

Stop press

Updated advice—Over-the-counter cough and cold medicines for children

information from Professor Rosalind Smyth, Chair of the Paediatric Medicines Expert Advisory Group

For further information about the Paediatric Medicines Expert Advisory Group, see <http://www.mhra.gov.uk/mhra/drugsafety/update>

For further information about the US Food and Drug Administration safety review, see <http://www.fda.gov/bbs/topics/NEWS/2008/NEW01778.html>

The Paediatric Medicines Expert Advisory Group and the Commission on Human Medicines have recently assessed the safety of cough and cold medicines for children. This assessment follows recent advice from the US Food and Drug Administration about the safety of these medicines in children.

The Commission noted that although UK data do not raise the same level of concern as those for the USA, five reports of deaths (the first in 1981) associated with use of cough and cold medicines in children younger than 2 years have been received via the Yellow Card scheme. Moreover, the Commission noted a lack of robust evidence for the efficacy of these medicines in children. It was noted that medication does not affect the course of the illness: it can only provide, at best, symptomatic relief.

Information for these medicines contains age-appropriate dose advice and many are sold under the supervision of a pharmacist. However, parents and carers may be unaware of the risk of overdose that results from the simultaneous use of different products that may duplicate ingredients. The small body size of children younger than 2 years increases the risk of serious adverse events from such dosing errors.

Both the Expert Advisory Group and the Commission concluded, on the basis of available evidence, that the balance of risks and benefits associated with the use of cough and cold medicines for children younger than 2 years is no longer favourable. Furthermore, the Commission advised that medicines in this therapeutic range that are suitable for children age 2–6 years should contain updated information.

Advice for healthcare professionals:

- Parents and carers should be encouraged to use the following medicines to alleviate the symptoms of coughs and colds in children: single-constituent paracetamol or ibuprofen; simple cough medicines (eg, those that contain glycerol or honey and lemon); vapour rubs and inhalant decongestants (which can be applied to a child's clothing); and, particularly in infants, saline nasal drops
- Non-prescription cough and cold medicines that contain the following active ingredients **should not be used in children younger than 2 years**:
 - brompheniramine, chlorphenamine, and diphenhydramine (antihistamines)
 - dextrometorphan and pholcodine (antitussives)
 - guaifenesin and ipecacuanha (expectorants)
 - phenylephrine, pseudoephedrine, ephedrine, oxymetazoline, and xylometazoline (decongestants)
- Products that contain these active substances and that are licensed for use in **children age 2–6 years** will be updated to include: information on maximum daily dose; a warning not to take other cough and cold medicines at the same time; and an instruction for parents or carers to seek the advice of a pharmacist or other healthcare professional before using the medicine
- For **children older than 2 years**, cough and cold medicines are considered safe at the recommended doses, which should be followed carefully and not exceeded. Parents and carers should be advised not to give a child more than one cough and cold medicine because different brands may contain the same active ingredient(s)

I hope that you find this information useful to your practice. Further information, including an information leaflet for parents and carers, is available at www.mhra.gov.uk

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