

## Opioid cough suppressants in children – FDA Advisory Committee Recommendations

- On September 11, 2017, the [FDA held](#) a Pediatric Advisory Committee Meeting to discuss the benefit/risk of prescription codeine and hydrocodone antitussives in pediatric patients.
- Opioids can cause respiratory depression, and children are particularly vulnerable. Labels on products containing opioids warn about this risk in children. Other risks include misuse, abuse, addiction, overdose, and death.
- FDA advisory committee votes:
  - The committee voted (21 no, 2 yes, 1 abstain) that the benefit/risk profile is not favorable for use of prescription opioid cough suppressants for treatment of cough in pediatric patients.
  - The committee voted unanimously (24 no, 0 yes) that the benefit/risk profile is not favorable for use of prescription codeine cough suppressants for treatment of cough associated with allergy or the common cold in pediatric patients aged 12 to < 18 years of age.
  - The committee voted by a majority that the benefit/risk profile is not favorable for use of hydrocodone cough suppressants for treatment of cough associated with allergy or the common cold in pediatric patients aged 6 to < 12 years (23 no, 1 yes) or in pediatric patients aged 12 to < 18 years (23 no, 1 yes).
- Examples of codeine-containing cough syrups include [promethazine/codeine](#), [promethazine/phenylephrine/codeine](#), and [M-End® PE, Poly-Tussin® AC \(brompheniramine/phenylephrine/codeine\)](#).
- Examples of hydrocodone-containing cough syrups include [Rezira® \(pseudoephedrine/hydrocodone\)](#), [Zutripro® \(chlorpheniramine/pseudoephedrine/hydrocodone\)](#), and [chlorpheniramine/hydrocodone](#).
- A FDA expert roundtable meeting was held on [April 27, 2017](#) to discuss the use of cough suppressants in children < 18 years of age. This meeting provided [background](#) information and framed the questions for the FDA Pediatric Advisory Committee.
- Codeine-containing cough suppressants contain a boxed warning for respiratory depression in children, death related to ultra-rapid metabolism of codeine to morphine and risks from concomitant use with benzodiazepines or other central nervous system (CNS) depressants.
- Hydrocodone-containing cough suppressants contain a boxed warning for risks from concomitant use with benzodiazepines or other CNS depressants.
- A prior FDA Drug Safety Communication regarding use of codeine in children can be found [here](#).
  - The FDA announced that new updates will be made to the *Contraindications* and *Warnings* sections of all prescription codeine and tramadol drug products regarding their use in children, adolescents and breastfeeding women.