OPTUMRx®

Prescription Cough and Cold Medicines – Safety Updates

- On January 11, 2018, the FDA announced that they are 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 of age because the risks of these medicines outweigh their benefits in children < 18 years of age.

- Similar to opioids used for pain, the FDA is 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* of the drug labels for prescription cough and cold medicines containing codeine or hydrocodone.

- Additional updates will be made to the *Boxed Warnings* and *Warnings and Precautions* sections of prescription cough and cold medicine labels containing codeine or hydrocodone, to be consistent with the safety issues described in the labels of prescription opioid pain medicines.

    - The FDA previously communicated these safety updates for immediate- and extended-release/long-acting opioids.
    - Some codeine cough medicines are available over-the-counter (OTC) in a few states, and the FDA is considering regulatory action for these products.

- Examples of prescription cough and cold medicines containing codeine or hydrocodone include Tuzistra® XR (codeine/chlorpheniramine), promethazine/codeine, and Tussionex® (hydrocodone/chlorpheniramine).

- Healthcare providers should be aware that the 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.

- 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.

    - Alternatives include OTC products such as dextromethorphan and prescription benzonatate products.

- *FDA recommendations for parents and caretakers:*

    - Read the labels on prescription bottles to find out if a medicine contains codeine or hydrocodone, or ask the child's healthcare provider or a pharmacist.
    - If a child is currently prescribed a cough and cold medicine containing codeine or hydrocodone, inquire with a healthcare provider about other treatments.
    - Healthcare providers should be informed of all prescription and OTC medicines you or your child is taking.
    - 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.
    - Common side effects of opioids include drowsiness, dizziness, nausea, vomiting, constipation, shortness of breath, and headache.
    - Opioids can depress the central nervous system (CNS), which can cause serious breathing problems or death. They can be used to get "high" or may result in an opioid addiction.

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- *Additional FDA recommendations:*

    — Adults that are currently prescribed a cough and cold medicine containing codeine, hydrocodone or any other opioid, should not use these with other medicines that depress the CNS without discussing it with their healthcare provider. Alcohol also depresses the CNS and can increase the risk for these serious and life-threatening side effects.
    — Patients should not take more of these medicines than the dose prescribed or listed on the label, as doing so can cause serious problems.
    — An accurate measuring device should be used to measure and administer liquid medicines.
    — Breastfeeding is not recommended during treatment with opioid cough and cold medicines, because the medicines can pass through breast milk and harm the baby.

- The FDA safety update is based on an extensive review and an FDA Advisory Committee Meeting. Both determined that the risks of slowed or difficult breathing, misuse, abuse, addiction, overdose, and death with these medicines outweigh their benefits in patients < 18 years.

- In 2017, the FDA announced that updates were made to the *Contraindications* and *Warnings* sections of all prescription codeine and tramadol drug products regarding their use in children, adolescents and breastfeeding women.

- In 2013, the 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.

- In 2015, the FDA also issued drug safety communications warning about the risk of serious breathing problems in children identified as CYP2D6 ultra-rapid metabolizers.