



FDA evaluating the potential risks of using codeine cough-and-cold medicines in children

Safety Announcement

[7-1-2015] The U.S. Food and Drug Administration (FDA) is investigating the possible risks 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. We are evaluating all available information and will also consult with external experts by convening an advisory committee to discuss these safety issues. We will communicate our final conclusions when our review is complete.

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.

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. Codeine works by changing the way the brain responds to pain and by decreasing the activity in the part of the brain that causes coughing.

In the body, codeine is converted to the opioid morphine. Some people convert codeine to morphine faster and more completely than usual, resulting in higher amounts of morphine in their blood. High levels of morphine can result in problems, including breathing difficulty that may lead to death.

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. We will convene a public advisory committee meeting to discuss these issues and provide input regarding whether additional action by FDA is needed. We will notify the public of this meeting by posting notices in the [Federal Register](#) and on the [Advisory Committees web page](#).

We urge health care professionals, parents, and caregivers to report side effects involving codeine to the FDA MedWatch program, using the information in the “Contact FDA” box at the bottom of the page.