# הודעה על החמרה ( מידע בטיחות) בעלון לרופא

# (מעודכן 05.2013)

**תאריך:**

**שם תכשיר באנגלית: Anafranil 25mg, Anafranil SR 75mg tablets**

**מספר הרישום: [24600], [26407]**

**שם בעל הרישום:** נוברטיס פארמה סרויסס איי ג'י

טופס זה מיועד לפירוט ההחמרות בלבד!

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| טקסט שחור – טקסט מאושרטקסט עם קו תחתי – הוספת טקסט לעלון המאושר~~טקסט עם קו חוצה~~ – מחיקת טקסט מהעלון המאושרטקסט המסומן בצהוב – החמרה |

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| **ההחמרות המבוקשות** |
| **פרק בעלון** | **טקסט נוכחי** | **טקסט חדש** |
| **Overdosage** | The signs and symptoms of overdose with Anafranil are similar to those reported with other tricyclic antidepressants. Cardiac abnormalities and neurological disturbances are the main complications. In children, accidental ingestion of any amount should be regarded as serious and potentially fatal. | The signs and symptoms of overdose with Anafranil are similar to those reported with other tricyclic antidepressants. Cardiac abnormalities and neurological disturbances are the main complications. In children, accidental ingestion of any amount should be regarded as serious and potentially fatal.Rare cases of pharmacobezoar, of varying severity including fatal outcome, have been reported in association with overdose of sustained release Anafranil. The pharmacobezoar may be radiopaque, facilitating radiologic (X-ray or CT scan) confirmation but cannot exclude the diagnosis. The formation of pharmacobezoar may cause slow but continual release and absorption of clomipramine which may lead to overdose complications, including death, hours after drug ingestion and initial treatment with gastric lavage and activated charcoal. Since gastric lavage may be ineffective and could further increase systemic drug levels, consideration should be given to physical removal of the pharmacobezoar by endoscopy or surgery in selected patients. Since these cases are rare, there is insufficient clinical data regarding optimal treatment which should take into account the size and location of the pharmacobezoar, patient symptoms and condition and drug levels. |