

הודעה על החמרה (מידע בטיחות)

תאריך: 14/11/2012

שם תכשיר באנגלית ומספרי 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 פרמצבטיקה ישראל בע"מ

השינויים בעלון מסומנים על רקע צהוב

בעלון לרופא

פרטים על השינויים המבוקש/ים

טקסט חדש	טקסט נוכחי	פרק בעלון
<p>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.</p> <p>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 ($< 1/1000$)).</p> <p>Store below 25°C.</p>	<p>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 ($< 1/1000$)).</p> <p>Store at room temperature (25°C).</p>	<p>4.4 Special warnings and precautions for use</p> <p>4.8 Undesirable effects</p> <p>6.3 Special precautions for storage</p>