

Opioid cough suppressants in children - FDA Advisory Committee Recommendations

- On September 11, 2017, the <u>FDA held</u> 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.</p>
 - 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).</p>
- Examples of codeine-containing cough syrups include <u>promethazine/codeine</u>, <u>promethazine/phenylephrine/codeine</u>, and <u>M-End® PE, Poly-Tussin® AC</u> (<u>brompheniramine/phenylephrine/codeine</u>).
- 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 <u>April 27, 2017</u> to discuss the use of cough suppressants in children < 18 years of age. This meeting provided <u>background</u> 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.



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