

McNeil Consumer Healthcare, Division of Johnson & Johnson Inc.
Use of Cough and Cold Products in Children Under Six

QUESTIONS & ANSWERS

1. What did I hear on the news about cough and cold products in children under 6 years of age?

In cooperation with Health Canada, the manufacturers of cough and cold medicines are taking actions to help further encourage the continued appropriate use of children's cough and cold medicines. We are directing parents and healthcare professionals to only give children's cough and cold medicines to children age six years and older.

The following children's cough and cold medicines should not be used in children under six years of age:

- BENYLIN DM-D® for Children Cough & Cold
- BENYLIN DM® for Children Dry Cough
- BENYLIN DM® for Children Dry Cough Bedtime 12 hr.
- BENYLIN® for Children All-In-One Cold & Fever
- BENYLIN® for Children All-In-One Cold & Fever Nighttime
- Children's TYLENOL® Cold
- Children's TYLENOL® Cold & Cough
- Children's TYLENOL® Cold & Cough Nighttime
- Children's TYLENOL® Cough & Runny Nose
- Children's TYLENOL® Decongestant
- Children's TYLENOL® Cold & Cough (Cold DM)
- Junior Strength TYLENOL® Cold & Cough (Cold DM)

The following adult cough and cold medicines with children's dosing should not be used in children under 6 years of age:

- Benylin® DM Dry Cough
- Benylin® DM-D Dry Cough & Cold
- Benylin® DM-E Chest Cough
- Benylin® DM-D-E Chest Cough & Cold
- Benylin® DM 12 Hr Bedtime.

It is important for you to know that parents can continue to use these medicines with confidence in children age six and older. As with all medicines, parents and caregivers should always follow the directions on the label. Pain reliever/fever reducers containing a single active ingredient such as INFANTS' and CHILDREN'S TYLENOL® (acetaminophen) and INFANTS' and CHILDREN'S MOTRIN® (ibuprofen) are not affected by this label change.

2. Are any of your products being recalled?

No. McNeil Consumer Healthcare will begin relabeling our children's cough and cold medicines to state "do not use in children under 6" and this transition to updated labeling will be completed by fall 2009. Medicines with current labeling will remain on store shelves during the current cough and cold season. Parents can continue to use these products with confidence in children age six years and older, when the label is followed as directed.

3. Do these labeling changes affect all children's OTC medicines?

No. The label changes do not apply to those pain reliever/fever reducers containing a single active ingredient such as INFANTS' and CHILDREN'S TYLENOL® (acetaminophen) and INFANTS' and CHILDREN'S MOTRIN® (ibuprofen).

4. Will cough and cold medicines harm my child?

Children's cough and cold medicines are safe and effective, when used as directed in children age six years and older. It's always important to:

- Always read and follow the label
- Not give more than the recommended dose
- Ask a doctor, physician, or health care professional questions about the correct use of this product
- Not use two products with the same ingredient
- Always keep all medicines out of the reach and sight of children

5. What are the actual health risks associated with these products in children under six?

Reports of adverse events are very rare, and mostly associated with misuse or accidental ingestion in younger children. There is no new scientific data to suggest that these products are not safe and effective when used as directed.

6. Can I continue to use these products in my child who is under six?

Following consultation with Health Canada, we are directing parents and healthcare professionals to only give children's cough and cold medicines to children age six years and older. Parents can continue to use these medicines with confidence in children age six and older. As with all medicines, parents should always follow the directions on the label.

If parents have any questions about the use of these products, they should speak with a pharmacist or other healthcare professional.

7. What am I supposed to use for my child who is under six and suffering from a cough or cold?

There are many things you can do for your child to help them (and you) feel better. Start with these few tips, and consult a doctor if your child doesn't seem to be getting better.

- As simple as it sounds, making sure your child gets plenty of rest is one of the best ways you can help them feel better.
- Giving them plenty of fluids can help ease congestion, cool a fever, and soothe a scratchy throat.
- To help with a dry or stuffy nose, use saline nose drops to help loosen things up. Ask your pediatrician which ones to use.
- Using a cool mist humidifier will keep air moist, which can help clear your child's clogged nasal passages. Just be sure to clean the humidifier often to avoid spreading germs.

8. What should I do if I have affected products in my home?

If you have these medicines in your home, we recommend that you discontinue use in children under six years of age. If you have no further use for the medicine, you can speak with your pharmacist about proper disposal.

If you have any specific questions about managing your child's cough and cold symptoms, you should speak with a pharmacist or other healthcare professional.

If you have any additional questions please go to the contact us section of this site for information on how to reach us by email or by telephone.