

Don't Use Tramadol and Codeine in Kids Under 12, FDA Warns

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UPDATED April 20, 2017 // Children younger than 12 years should not take tramadol (multiple brands) or codeine, which pose the serious risk for slowed or difficult breathing and death, the US Food and Drug Administration (FDA) announced today.

The FDA also is restricting the use of tramadol and codeine in children older than 12 years and strengthening its label recommendation that breastfeeding mothers not take the two opioids because breastfed children could experience potentially fatal respiratory depression.

Tramadol is indicated for pain, while codeine is indicated for both pain and cough. The latter opioid is found in some prescription pain and cough medicines and in some over-the-counter cough medicines. The FDA has approved all tramadol-containing products and single-ingredient codeine only for adult use. However, some clinicians prescribe tramadol to children on an off-label basis.

The two opioids are problematic, the FDA said, because some people metabolize the drugs much more quickly than usual, causing life-threatening, high levels of the active ingredients that can lead to respiratory depression. This trait stems from a variation in an enzyme — cytochrome P450 isoenzyme 2D6 (CYP2D6) — that converts codeine into morphine and tramadol into a metabolite called O-desmethyiltramadol (M1). The prevalence of CYP2D6 ultrametabolizers varies by race and ethnic group.

Labels for products containing codeine and tramadol will be revised as follows:

- For children under 12 years of age, codeine is contraindicated for cough or pain, and tramadol for pain.
- Tramadol is contraindicated for treating pain following tonsillectomy or adenoidectomy in children younger than 18 years of age.
- Codeine and tramadol is not recommended in children 12 to 18 years of age who are obese, or have severe lung disease or obstructive sleep apnea. These conditions may increase the risk for breathing problems.
- The FDA is cautioning nursing mothers that although the medical literature does not report adverse events associated with tramadol and breastfeeding, the drug poses the same risk for ultrametabolizers as codeine, which has a lengthy track record of respirator depression in breastfed infants. Tramadol and its metabolite M1 show up in breast milk.

Ever Tightening Regulations

The FDA has been tightening its regulation of codeine and tramadol for pediatric use for some time. In 2013, the agency added a boxed warning to codeine's label cautioning clinicians not to prescribe it to children of any age to relieve pain after a tonsillectomy or adenoidectomy. Two years later, the FDA warned that children who were ultrametabolizers of codeine and tramadol were at risk of breathing problems, and promised to investigate the matter.

One thing the FDA did was to look at adverse events reports it's received since January 1969. It identified 64 cases of serious breathing problems, including 24 deaths, through May 2015 among children younger than 18 years who took codeine-containing drugs. Likewise, the FDA found nine instances of serious breathing problems and three deaths from January 1969 to March 2016 with children receiving tramadol. With both drugs, most of the adverse events occurred in children younger than 12 years, and for some it took only one dose.

The agency said it will continue to investigate the safety issues surrounding tramadol and codeine. It is mulling over further regulation for over-the-counter codeine products, and may convene an FDA advisory panel to discuss the role of prescription "cough and cold" opioid drugs, including codeine, to treat coughing in children.

More information on today's announcement [is available](#) on the FDA website.

To report any problems with tramadol or codeine, contact MedWatch, the FDA's safety information and adverse event reporting program, by telephone at 1-800-FDA-1088; by fax at 1-800-FDA-0178; online at <https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm>; with postage-paid FDA form 3500, available at <http://www.fda.gov/MedWatch/getforms.htm>; or by mail to MedWatch, 5600 Fishers Lane, Rockville, Maryland 20852-9787.

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