

MEDICINES CONTROL COUNCIL



MEDICINE SAFETY ALERT: COUGH AND COLD MEDICINES NO LONGER TO BE USED IN CHILDREN UNDER THE AGE OF TWO YEARS

The Medicines Control Council (MCC) of South Africa wishes to alert healthcare professionals that the use of oral cough and cold medicines containing certain ingredients is now contraindicated in children under the age of two years.

This decision is in line with international recommendations regarding the use of oral cough and cold medicines in children.

Based on the available information, the MCC decided to contraindicate the use of oral cough and cold medicines containing brompheniramine, chlorpheniramine, dextromethorphan, diphenhydramine, ephedrine, guaifenesin, ipecacuanha, phenylephrine, pholcodine and pseudoephedrine in children under the age of two years due to an unfavourable risk benefit profile of these medicines in this age group. This decision, however does not preclude the use of medicines containing antihistamines as a single agent when used for allergic reactions (hypersensitivity).

The manufacturers of these oral cough and cold medicines will be updating the product information to reflect the contraindication in children under the age of two years. This may however take some time to be fully implemented.

The MCC urges healthcare professionals to heed the following warnings and advice before recommending the use of cough and cold medicines in children:

- Cough and cold medicines containing the above listed ingredients should not be prescribed or used in children under the age of two years.

For children **over** the age of two years

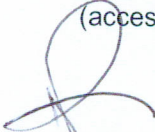
- The referred ingredients may only be prescribed by a doctor or pharmacist.
- The concurrent use of two or more different cough and cold products in the same patient should be avoided as these can result in serious adverse effects.
- The dosing instructions in the package insert should be read carefully to ensure that the prescribed dosage is within the recommended dosage range and frequency for the patient's age and/or weight.

- Parents or caregivers should be warned to keep all medicines out of the reach of children.
- Parents and caregivers should be reminded that cough and cold medicines may only relieve symptoms and will not treat the cause of the symptoms and will not shorten the length of time a child is ill.

Healthcare professionals are encouraged to report any adverse drug reactions to the National Adverse Drug Event Monitoring Centre at Fax Number: 021 448 6181 or telephone 021 4471618.

References

- 1) Royal Pharmaceutical Society of Great Britain. New advice for the treatment of cough and colds in children. 28 February 2009. Available at:
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- 3) TGA. TGA announcement regarding the use of cough and cold medicines in children. Updated on 17 April 2008. Available at:
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- 4) US FDA. OTC Cough and Cold Products: Not For Infants and Children Under 2 Years of Age. 23 January 2008. Available at:
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