



**The FDA Safety Information and  
Adverse Event Reporting Program**

**Codeine Use in Certain Children After Tonsillectomy and/or Adenoidectomy:  
Drug Safety Communication - Risk of Rare, But Life-Threatening Adverse  
Events or Death**

[Posted 08/15/2012]

美國FDA檢視兒童嚴重不良反應案例：扁桃腺切除和/或腺體切除(治療阻塞性睡眠呼吸中止症)後為了緩解疼痛而服用codeine造成死亡的報告。近來，有3件兒童死亡案例，與1件非致命卻危及生命的呼吸抑制情形被記載於醫學文獻中。這些兒童(年齡2到5歲)使用codeine的劑量在正常範圍內。

醫療人員應了解兒童使用codeine的風險，尤其針對扁桃腺切除和/或腺體切除(治療阻塞性睡眠呼吸中止症)的兒童。如果使用含codeine的藥物，應於最短的期間內使用最低有效劑量，且需要時使用(不需常規使用)。父母和照顧人若發現兒童有不正常嗜睡、精神錯亂、呼吸困難，應立即就醫。

[Posted 08/15/2012]

**AUDIENCE:** Pediatricians, Surgery, Consumer

**ISSUE:** The 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.

**RECOMMENDATION:** 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).

Parents and caregivers who observe unusual sleepiness, confusion, or difficult or noisy breathing in their child should seek medical attention immediately, as these are signs of overdose.