

## הודעה על החומרה ( מידע בטיחות)

תאריך: 14/11/2012

שם תכשיר באנגלית ומספר הרישום :

**LYRICA 25 MG 132.97.31185**

**LYRICA 50 MG 132.98.31186**

**LYRICA 75 MG 132.99.3118**

**LYRICA 100 MG 133.01.31188**

**LYRICA 150 MG 133.02.31189**

**LYRICA 200 MG 133.03.31190**

**LYRICA 225 MG 148.19.33471**

**LYRICA 300 MG 133.04.31191**

שם בעל הרישום: פיזר פרמצטטיקה ישראל בע"מ

השינויים בעליון מסומנים על רקע צהוב

**בעלון ל佗פא**

### פרטים על השינויים המבוקש/ים

פרק בעלון	טקסט נוכחי	טקסט חדש
<b>4.4 Special warnings and precautions for use</b>		Pregabalin is not known to be active at receptor sites associated with drugs of abuse. Cases of abuse have been reported in the post-marketing database. As with any CNS active drug, carefully evaluate patients for history of drug abuse and observe them for signs of pregabalin abuse.
<b>4.8 Undesirable effects</b>	Select adverse events that were treatment related in the pooled analysis of clinical trials are listed in the table below by system organ class and frequency (very common ( $\geq 1/10$ , common ( $\geq 1/100, < 1/10$ ), uncommon ( $\geq 1/1000, < 1/100$ ) and rare ( $<1/1000$ )).	Select adverse events that were treatment related in the pooled analysis of clinical trials are listed in the table below by system organ class and frequency (very common ( $> 1/10$ , common ( $> 1/100, < 1/10$ ), uncommon ( $>1/1000, <1/100$ ) and rare ( $<1/1000$ )).
<b>6.3 Special precautions for storage</b>	Store at room temperature (25°C).	Store below 25°C.

X