

Codeine and Tramadol Can Cause Breathing Problems for Children



[En Español \(/ForConsumers/ConsumerUpdates/ConsumerUpdatesEnEspañol/ucm316466.htm\)](https://www.fda.gov/ForConsumers/ConsumerUpdates/ConsumerUpdatesEnEspañol/ucm316466.htm)

✉ Get Consumer Updates by email.

Codeine and tramadol are opioid medicines that may be used to treat pain. Codeine is also in some cough and cold remedies.

These medicines can cause life-threatening breathing problems in children. Some children and adults break down codeine and tramadol into their active forms faster than other people. That can cause the level of opioids in these people to rise too high and too quickly.

Nursing mothers who are taking codeine or tramadol can pass unsafe levels of opioids to their babies through breast milk. Those infants can become too sleepy, have difficulty breastfeeding, or have serious breathing problems.

That's why [the U.S. Food and Drug Administration is strengthening drug labels for codeine and tramadol \(/Drugs/DrugSafety/ucm549679.htm\)](http://www.fda.gov/ForConsumers/ConsumerUpdates/default.htm) to protect children and nursing babies.

Beware of Giving Kids Codeine or Tramadol

The FDA is warning that children younger than 12 shouldn't take codeine products to treat pain or cough or tramadol to treat pain.

The FDA hasn't approved tramadol for use in children. Kids younger than 18 shouldn't take tramadol to treat pain after surgery to remove the tonsils (tonsillectomy) or adenoids (adenoidectomy). (Codeine labeling already warns that children should not be treated for post-surgery pain with codeine in these cases.)

Youths ages 12 through 18 who are obese or have obstructive sleep apnea (blocked airflow during sleep) or a weakened respiratory system shouldn't take codeine or tramadol. These risk factors can increase their chances of serious breathing problems.

Tramadol is available only for adults and by prescription to treat pain. Codeine products are available by prescription and, in some states, over-the-counter (OTC). Codeine is often combined with acetaminophen in prescription pain medicines and with other cold medicines for treatment of cough.

Alternatives to Codeine and Tramadol

There are several alternatives for pain management in children, which you should discuss with your health care professional or pharmacist.

There are also alternative OTC and prescription medications available for cough. The FDA doesn't recommend OTC cold and cough medicines for children younger than 2. Even in older children who have colds, coughs are generally mild and go away in a few days, so they may not need to take any medicine.

How to Know if Your Child's Medicine Has Codeine or Tramadol

Read the label to make sure the medicine doesn't have codeine or tramadol. Also, ask your health care provider or pharmacist if your medicine has codeine or tramadol.

This article appears on [the FDA's Consumer Updates page \(http://www.fda.gov/ForConsumers/ConsumerUpdates/default.htm\)](http://www.fda.gov/ForConsumers/ConsumerUpdates/default.htm), which features the latest on all FDA-regulated products.

April 20, 2017

[back to top](#)

Subscribe

FDA Drug Safety Communication: FDA restricts use of prescription codeine pain and cough medicines and tramadol pain medicines in children; recommends against use in breastfeeding women

This is an update to the FDA Drug Safety Communications:

- FDA evaluating the potential risks of using codeine cough-and-cold medicines in children issued on [July 1, 2015 \(/Drugs/DrugSafety/ucm453125.htm\)](#), and
- FDA evaluating the risks of using the pain medicine tramadol in children aged 17 and younger issued on [September 21, 2015 \(/Drugs/DrugSafety/ucm462991.htm\)](#).

Safety Announcement

[4-20-2017] The Food and Drug Administration (FDA) is restricting the use of codeine and tramadol medicines in children. Codeine is approved to treat pain and cough, and tramadol is approved to treat pain. These medicines carry serious risks, including slowed or difficult breathing and death, which appear to be a greater risk in children younger than 12 years, and should not be used in these children. These medicines should also be limited in some older children. Single-ingredient codeine and all tramadol-containing products are FDA-approved only for use in adults. We are also recommending against the use of codeine and tramadol medicines in breastfeeding mothers due to possible harm to their infants.

As a result, we are requiring several changes to the labels of all prescription medicines containing these drugs. These new actions further limit the use of these medicines beyond our [2013 restriction of codeine use \(/Drugs/DrugSafety/ucm339112.htm\)](#) in children younger than 18 years to treat pain after surgery to remove the tonsils and/or adenoids. We are now adding:

- FDA's strongest warning, called a *Contraindication*, to the drug labels of codeine and tramadol alerting that codeine should not be used to treat pain or cough and tramadol should not be used to treat pain in children younger than 12 years.
- A new *Contraindication* to the tramadol label warning against its use in children younger than 18 years to treat pain after surgery to remove the tonsils and/or adenoids.
- A new *Warning* to the drug labels of codeine and tramadol to recommend against their use in adolescents between 12 and 18 years who are obese or have conditions such as obstructive sleep apnea or severe lung disease, which may increase the risk of serious breathing problems.

