

# MEDICINES CONTROL COUNCIL



## MEDICINE SAFETY ALERT: PROMETHAZINE CONTRAINDICATED IN CHILDREN UNDER TWO YEARS OF AGE

***The Medicines Control Council (MCC) alerts all health care professionals to new prescribing information for promethazine.***

The package inserts for promethazine-containing products are currently being updated to reflect a contraindication for use in children under the age of two years because of the potential for fatal respiratory depression in this age group.

Serious life-threatening cases of respiratory depression, including fatalities have been reported with promethazine use in paediatric patients less than 2 years of age.<sup>1,2,3</sup>

Therefore, promethazine should not be administered to children under two years of age and with caution in children of two years and older and the lowest effective dose should be used in this group.<sup>2</sup>

Promethazine is used as an antihistamine, sedative, and anti-emetic. There are several over-the-counter products that contain promethazine. These include antihistamines, combination analgesics/antipyretic paediatric syrups and cough and cold preparations. Prescribers and users of these products should check the ingredients and review the revised package insert and patient information leaflet before prescribing or using promethazine-containing products.

Health care professionals are encouraged to report any adverse reactions associated with the use of medicines to the MCC's National Adverse Drug Event Monitoring Centre (NADEMC) by telephone (021 447 1618) or fax (021 448 6181).

### References:

1. Martindale: The Complete Drug Reference, 34<sup>th</sup> ed. p439-440.
2. Starke P.R., Weaver J., Badrul A. Comment from FDA. Boxed Warning added to Promethazine Labeling for Paediatric Use. N Eng J Med 2005, 352 (25): 2653.
3. Hickson G.B., Altemeier W.A., Clayton E.W. Should promethazine in liquid form be available without prescription? Pediatrics 1990; 86: 221-5 (Abstract).