

Safety and Effectiveness of Cough and Cold Medicine in Children

The Food and Drug Administration (FDA) is warning parents not to give children age 2 and younger over-the-counter cough or cold medicines unless directed by a health care provider. This advisory is in response to the popular medicines being blamed for infant deaths and serious and life-threatening side effects. Safety experts asked the FDA to consider an outright ban on such products.

Cough and cold products do not work in children

Most pediatricians are against giving over-the-counter cough and cold medication to young children. Studies suggest that there is not any evidence that over-the-counter cough and cold medicines are effective in making children well sooner. These products only treat the symptoms of the common cold. Cold symptoms include runny nose, sore throat, coughing or sneezing, watery eyes, chills and fever. These symptoms are generally mild and self-limited in healthy children. In other words, children get better with time. Many comfort measures like vaporizers work to make children feel better without side effects.

Why aren't they safe?

Most of the serious bad events associated with the use of cough and cold products are caused by two ingredients:

1. Dextromethorphan, which is listed as "DM" in many preparations. DM can cause neurological problems including abnormal movements and hallucinations, even in standard doses.
2. Pseudoephedrine, which is a decongestant that has been associated with increased blood pressure, arrhythmia (irregularity in the rhythm or force of the heartbeat) and infant deaths.

Problems are usually the result of giving too much medicine

Overdose may happen when you give:

- More than the recommended amount of medicine.
- Two different products with the same active ingredients—not realizing that both contain identical medicines.
- The medicine too often.

Cough and cold medicines come in many different names and strengths

To avoid giving too much medicine to your child, carefully follow the directions for use of the product. For more accurate dosing, determine your child's dose based on his weight rather than his age. If a measuring device is not included with the product, you may 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 package label, or is recommended by the child's health care provider. If you are confused, or do not understand the instructions on the product or how to use the dosing device, consult your pharmacist or health care provider.

FDA's Safety Tips about using cough and cold products in children

- Do not use cough and cold products in children under 2 years of age unless directed by a health care provider.
- Do not give children medicine that is packaged and made for adults.
- If other medicines (over-the-counter or prescription) are being given to a child, the child's health care provider should review and approve their combined use.
- Read the label to know the active ingredients and the warnings.
- Follow the directions. Do not give the medicine more often or in greater amounts than is stated on the package.
- For liquid products use the measuring device that is packaged with each different medicine and that is marked to deliver the recommended dose. A teaspoon or tablespoon is not an appropriate measuring device for giving medicines to children.
- 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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Resources and References

FDA's Public Health Advisory on Cough and cold medicine online at www.fda.gov/CDER/drug/advisory/cough_cold.htm.

Over-the-Counter Drugs, a CCHP Fact Sheets for Families available online at www.ucsfchildcarehealth.org/html/pandr/factsheetsmain.htm.

Medication Administration in Child Care Programs, a CCHP Health & Safety Note available online at www.ucsfchildcarehealth.org/html/pandr/hsnotesmain.htm.



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