- A strengthened *Warning* to mothers that breastfeeding is not recommended when taking codeine or tramadol medicines due to the risk of serious adverse reactions in breastfed infants. These can include excess sleepiness, difficulty breastfeeding, or serious breathing problems that could result in death.

Caregivers and patients should always read the label on prescription bottles to find out if a medicine contains codeine or tramadol. You can also ask your child's health care provider or a pharmacist. Watch closely for signs of breathing problems in a child of any age who is taking these medicines or in infants exposed to codeine or tramadol through breastmilk. These signs include slow or shallow breathing, difficulty or noisy breathing, confusion, more than usual sleepiness, trouble breastfeeding, or limpness. If you notice any of these signs, stop giving the medicine and seek medical attention immediately by going to an emergency room or calling 911.

Health care professionals should be aware that tramadol and single-ingredient codeine medicines are FDA-approved only for use in adults. Consider recommending over-the-counter (OTC) or other FDA-approved prescription medicines for cough and pain management in children younger than 12 years and in adolescents younger than 18 years, especially those with certain genetic factors, obesity, or obstructive sleep apnea and other breathing problems. Cough is often secondary to infection, not serious, and usually will get better on its own so treatment may not be necessary.

Codeine and tramadol are a type of narcotic medicine called an opioid. Codeine is used to treat mild to moderate pain and also to reduce coughing. It is usually combined with other medicines, such as acetaminophen, in prescription pain medicines. It is frequently combined with other drugs in prescription and over-the-counter (OTC) cough and cold medicines. Tramadol is a prescription medicine approved only for use in adults to treat moderate to moderately severe pain. However, data show it is being used in children and adolescents despite the fact that it is not approved for use in these patients.

In early **2013** (</Drugs/DrugSafety/ucm339112.htm>), FDA added a *Boxed Warning* to the codeine drug label cautioning against prescribing codeine to children of any age to treat pain after surgery to remove tonsils or adenoids. We also issued Drug Safety Communications in **July 2015** (</Drugs/DrugSafety/ucm453125.htm>) and **September 2015** (</Drugs/DrugSafety/ucm462991.htm>) warning about the risk of serious breathing problems in some children who metabolized codeine and tramadol much faster to their active form than usual (called ultra-rapid metabolism), causing potentially dangerously high levels in their bodies too quickly. At that time, we said we would continue to evaluate this safety issue. As part of that safety review, the codeine-related safety issues were discussed at an FDA Advisory Committee meeting in **December 2015** (</AdvisoryCommittees/Calendar/ucm469466.htm>).

Our review of several decades of adverse event reports submitted to FDA* from January 1969 to May 2015 identified 64 cases of serious breathing problems, including 24 deaths, with codeine-containing medicines in children younger than 18 years. This includes only reports submitted to FDA, so there may be additional cases about which we are unaware. We also identified nine cases of serious breathing problems, including three deaths, with the use of tramadol in children younger than 18 years from January 1969 to March 2016 (see Data Summary). The majority of serious side effects with both codeine and tramadol occurred in children younger than 12 years, and some cases occurred after a single dose of the medicine.

In our review of the medical literature¹⁻¹⁹ for data regarding codeine use during breastfeeding, we found numerous cases of excess sleepiness and serious breathing problems in breastfed infants, including one death. A review of the available medical literature^{4,5,23,24} for data regarding tramadol use during breastfeeding did not reveal any cases of adverse events. However, tramadol and its active form are also present in breast milk, and tramadol has the same risks associated with ultra-rapid metabolism as codeine.

We will continue to monitor this safety issue. We are considering additional regulatory action for the OTC codeine products that are available in some states. OTC codeine products are available in combination with other medicines for cough and cold symptoms. We are also considering an FDA Advisory Committee meeting to discuss the role of prescription opioid cough-and-cold medicines, including codeine, to treat cough in children.

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

*The cases were reported to the [FDA Adverse Event Reporting System \(FAERS\)](https://www.fda.gov/oc/ohrt/faers/) ([/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm2007060.htm](https://www.fda.gov/oc/ohrt/faers/)).

