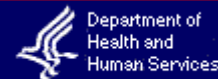


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Public Health Advisory

Nonprescription Cough and Cold Medicine Use in Children

August 15, 2007

[Federal Register Meeting Notice](#)

FDA announced today that, in October, the Nonprescription Drugs Advisory Committee will discuss the safety and effectiveness of cough and cold drug product use in children. Questions have been raised about the safety of these products and whether the benefits justify any potential risks from the use of these products in children, especially in children under 2 years of age. In preparation for the meeting, FDA is reviewing safety and efficacy data for the ingredients of these products.

Some reports of serious adverse events associated with the use of these products appear to be the result of giving too much of these medicines to children. An over-the-counter cough and cold medicine can be harmful if more than the recommended amount is used, if it is given too often, or if more than one cough and cold medicine containing the same active ingredient are being used. To avoid giving a child too much medicine, parents must carefully follow the directions for use of the product in the “Drug Facts” box on the package label.

What should parents know about using cough and cold products in children?

- Do **not** use cough and cold products in children under 2 years of age UNLESS given specific directions to do so by a healthcare provider.
- Do not give children medicine that is packaged and made for adults. Use only products marked for use in babies, infants or children (sometimes called “pediatric” use).
- Cough and cold medicines come in many different strengths. If you are unsure about the right product for your child, ask a healthcare provider.
- If other medicines (over-the-counter or prescription) are being given to a child, the child’s healthcare provider should review and approve their combined use.
- Read all of the information in the “Drug Facts” box on the package label so that you know the **active ingredients** and the **warnings**.

- Follow the **directions** in the “Drug Facts” box. Do not give a child medicine more often or in greater amounts than is stated on the package.
- Too much medicine may lead to serious and life-threatening side effects, particularly in children aged 2 years and younger.
- For liquid products, parents should use the measuring device (dropper, dosing cup or dosing spoon) that is packaged with each different medicine formulation and that is marked to deliver the recommended dose. A kitchen teaspoon or tablespoon is not an appropriate measuring device for giving medicines to children.
- If a measuring device is not included with the product, parents should purchase one at the pharmacy. Make sure that the dropper, dosing cup or dosing spoon has markings on it that match the dosing that is in the **directions** in the “Drug Facts” box on the package label, or is recommended by the child’s health care provider.
- If you DO NOT UNDERSTAND the instructions on the product, or how to use the dosing device (dropper, dosing cup or dosing spoon), DO NOT USE the medicine. Consult your healthcare provider if you have questions or are confused.
- Cough and cold medicines only treat the symptoms of the common cold such as runny nose, congestion, fever, aches, and irritability. They do not cure the common cold. Children get better with time.
- If a child’s condition worsens or does not improve, stop using the product and immediately take the child to a health care provider for evaluation.

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