

2012 ספטמבר

רופא/ה נכבד/ה,  
רוקח/ת נכבד/ה,

**הנדון: הודעת ה-FDA ביחס לתכשירים המכילים קודאין**

אנו מבקשים להסב את תשומת ליבך להודעת ה-FDA, שפורסמה לפני זמן קצר, ביחס לתכשירים המכילים קודאין.

חברת תרימה, תוצרי רפואה ישראליים מעברות בע"מ, מייצרת ומשווקת את התכשיר:

**Histafed Compound Linctus Syrup**

**הרכב:**

כל 5 מ"ל (כפית) מכילים:

Pseudoephedrine HCl	30mg
Codeine phosphate	5mg
Tripolidine HCl	1.25mg

המאושר בישראל להתוויה:

Antitussive syrup for the symptomatic relief of cough accompanied by nasal congestion and congestion of the upper respiratory tract.

להלן קטעים מתוך הודעת ה-FDA:

- [8-15-2012] The U.S. Food and Drug Administration (FDA) is reviewing reports of children who developed serious adverse effects or died after taking codeine for pain relief after tonsillectomy and/or adenoidectomy for obstructive sleep apnea syndrome. Recently, three pediatric deaths and one non-fatal but life-threatening case of respiratory depression were documented in the medical literature. These children (ages two to five) had evidence of an inherited (genetic) ability to convert codeine into life-threatening or fatal amounts of morphine in the body. All children had received doses of codeine that were within the typical dose range.
- Taking codeine after tonsillectomy and/or adenoidectomy may increase the risk for breathing problems and death in children who are "ultra-rapid metabolizers." The estimated number of "ultra-rapid metabolizers" is generally 1 to 7 per 100 people, but may be as high as 28 per 100 people in some ethnic groups.
- **Health care professionals** should be aware of the risks of using codeine in children, particularly in those who have undergone tonsillectomy and/or adenoidectomy for obstructive sleep apnea syndrome. If prescribing codeine-containing drugs, the lowest effective dose for the shortest period of time should be used on an as-needed basis (i.e., not scheduled around the clock).

מצ"ב קישור עם הודעת ה-FDA המלאה:

[Codeine use in certain children after tonsillectomy and/or adenoidectomy may lead to rare, but life-threatening adverse events or death<sup>5</sup>](#)

בכבוד רב,

מגר' חיים זגרמן  
ראש האגף למינהל רפואי  
תרימה, תוצרי רפואה ישראליים מעברות בע"מ