

Do not use codeine, tramadol in children: FDA

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Codeine and tramadol should not be used to treat pain or cough in children younger than 12 years as they could be fatal, the Food and Drug Administration (FDA) said Thursday.

The FDA unveiled several changes to the labels of the medications to protect children, adolescents and infants being breastfed.

“We are requiring these changes because we know that some children who received codeine or tramadol have experienced life-threatening respiratory depression and death because they metabolize (or break down) these medicines much faster than usual (called ultra-rapid metabolism), causing dangerously high levels of active drug in their bodies,” Douglas Throckmorton, M.D., deputy center director for regulatory programs in the FDA’s Center for Drug Evaluation and Research, said in a [statement](#).

The FDA is adding the following new restrictions to the warning labels of codeine and tramadol:

- Codeine is contraindicated to treat pain or cough, and tramadol is contraindicated for treating pain in children under 12.
- Tramadol is contraindicated for treating pain after surgery to remove tonsils and/or adenoids for children under 18. Use of codeine for this purpose was placed under the same restriction in 2013.
- Codeine and tramadol are not recommended for use in adolescents ages 12-18 who are obese or have conditions such as obstructive sleep apnea or severe lung disease.
- Mothers should not breastfeed when taking codeine or tramadol.

Since 1969, codeine has been linked to 64 cases of serious breathing problems, including 24 deaths in children and adolescents. Tramadol is not approved for pediatric use but has been tied to nine cases of serious breathing problems, including three deaths in children and adolescents, according to the FDA. There also have been cases of breathing problems in breastfed infants whose mothers were taking codeine.

In September 2016, the Academy released a clinical report [Codeine: Time to Say “No”](#) that expressed concerns about the dangers of codeine use in children and called for more formal restrictions.

The FDA recommends physicians use other medications for treating cough and pain. Officials also encouraged parents to pay close attention to the ingredients in medication they give their children and seek immediate medical attention if children taking the restricted medications experience difficulty breathing, confusion, unusual sleepiness, trouble breastfeeding or limpness.

Resources

- [FDA Drug Safety Communication](#)
- [FDA Q&A on the use of codeine and tramadol in breastfeeding women](#)
- [FDA Consumer Update: Codeine and Tramadol Can Cause Breathing Problems for Children](#)

- [Healthychildren.org](https://www.healthychildren.org) information for parents on the use of codeine

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