List of Prescription Codeine and Tramadol Pain and Cough Medicines

Medicines Containing Codeine	Medicines Containing Tramadol
Codeine Sulfate	Conzip
Butalbital, Acetaminopen, Caffeine, and Codeine phosphate	Ultracet
Fiorinal with codeine	Ultram
Soma Compound with codeine	Ultram ER
Tylenol with codeine	Generic products containing tramadol
Promethazine with codeine (cough)	
Prometh VC with codeine (cough)	
Triacin-C (cough)	
Tuxarin ER (cough)	
Tuzistra-XR (cough)	
Generic products containing codeine	
Medicines Containing Dihydrocodeine	
Synalgos-DC	

Facts about Codeine and Tramadol

Additional Information for Caregivers and Patients

Additional Information for Health Care Professionals

Data Summary 

References 

[Drug Safety Communication \(/downloads/Drugs/DrugSafety/UCM553814.pdf\)](/downloads/Drugs/DrugSafety/UCM553814.pdf) (PDF - 72KB)

Related Information

- **[FDA statement from Douglas Throckmorton, M.D., Deputy Center Director for Regulatory Programs, Center for Drug Evaluation and Research, on new warnings about the use of codeine and tramadol in children \(/NewsEvents/Newsroom/PressAnnouncements/ucm553285.htm\)](/NewsEvents/Newsroom/PressAnnouncements/ucm553285.htm)**
- **[Consumer Update: Codeine and Tramadol Can Cause Breathing Problems for Children \(/ForConsumers/ConsumerUpdates/ucm315497.htm\)](/ForConsumers/ConsumerUpdates/ucm315497.htm)**
- **[Use of Codeine and Tramadol Products in Breastfeeding Women - Questions and Answers \(/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm118113.htm\)](/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm118113.htm)**
- **[Codeine Information \(/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm118108.htm\)](/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm118108.htm)**
- **[Tramadol Information \(/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm462997.htm\)](/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm462997.htm)**
- **[Opioid Medications \(/Drugs/DrugSafety/InformationbyDrugClass/ucm337066.htm\)](/Drugs/DrugSafety/InformationbyDrugClass/ucm337066.htm)**
- **[What's on the Label \(high resolution\) \(PDF - 546KB\) \(/downloads/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingOver-the-CounterMedicines/UCM285993.pdf\)](/downloads/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingOver-the-CounterMedicines/UCM285993.pdf)**
- **[The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective \(/Drugs/ResourcesForYou/Consumers/ucm143534.htm\)](/Drugs/ResourcesForYou/Consumers/ucm143534.htm)**
- **[Think It Through: Managing the Benefits and Risks of Medicines \(/Drugs/ResourcesForYou/Consumers/ucm143558.htm\)](/Drugs/ResourcesForYou/Consumers/ucm143558.htm)**
- **[Advisory Committees: Critical to the FDA's Product Review Process \(/Drugs/ResourcesForYou/Consumers/ucm143538.htm\)](/Drugs/ResourcesForYou/Consumers/ucm143538.htm)**

Contact FDA

For More Info

855-543-DRUG (3784)
and press 4

[druginfo@fda.hhs.gov \(mailto:druginfo@fda.hhs.gov\)](mailto:druginfo@fda.hhs.gov)

Report a Serious Problem to MedWatch

Complete and submit the report **[Online \(https://www.accessdata.fda.gov/scripts/medwatch/\)](https://www.accessdata.fda.gov/scripts/medwatch/)**.

[Download form \(http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM163919.pdf\)](http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM163919.pdf) or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

[More in Drug Safety and Availability \(/Drugs/DrugSafety/default.htm\)](/Drugs/DrugSafety/default.htm)

[Drug Alerts and Statements \(/Drugs/DrugSafety/ucm215175.htm\)](/Drugs/DrugSafety/ucm215175.htm)

[Medication Guides \(/Drugs/DrugSafety/ucm085729.htm\)](/Drugs/DrugSafety/ucm085729.htm)

[Drug Safety Communications \(/Drugs/DrugSafety/ucm199082.htm\)](/Drugs/DrugSafety/ucm199082.htm)

[Drug Shortages \(/Drugs/DrugSafety/DrugShortages/default.htm\)](/Drugs/DrugSafety/DrugShortages/default.htm)



[Postmarket Drug Safety Information for Patients and Providers \(/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/default.htm\)](/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/default.htm)



[Information by Drug Class \(/Drugs/DrugSafety/InformationbyDrugClass/default.htm\)](/Drugs/DrugSafety/InformationbyDrugClass/default.htm)

[Medication Errors \(/Drugs/DrugSafety/MedicationErrors/default.htm\)](/Drugs/DrugSafety/MedicationErrors/default.htm)

[Drug Safety Podcasts \(/Drugs/DrugSafety/DrugSafetyPodcasts/default.htm\)](/Drugs/DrugSafety/DrugSafetyPodcasts/default.htm)



[Safe Use Initiative \(/Drugs/DrugSafety/SafeUseInitiative/default.htm\)](/Drugs/DrugSafety/SafeUseInitiative/default.htm)



[Drug Recalls \(/Drugs/DrugSafety/DrugRecalls/default.htm\)](/Drugs/DrugSafety/DrugRecalls/default.htm)

[Drug Supply Chain Integrity \(/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/default.htm\)](/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/default.htm)

