



U.S. Food and Drug Administration
Protecting and Promoting Your Health

Drug Safety Communications

FDA requires labeling changes for prescription opioid cough and cold medicines to limit their use to adults 18 years and older

This provides updated information to the [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](#) issued on April 20, 2017.

Safety Announcement

[1-11-2018] The U.S. Food and Drug Administration (FDA) is requiring safety labeling changes for prescription cough and cold medicines containing codeine or hydrocodone to limit the use of these products to adults 18 years and older because the risks of these medicines outweigh their benefits in children younger than 18. We are also requiring the addition of safety information about the risks of misuse, abuse, addiction, overdose, death, and slowed or difficult breathing to the *Boxed Warning*, our most prominent warning, of the drug labels for prescription cough and cold medicines containing codeine or hydrocodone.

We are taking this action after conducting an extensive review and convening a [panel of outside experts](#). Both of these determined the risks of slowed or difficult breathing, misuse, abuse, addiction, overdose, and death with these medicines outweigh their benefits in patients younger than 18.

Health care professionals should be aware that FDA is changing the age range for which prescription opioid cough and cold medicines are indicated. These products will no longer be indicated for use in children, and their use in this age group is not recommended. Health care professionals should reassure parents that cough due to a cold or upper respiratory infection is self-limited and generally does not need to be treated. For those children in whom cough treatment is necessary, alternative medicines are available. These include over-the-counter (OTC) products such as dextromethorphan, as well as prescription benzonatate products.

Parents and caregivers should be aware that prescription opioid cough and cold medicines that include codeine or hydrocodone should not be used in children. Codeine and hydrocodone are narcotic medicines called opioids and may carry serious risks when used in children. It is important for parents and caregivers to understand that a cough due to a common cold often does not need medicines for treatment. If a cough medicine is prescribed, ask your child's health care professional or a pharmacist if it contains an

opioid such as codeine or hydrocodone. Always read the labels on prescription bottles. If the medicine prescribed for your child contains an opioid, talk to your child's health care professional about a different, non-opioid medicine, or if you have any questions or concerns.

Codeine and hydrocodone are available in combination with other medicines, such as antihistamines and decongestants, in prescription medicines to treat coughs and symptoms associated with allergies or the common cold. Other non-opioid prescription and OTC medicines are available to treat these symptoms.

Other *Boxed Warnings* and *Warnings and Precautions* will also be added to the label for prescription cough and cold medicines containing codeine or hydrocodone, to be consistent with the safety issues described in the labels of prescription opioid pain medicines. We previously communicated about these safety issues for [immediate-release opioid pain medicines](#) and [extended-release and long-acting opioid pain medicines](#).

Today's action is for opioid cough and cold medicines requiring a prescription. Some codeine cough medicines are available OTC in a few states, and we also are considering regulatory action for these products.

We urge health care professionals and patients to report side effects involving opioid cough and cold medicines or other medicines to the FDA MedWatch program, using the information in the "Contact FDA" box at the bottom of the page.

List of Prescription Cough and Cold Medicines Containing Codeine

Active Ingredient(s)	Brand Name(s)
codeine, chlorpheniramine	Tuxarin ER, Tuzistra XR
codeine, phenylephrine, promethazine	Only generics available
codeine, promethazine	Only generics available
codeine, pseudoephedrine, tripolidine	Triacin C

List of Prescription Cough and Cold Medicines Containing Hydrocodone

Active Ingredient(s)	Brand Name(s)
hydrocodone, guaifenesin	FlowTuss, Obredon
hydrocodone, pseudoephedrine, guaifenesin	Hycofenix, Rezira
hydrocodone, chlorpheniramine	Tussionex Pennkinetic, Vituz
hydrocodone, chlorpheniramine, pseudoephedrine	Zutripro
hydrocodone, homatropine	Only generics available

Additional Information for Parents/Caregivers and Patients

- FDA is requiring labeling changes for prescription cough and cold medicines containing the opioid medicines codeine or hydrocodone to limit their use to adults 18 years and older because the risks of these medicines for cough outweigh

their benefits in children younger than 18. These risks include slowed or difficult breathing, misuse, abuse, addiction, overdose, and death.

- Always read the labels on prescription bottles to find out if a medicine contains codeine or hydrocodone, or ask your child's health care professional or a pharmacist.
- If your child is currently prescribed a cough and cold medicine containing codeine or hydrocodone, talk to your child's health care professional about other treatments.
- Common side effects of opioids include drowsiness, dizziness, nausea, vomiting, constipation, shortness of breath, and headache.
- Opioids also carry serious risks, including that these medicines depress the central nervous system, which can cause serious breathing problems or death. They can be used to get "high" or may result in someone becoming addicted to them.
- If you are an adult currently prescribed a cough and cold medicine containing codeine, hydrocodone or any other opioid, do not use these with other medicines that depress the central nervous system (CNS) without discussing it with your health care professional. Alcohol also depresses the CNS and can increase the risk for these serious and life-threatening side effects.
- Do not take more of these medicines than the dose prescribed or listed on the label, as doing so can cause serious problems.
- Always use an accurate measuring device to measure and administer liquid medicines. If you are not sure how to measure liquid medicines, ask a pharmacist for help.
- Breastfeeding is not recommended during treatment with opioid cough and cold medicines, because the medicine passes through breast milk and can harm the baby.
- Always tell your health care professionals about all the medicines you or your child are taking, including over-the-counter (OTC) medicines.
- Always [lock up medicines](#) and [dispose](#) of them properly when no longer needed to keep them from being taken accidentally by children or teenagers or falling into the wrong hands.
- Read the patient [Medication Guide](#) or patient information leaflet that comes with filled prescription(s).
- If you have any questions or concerns about a medicine you or your child has been prescribed, talk with your health care professional or your pharmacist.
- Report side effects from opioid cough and cold medicines or other medicines to the FDA MedWatch program, using the information in the "Contact FDA" box at the bottom of this page.

Related Information

[Codeine Information](#)

[Opioid Medications](#)

[Expert Roundtable Meeting: Use of Cough Suppressants in Children](#)

[Disposal of Unused Medicines: What You Should Know](#)

[The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective](#)

[Think It Through: Managing the Benefits and Risks of Medicines](#)

[Advisory Committees: Critical to the FDA's Product Review Process](#)