

# Drug FAQs for Members FREQUENTLY ASKED QUESTIONS

### **OTC Cough & Cold Medicines for Children**

The Food and Drug Administration (FDA) recently announced new recommendations for the use of children's over-the-counter (OTC) cough and cold medicines:

- These medicines are no longer recommended for children under the age of 4 years. Some of these products will also caution about use in children under 6 years.
- Medicines containing antihistamines (e.g., Dimetapp, Benadryl, etc) should not be used to sedate or make a child sleepy.

These changes were made because of concerns that cough and cold medicines do not actually help lessen symptoms in young children and can (rarely) cause serious side effects, especially when used improperly. Of note, some physician groups, including the American Academy of Pediatrics, do not feel the data shows OTC cough and cold products work in children under 6 years and can cause potentially serious side effects. The FDA has requested additional studies of cough and cold medicines be completed in children to find out more about their efficacy and proper dosing for various age groups. At this time, Kaiser Permanente Pediatricians and Allergists recommend that children under 4 years of age not be given OTC cough and cold medicines unless specifically instructed to do so by a healthcare provider.

Leading manufacturers have already taken their OTC infant cough and cold products off the market. They are changing the labeling of remaining products to reflect the new recommendations and to encourage proper use of these medicines. In addition, they will provide dosing spoons or devices with all liquid medicines.

## Which products will be affected by the labeling change?

- Children's cough and cold products already in stores will remain available and are not being recalled or withdrawn. Products with the new labeling will soon be added to stock. During this transition period, you might find medicines with old labeling (which cautions not to use in children under 2 years of age) and new labeling for age 4 and above. If you have questions about a particular product, please ask your pharmacist or pediatrician.
- Affected products include: Children's Tylenol Plus, Pediacare, Children's Sudafed, Children's Benadryl, Triaminic, Children's NyQuil, Vicks Pediatric, Delsym, Children's

Warnings

Do not use

■ in a child under 4 years of age
■ if you are now taking a prescription monoamine oxidase
minoritor (NAO) (certain drugs for depression, psychiatric, or
emotional conditions, or Parkinson's disease), or for 2 weeks
after stopping the MAOI drug. If you do not know if your
prescription drug contains an MAOI, ask a doctor or
pharmacist before taking this product.

Ask a doctor before use if you have
■ cough that occurs with too much phlegm (mucus)
■ cough that lasts or is chronic such as occurs with smoking,
asthma, chronic bronchitis, or emphysema

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Mucinex, Children's Dimetapp, Robitussin Pediatric, and others. Further details on these products can be found at: http://otcsafety.org/Media/128678607135956061.pdf.

Adult cough and cold medications are not affected by this labeling change.



#### Tips for managing cough and cold symptoms in children under 4 years of age:

- Make sure that your child gets plenty of rest and fluids.
- Remember that colds last about a week, but some symptoms like cough can last longer, e.g., up to several weeks.
- Understand that using OTC cough and cold medicines will not cure a cold or cough.
- Use a rubber suction bulb to gently clean an infant's clogged nose.
  - Saline nose drops can be used to soften the mucus.
- Because colds are caused by viruses, antibiotics have no effect on the symptoms of the infection. Many
  Pediatricians, however, recommend use of a humidifier to relieve the symptoms of nasal congestion caused by the
  cold viruses and acetaminophen (any age) or ibuprofen (if over 6 months of age) to alleviate pain, fever or body
  aches. Check that these medications do not contain extra ingredients.

Parents can also find information in the Kaiser Permanente Healthwise Handbook online at the Kaiser Permanente website (http://www.kp.org).

#### General tips to consider before giving your child OTC medicines:

#### Choose medicines wisely

- Choose a product suitable for your child's age. Do not give your child a medication that is intended for adult
  use only.
- Check the "active ingredients" section of the Drug Facts label of the medications that you plan to use.
- Only give the medicine that targets the symptoms that your child is having.
- Low-sedating antihistamines (e.g., Claritin) are generally preferred over sedating antihistamines (e.g., Benadryl) for the treatment of allergic rhinitis.

#### Give medicines properly

- Always read and follow the dosing directions on the Drug Facts label of any OTC medication.
- Only use measuring spoons or cups that come with the medicine or those made especially for measuring drugs.
- Never give your child two medicines at the same time that contain the same active ingredient.
- If your child develops side effects to the medication that concern you, stop giving the OTC medicine and immediately contact a physician.
- Never use an OTC medicine to sedate or make your child sleepy.
- Never give products containing aspirin to a child to treat cold or flu symptoms unless instructed by a physician.

#### Keep medicines safely

- Choose OTC cough and cold medicines that have child resistant safety caps, when available.
- Keep all medications out of the reach and sight of your child.

#### For more information

- If you have any questions about cough and cold products, talk to a healthcare professional.
- For more safety tips for OTC medicines, see the OTCsafety.org website: http://www.otcsafety.org/Parents/.

