

FDA: no cough, cold drugs for tots

FDA rules that over-the-counter cough and cold medicines should not be given to kids younger than 2

By Miranda Hitti, *WebMD Medical News*, *webmd.com*, January 2008

Jan. 17, 2008 The FDA today urged parents and caregivers not to give over-the-counter (OTC) cough and cold medicines to children younger than 2 because of dangerous side effects.

"We strongly recommend that over-the-counter cough and cold products should not be used in infants and young children under 2 years of age because serious and potentially life-threatening side effects can occur from use of these products," Charles Ganley, MD, director of the FDA's Office of Nonprescription Products, said at a news conference.

OTC cough and cold products include decongestants, expectorants, antihistamines, and antitussives (cough suppressants) for the treatment of colds.

An FDA news release states that rare, serious adverse events -- including convulsions, rapid heart rates, decreased levels of consciousness, and death -- have been reported with use of cough and cold products.

The FDA is still reviewing the use of cough and cold medicines in children aged 2-11.

FDA Timeline

Today's FDA recommendation is in line with the findings of an FDA advisory panel that weighed in on the topic last October, shortly after makers of OTC cough and cold drugs for infants voluntarily took those products off the market.

A key concern has been the potential for accidental overdoses if the dosing instructions for those drugs aren't followed exactly as instructed.

"I will point out that the FDA has never endorsed the use of these products in children less than 2 years of age," Ganley says. "We've always acknowledged that there was no safety and efficacy data. It was really left to the discretion of health providers to determine whether use of one of these products was appropriate in these age groups."

Ganley says the FDA decided to issue today's advisory after learning of recent surveys that show that some parents aren't aware of the warnings issued last fall about the use of OTC cough and cold drugs in kids younger than 2.

"This announcement will bring this issue back into the public consciousness, particularly since it's cold season now," Ganley says.

Industry Responds

The Consumer Healthcare Products Association (CHPA), a trade group representing makers of over-the-counter (OTC) medicines, issued a statement supporting today's FDA's decision.

"Safety has always been and continues to be our top priority," says CHPA President Linda Suydam, DPA.

"Today's decision by the FDA reaffirms the correct course of action taken by the leading makers of these medicines last fall," says Suydam, referring to the voluntary withdrawal of over-the-counter cough and cold drugs for infants.

The CHPA is working with retailers, doctors, and the FDA "to ensure that parents have the tools they need to safely and appropriately administer OTC oral cough and cold medicines to children over the age of two," Suydam says.

Tips for Parents of Older Kids

Speaking at today's FDA news conference, Lisa Mathis, MD, associate director of the FDA's Pediatric and Maternal Health Staff in the Office of New Drugs, reminded parents that the FDA hasn't finished reviewing cough and cold drugs for older children.

Mathis provided the following tips for parents who choose to give over-the-counter cough and cold medicines to children aged 2-11:

- Always remember that these medications do not cure the cold. They don't shorten the time that your child has a cold, and they're only meant to help a child's symptoms.
- Look at the active ingredients in the Drug Facts label. This will help you understand what active ingredients are in the medication and what symptoms each active ingredient is intended to treat. Cough and cold medications often have more than one active ingredient.
- Be very careful in giving more than one over-the-counter cough and cold medication to your child. Remember that many over-the-counter cough and cold products have multiple medications in them. If you use two medications that have similar active ingredients, a child could get too much of the ingredient, which could be harmful.
- Make sure to carefully follow the directions in the Drug Facts part of the label. These directions tell you how much medicine to give and how often to give it.
- Only use the measuring device -- spoon, dropper, or cup -- that comes with the medication. Common household spoons come in different sizes and are not meant for measuring medicines. If you use these, you may not be giving the right dose.
- If you have the opportunity to choose cough and cold medications with a childproof safety cap, you should do so, and store these medications out of the reach of children.

"Most importantly," Mathis says, "call your physician, pharmacist, or other health care professional if you have any questions about using these medications in children 2 years of age and older."

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