

Molina Healthcare of Ohio , Inc. would like to make you aware of the recent FDA warning for cough and cold preparations and their use in children under 2 years of age. Following is the FDA warning as well as a statement from the American Academy of Pediatrics.

FDA Releases Recommendations Regarding Use of Over-the-Counter Cough and Cold Products

Products should not be used in children under 2 years of age; evaluation continues in older populations

The U.S. Food and Drug Administration today issued a Public Health Advisory for parents and caregivers, recommending that over-the-counter (OTC) cough and cold products should not be used to treat infants and children less than 2 years of age because serious and potentially life-threatening side effects can occur from such use. OTC cough and cold products include decongestants, expectorants, antihistamines, and antitussives (cough suppressants) for the treatment of colds.

There are a wide variety of rare, serious adverse events reported with cough and cold products. They include death, convulsions, rapid heart rates, and decreased levels of consciousness.

Pending completion of the FDA's ongoing review, parents and caregivers that choose to use OTC cough and cold medicines to children ages 2 to 11 years should:

- Follow the dosing directions on the label of any OTC medication,
- Understand that these drugs will NOT cure or shorten the duration of the common cold,
- Check the "Drug Facts" label to learn what active ingredients are in the products because many OTC cough and cold products contain multiple active ingredients, and
- Only use measuring spoons or cups that come with the medicine or those made specially for measuring drugs.

The FDA recommends that anyone with questions contact a physician, pharmacist or other health care professional to discuss how to treat a child with a cough or cold.

For more information and the full list of the FDA's recommendations, visit: *Public Health Advisory: Nonprescription Cough and Cold Medicine Use in Children*
http://www.fda.gov/cder/drug/advisory/cough_cold_2008.htm

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AMERICAN ACADEMY OF PEDIATRICS URGES CAUTION IN USE OF OVER-THE-COUNTER COUGH AND COLD MEDICINES

For Immediate Release: January 17, 2008

The U.S. Food and Drug Administration today issued an advisory strongly recommending that over-the-counter cough and cold medications not be given to infants and children under two years old because of the risk of life-threatening side effects. The American Academy of Pediatrics (AAP) supports this recommendation and urges parents to seek safer ways to soothe infants and young children suffering from colds and coughs.

Studies have shown cough and cold products are ineffective in treating symptoms of children under six years old, and may pose serious risks. A variety of rare, serious health problems have been associated with use of these medications in children, including death, convulsions, rapid heart rates and decreased levels of consciousness. (A review by the U.S. Centers for Disease Control and Prevention of national emergency department visits due to adverse drug events from cough and cold medications will be published in the online version of Pediatrics Jan. 28.)

“It is critically important for parents to receive clear information about the risks and lack of benefit from these drugs, and ways to help take care of children suffering from colds and coughs,” said Renee Jenkins, M.D., FAAP, president of the American Academy of Pediatrics. “We urge FDA to continue its analysis of the existing data on these medicines intended for children over age 2 and take appropriate action, including initiation of immediate, rigorous scientific studies as needed to determine the drugs’ safety and efficacy.”

Children metabolize and react to medications differently than adults, often in unanticipated ways. For more than 30 years the AAP has emphasized the importance of studying medicines in pediatric populations. As part of the FDA’s ongoing review of over-the-counter cough and cold medications, the AAP in October urged regulators to pursue further studies into whether these drugs have any benefit to children. The AAP also advised labeling that would inform parents that the products have been shown to be ineffective in children under 6 and could lead to serious adverse reactions. Thursday’s advisory is an important first step. The FDA expects to announce its recommendation for children ages 2 to 11 in early spring.

While annoying, cough and cold symptoms are usually benign and self-limiting. Over-the-counter cough and cold medications will not cure these illnesses nor shorten their duration. Parents should seek safer ways to nurse their children back to health, Dr. Jenkins said. “Although these medications have been in use for a long time, now we’ve learned they have some risks, especially because of the difficulty in determining a safe and accurate dose for small children,” Dr. Jenkins said. “Instead of drugs, there are symptomatic interventions parents can do that are much safer for children.”

Dr. Jenkins recommended saline nose drops and suctioning bulbs to thin and clear mucus from a baby’s nose, and using a cool-mist humidifier. Chest physical therapy can also loosen mucus and may help infants and young children expel mucus. If a child under age 2 develops a fever, consult a pediatrician.

For more suggestions on treating children without over-the-counter cough and cold drugs, www.aap.org/publiced/BR_Infections.htm