

הודעה על החמרה (מידע בטיחות) בעלון לרופא
 (מעודכן 05.2013)

תאריך: **08 פברואר 2017**

שם תכשיר באנגלית ומספרי רישומו : **טרג'נטה 5 מ"ג טבליות 149-96-33738-00**

שם בעל הרישום: **בורינגר אינגלהיים ישראל**
 ההחמרות מסומנות על רקע **צהוב**.

ההחמרות המבוקשות		
טקסט חדש	טקסט נוכחי	פרק בעלון
<p>Changes in laboratory findings were similar in patients treated with TRAJENTA 5 mg compared to patients treated with placebo.</p> <p>Increase in Uric Acid: Changes in laboratory values that occurred more frequently in the TRAJENTA group and $\geq 1\%$ more than in the placebo group were increases in uric acid (1.3% in the placebo group, 2.7% in the TRAJENTA group).</p> <p>Increase in Lipase: In a placebo-controlled clinical trial with TRAJENTA in type 2 diabetes mellitus patients with micro- or macroalbuminuria, a mean increase of 30% in lipase concentrations from baseline to 24 weeks was observed in the TRAJENTA arm compared to a mean decrease of 2% in the placebo arm. Lipase levels above 3 times upper limit of normal were seen in 8.2% compared to 1.7% patients in the TRAJENTA and placebo arms, respectively.</p>	<p>Changes in laboratory findings were similar in patients treated with TRAJENTA 5 mg compared to patients treated with placebo.</p> <p>Changes in laboratory values that occurred more frequently in the TRAJENTA group and $\geq 1\%$ more than in the placebo group were increases in uric acid (1.3% in the placebo group, 2.7% in the TRAJENTA group).</p>	<p>6.1 Clinical trial expertise</p>