



Advisory

Health Canada Releases Decision on the Labeling of Cough and Cold Products for Children

December 18, 2008

For immediate release

OTTAWA – Health Canada is advising consumers of the outcome of its review of cough and cold medicines for children under the age of 12.

Health Canada is requiring manufacturers to relabel over-the-counter cough and cold medicines that have dosing information for children to indicate that these medicines should not be used in children under 6. The products affected are those containing any of the active ingredients listed below that are given orally:

Table 1: Active Ingredients Affected by Health Canada’s Decision on Cough and Cold Products for Children

Therapeutic Category (Purpose)	Active Ingredients
Antihistamines in cough and cold medicines (used to treat sneezing, runny nose)	brompheniramine maleate chlorpheniramine maleate clemastine hydrogen fumarate dexbrompheniramine maleate diphenhydramine hydrochloride diphenylpyraline hydrochloride doxylamine succinate pheniramine maleate phenyltoloxamine citrate promethazine hydrochloride pyrilamine maleate triprolidine hydrochloride
Antitussives (used to treat cough)	dextromethorphan dextromethorphan hydrobromide diphenhydramine hydrochloride
Expectorants (used to loosen mucus)	guaifenesin (glyceryl guaiacolate)
Decongestants (used to treat congestion)	ephedrine hydrochloride/sulphate phenylephrine hydrochloride/sulphate pseudoephedrine hydrochloride/sulphate

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The relabelling of these medicines (http://www.hc-sc.gc.ca/dhp-mps/prodpharma/activit/announce-annonce/notice_avis_decision_pedlscs_pednecr-eng.php) will be completed by fall 2009, in time for the next cough and cold season. During the current cough and cold season, medicines will remain on store shelves and in homes with the current labelling, which could include dosing information for children under 6, because many of these products also have dosing information for adults and older children on the same label. As a result, for this cough and cold season, parents or caregivers should consult a pharmacist or a health care practitioner when buying or using these products. These medicines can still be used in children 6 and older, and adults.

This decision is the result of a Health Canada review of these medicines, including the input of a Scientific Advisory Panel convened in March 2008. Health Canada has concluded that while cough and cold medicines have a long history of use in children, there is limited evidence supporting the effectiveness of these products in children. In addition, reports of misuse, overdose and rare side-effects have raised concerns about the use of these medicines in children under 6. The rare but serious potential side-effects include convulsions, increased heart rate, decreased level of consciousness, abnormal heart rhythms and hallucinations. The [Scientific Advisory Panel's conclusions](http://www.hc-sc.gc.ca/dhp-mps/prodpharma/activit/sci-consult/pediat/sapnccm_gcsmltr_rop_crd_2008-03-20-eng.php) (http://www.hc-sc.gc.ca/dhp-mps/prodpharma/activit/sci-consult/pediat/sapnccm_gcsmltr_rop_crd_2008-03-20-eng.php) and details of the [new Health Canada recommendations](http://www.hc-sc.gc.ca/dhp-mps/prodpharma/activit/announce-annonce/notice_avis_decision_pedlscs_pednecr-eng.php) (http://www.hc-sc.gc.ca/dhp-mps/prodpharma/activit/announce-annonce/notice_avis_decision_pedlscs_pednecr-eng.php) are posted on the Health Canada Web site.

Health Canada previously issued advice on the use of these medicines in an [October 2007 Public Advisory](http://www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/_2007/2007_147-eng.php) (http://www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/_2007/2007_147-eng.php). Based on a preliminary review, Health Canada at that time recommended not using over-the-counter cough and cold medicines in children under 2 years of age, unless instructed to do so by a health care practitioner. The [current decision](http://web.hc-sc.gc.ca/ahc-asc/media/advisories-avis/_2008/2008_184info1-eng.php) (http://web.hc-sc.gc.ca/ahc-asc/media/advisories-avis/_2008/2008_184info1-eng.php) expands on those preliminary recommendations.

Until the relabelling of these products is completed, Health Canada advises parents and caregivers to follow these important guidelines:

- Do not use these over-the-counter cough and cold medicines in children under 6 years of age.
- With children older than 6, always follow all the instructions carefully, which includes the dosing and length-of-use directions, and use the dosing device if one is included.
- Do not give children medications labelled only for adults.
- Do not give more than one kind of cough and cold medicine to a child. Cough and cold medications often contain multiple ingredients. Combining products with the same ingredient(s) could cause an overdose that may result in harm to a child.
- Talk to your health care practitioner (doctor, pharmacist, nurse, etc.) if you have questions about the proper use of over-the counter cough and cold medicines.
- The common cold is a viral infection for which there is no cure. Cough and cold medicines offer only temporary relief of symptoms such as runny nose, cough, or nasal congestion.

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Symptoms can also be managed using a variety of non-medicinal measures such as adequate rest, increased fluid intake and a comfortable environment with adequate humidity.

- For babies and young children, it is important to rule out serious illnesses that have cold-like signs and symptoms (for example, pneumonia, ear ache or other infections). This is especially important if symptoms do not improve, or if the child's condition worsens.
- If you are concerned about the child's health (such as if symptoms worsen, last for more than a week, or are accompanied by a fever higher than 38 C or the production of thick phlegm), consult a health care practitioner for a medical evaluation.

For more information about Health Canada's decision and the use of [cough and cold products in children](http://www.hc-sc.gc.ca/dhp-mps/medeff/res/cough-toux-eng.php) (<http://www.hc-sc.gc.ca/dhp-mps/medeff/res/cough-toux-eng.php>), consult the [Health Canada Web site](http://www.healthcanada.gc.ca/coughandcold) (<http://www.healthcanada.gc.ca/coughandcold>) or call toll free at 1-866-558-2946.

For advice on how to properly dispose of medications, see the "It's Your Health" article entitled [The Proper Use and Disposal of Medication](http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/med/disposal-defaire-eng.php) (<http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/med/disposal-defaire-eng.php>).

For more information on the safe use of medicines, see the "It's Your Health" article entitled [Safe Use of Medicines](http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/med/safe-secure-eng.php) (<http://www.hc-sc.gc.ca/hl-vs/iyh-vsv/med/safe-secure-eng.php>).

You can report any adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following three ways:

- [Report online](http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php) (<http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>) at the MedEffect™ Canada Web site
- Call toll-free at 1-866-234-2345
- Complete a [Canada Vigilance Reporting Form](http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/ar-ei_form-eng.php) (http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/ar-ei_form-eng.php) and either:
 - Fax toll-free to 1-866-678-6789
 - Mail to: Canada Vigilance Program
Health Canada
AL 0701C
Ottawa, ON K1A 0K9

To have postage pre-paid, [download the postage paid label](http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/post_paid-affranchi-eng.php) (http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/post_paid-affranchi-eng.php) from the MedEffect™ Canada Web site. The [Canada Vigilance Reporting Form](http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/ar-ei_form-eng.php) (http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/ar-ei_form-eng.php) and the adverse reaction reporting guidelines may also be obtained via this Web site.

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