

Codeine risky for kids after certain surgeries, FDA says

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10 deaths, 3 overdoses reported following removal of tonsils or adenoids.

(HealthDay)—Children who are given codeine for pain relief after surgery to remove tonsils or adenoids are at risk for overdose and death, U.S. health officials said Thursday.

The U.S. <u>Food and Drug Administration</u> said a new boxed warning—the agency's strongest caution—will be added to the labels of codeine-containing products to warn about this danger.

The FDA strongly recommends against the use of codeine to manage pain in children after surgery to remove <u>tonsils</u> or <u>adenoids</u>, and suggests that doctors use an alternate <u>pain reliever</u>. The agency also said parents and caregivers need to be aware of the risks and ask for a different <u>pain medicine</u> if their children are prescribed codeine after having their



tonsils or adenoids removed.

Codeine is an opioid (narcotic) medication used to treat mild to moderate pain and is often prescribed to children after tonsil or adenoid removal. However, some children have died after being given codeine within the recommended dose range.

In August 2012, the FDA warned about the danger in children who are "ultra-rapid metabolizers" of codeine, which means their liver converts codeine to morphine in higher-than-normal amounts. High levels of morphine can result in potentially fatal breathing problems.

Since then, a safety review by the FDA identified 10 deaths and three overdoses associated with codeine that occurred among children in the United States between 1969 and May 2012. Many of these children were recovering from surgery to remove tonsils or adenoids.

All of the children, aged 21 months to 9 years old, received doses of codeine within the normal dose range. Signs of morphine overdose developed within one to two days after the children began taking codeine, the FDA said in an agency news release.

Codeine is available by prescription either alone or in combination with acetaminophen and aspirin, and in some cough and <u>cold medications</u>.

When prescribed to treat pain, codeine should not be given on a fixed schedule, but only when a child needs relief from pain. They should never receive more than six doses in a day, the FDA said.

Children receiving codeine for pain should be closely monitored for signs of morphine overdose. These include: unusual sleepiness, such as being difficult to wake up; confusion or disorientation; breathing problems; and blueness on the lips or around the mouth.



Parents and caregivers who notice such signs should stop giving codeine and immediately take the child to an emergency department or call 911, said Dr. Bob Rappaport, director of the division of anesthesia, analgesia and addiction products in FDA's Center for Drug Evaluation and Research.

More information: The U.S. National Library of Medicine has more about <u>codeine</u>.

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