

## Cough and Cold Medications in Children Less Than Two Years of Age

FDA informed consumers and healthcare professionals that the Agency has completed its review of information regarding the safety of over-the-counter (OTC) cough and cold medicines in children under 2 years of age and recommends that these drugs not be used to treat children in this age group because serious and potentially life-threatening side effects can occur. FDA's recommendation is based on both the review of the information the Agency received about serious side effects in children in the referenced age group and the discussion and recommendations made at the October 18 -19, 2007, public advisory committee meeting at which this issue was discussed. FDA has not completed its review of information about the safety of OTC cough and cold medicines in children 2 through 11 years of age. See the FDA Public Health Advisory for Agency recommendations regarding this issue.

[January 17, 2008 - [Public Health Advisory](#) - FDA]

## Public Health Advisory

### Nonprescription Cough and Cold Medicine Use in Children

FDA Recommends that Over-the-Counter (OTC) Cough and Cold Products not be used for Infants and Children under 2 Years of Age

FDA has completed its review of information about the safety of over-the-counter (OTC) cough and cold medicines in infants and children under 2 years of age. FDA is recommending that these drugs not be used to treat infants and children under 2 years of age because serious and potentially life-threatening side effects can occur.

FDA's recommendation is based on both the review of the information we received about serious side effects in children and the discussion and recommendations made at the October 18–19, 2007, [public advisory committee meeting](#) at which this issue was discussed. FDA strongly supports the actions taken by many pharmaceutical manufacturers to voluntarily withdraw cough and cold medicines that were being sold for use in this age group.

FDA has not completed its review of information about the safety of OTC cough and cold medicines in children 2 through 11 years of age. We are aware of reports of serious side effects from cough and cold medicines in children 2 years of age and older. FDA is committed to completing its comprehensive and thorough review of the safety of OTC cough and cold medicines in children 2 years of age and older as quickly as possible and expects to communicate our recommendations to the public in the near future.

Pending completion of FDA's ongoing review, if parents and caregivers use OTC cough and cold medicines in children 2 years of age and older, FDA recommends:

- **Checking the “active ingredients” section of the DRUG FACTS label.** This will help you understand what “active ingredients” are in the medicine and what symptoms each active ingredient is intended to treat. Cough and cold medicines often have more than one “active ingredient” (such as an antihistamine, a decongestant, a cough suppressant, an expectorant, or a pain reliever/fever reducer).

- **Being very careful if you are giving more than one OTC cough and cold medicine to a child.** Many OTC cough and cold medicines have more than one “active ingredient.” If you use two medicines that have the same or similar “active ingredients” a child could get too much of an ingredient which may hurt your child. For example, do not give a child more than one medicine that has an antihistamine.
- **Carefully following the directions in the DRUG FACTS part of the label.** These directions tell you how much medicine to give and how often you can give it.
- **Only using the measuring spoons or cups that come with the medicine or those made specially for measuring drugs.** Do not use common household spoons to measure medicines for children since household spoons come in different sizes and are not meant for measuring medicines.
- **Choosing OTC cough and cold medicines with childproof safety caps, when available, and store the medicines out of the reach of children.**
- **Understanding that using OTC cough and cold medicines are intended only to treat your child’s symptom(s).** OTC cough and cold medicines do not treat the cause of the symptoms or shorten the length of time your child is sick. They only relieve symptoms and make your child feel more comfortable.
- **Not using these products to sedate your child or make children sleepy.**
- **Calling a physician, pharmacist, or other healthcare professional if you have any questions about using cough or cold medicines in children 2 years of age and older.**

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