



## Codeine Cough-and-Cold Medicines in Children: Drug Safety Communication - FDA Evaluating Potential Risk of Serious Side Effects

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FDA 正在調查 18 歲以下孩童使用含可待因藥物治療咳嗽或感冒的安全性，因為使用期間可能出現嚴重的副作用包含呼吸減緩或呼吸困難。在 2015 年四月，歐洲藥品管理局 (EMA) 宣布，可待因不可用於治療 12 歲以下孩童的咳嗽和感冒，EMA 也表示，可待因不建議用在 12 至 18 歲有呼吸道疾病(包含哮喘與慢性呼吸道疾患)的孩童身上。

FDA 會依歐洲藥品管理局 (EMA) 的建議持續評估此安全議題，並於分析完畢後發布結論與建議。

### 建議

FDA 建議，病人或照護者若發現孩童使用含可待因藥物後出現呼吸微弱、困難、不尋常的嗜睡，須立即停藥並緊急送醫治療。父母與照護者在給予孩童藥品時，需閱讀藥品標籤以確認藥品中是否含可待因，如有任何疑慮，需與專業醫療人員或藥師確認。醫療人員當處方含可待因的咳嗽或感冒藥於孩童身上時，須遵循藥品標籤上的警示與使用建議。

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**AUDIENCE:** Family Practice, Pediatrics, Surgery, Patient

**ISSUE:** FDA is investigating the safety of using codeine-containing medicines to treat coughs and colds in children under 18 years because of the potential for serious side effects, including slowed or difficult breathing.

Children, especially those who already have breathing problems, may be more susceptible to these serious side effects. In 2013, FDA warned against using codeine in children who recently had surgery to remove their tonsils and/or adenoids.

In April 2015, the European Medicines Agency (EMA) announced that codeine must not be used to treat cough and cold in children under 12 years, and that codeine is not recommended in children and adolescents between 12 and 18 years who have breathing problems, including those with asthma and other chronic breathing problems.

FDA will continue to evaluate this safety issue and will consider the EMA recommendations. Final conclusions and recommendations will be communicated when the FDA review is complete.

**BACKGROUND:** Codeine is a specific type of narcotic medicine called an opioid that is used to treat mild to moderate pain and also to reduce coughing. It is usually combined with other medications in prescription and over-the-counter (OTC) cough-and-cold medicines.

**RECOMMENDATION:** Parents and caregivers who notice any signs of slow or shallow breathing, difficult or noisy breathing, confusion, or unusual sleepiness in their child should stop giving their child codeine and seek medical attention immediately by taking their child to the emergency room or calling 911. Parents and caregivers should always read the product label to find out if a medicine contains codeine and talk with their child's health care professional or a pharmacist if they have any questions or concerns. Health care professionals should continue to follow the recommendations in the drug labels and use caution

when prescribing or recommending codeine-containing cough-and-cold medicines to children.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program.