסט חדש	טקסט נוכחי	פרק בעלון
<p><i>Prophylaxis and premedication for tumour lysis syndrome (TLS)</i> Patients with a high tumour burden and/or a high circulating lymphocyte count ($> 25 \times 10^9/L$) and/or renal impairment ($CrCl < 70 \text{ mL/min}$) are considered at risk of TLS and should receive prophylaxis. Prophylaxis should consist of adequate hydration and administration of uricostatics (e.g. <i>allopurinol</i>), or suitable alternative treatment such as urate oxidase (e.g. <i>rasburicase</i>), starting 12-24 hours prior to start of Gazyva infusion as per standard practice (see section 4.4). Patients should continue to receive repeated prophylaxis prior to each subsequent infusion, if deemed appropriate.</p>	<p><i>Prophylaxis for tumour lysis syndrome (TLS)</i> Prophylaxis with adequate hydration and administration of uricostatics (e.g. <i>allopurinol</i>) starting 12-24 hours prior to start of therapy is recommended for patients with high circulating lymphocyte count ($> 25 \times 10^9/L$) to reduce the risk of tumour lysis syndrome (see section 4.4).</p>	<p>Posology and method of administration</p>
<p><u>Tumour lysis syndrome (TLS)</u> Tumour lysis syndrome (TLS) has been reported with Gazyva. Patients who are considered to be at risk of TLS (e.g. patients with a high tumour burden and/or a high circulating lymphocyte count [$> 25 \times 10^9/L$] and/or renal impairment [$CrCl < 70 \text{ mL/min}$]) should receive prophylaxis. Prophylaxis should consist of adequate hydration and administration of uricostatics (e.g. <i>allopurinol</i>), or a suitable alternative such as a urate oxidase (e.g. <i>rasburicase</i>) starting 12-24 hours prior to the infusion of Gazyva as per standard practice (see section 4.2). All patients considered at risk should be carefully monitored during the initial days of treatment with a special focus on renal function, potassium, and uric acid values. Any additional guidelines according to</p>	<p><u>Tumour lysis syndrome (TLS)</u> Tumour lysis syndrome (TLS) has been reported with Gazyva. Patients who are considered to be at risk of TLS (e.g. patients with a high tumour burden or a high circulating lymphocyte count [$> 25 \times 10^9/L$]) should receive adequate tumour lysis prophylaxis with uricostatics (e.g. <i>allopurinol</i> and hydration starting 12-24 hours prior to the infusion of Gazyva (see section 4.2). For treatment of TLS, correct electrolyte abnormalities, monitor renal function and fluid balance, and administer supportive care, including dialysis as indicated.</p>	<p>Special warnings and precautions for use</p>

ההחמרות המבוקשות - עלון לרופא

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<p>standard practice should be followed.</p> <p>For treatment of TLS, correct electrolyte abnormalities, monitor renal function and fluid balance, and administer supportive care, including dialysis as indicated.</p>		
<p><i>Reporting of suspected adverse reactions</i></p> <p>Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form (http://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdverseEffectMedic@moh.health.gov.il) or by email (adr@MOH.HEALTH.GOV.IL)</p>		Undesirable effects