



Fig. 1. Before (above) and 30 minutes after apraclonidine.

and if there is no response in the acute setting, cocaine is considered as the alternative.<sup>1</sup>

Topical apraclonidine is currently used for reduction of intra-ocular pressure in acute angle closure glaucoma and following YAG laser therapy. Because of the weak  $\alpha_1$ -activity it has been shown to be useful in diagnosing Horner's syndrome regardless of the site of the lesion.

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2. Kardon R. Are we ready to replace cocaine with apraclonidine in the pharmacologic diagnosis of Horner syndrome? *J Neuroophthalmol* 2005; 25: 69-70.
3. Brown SM. The utility of 0.5% apraclonidine in the diagnosis of Horner syndrome. *Arch Ophthalmol* 2005; 123: 578.
4. Bacal DA, Levy SR. The use of apraclonidine in the diagnosis of Horner syndrome in paediatric patients. *Arch Ophthalmol* 2004; 122: 276-279.
5. Koc F, Kavuncu S, Kansu T, et al. The sensitivity and specificity of 0.5% apraclonidine in the diagnosis of oculosympathetic paresis. *Br J Ophthalmol* 2005; 89: 1442-1444.

## DRUG ALERT

### Promethazine contraindicated in children under 2 years of age

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

The package inserts for promethazine-containing products are currently being updated to reflect a contraindication to use in children under the age of 2 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 under 2 years of age.<sup>1-3</sup> Promethazine should therefore not be administered to children under 2 years of age, and with caution to children of 2 years and older, and the lowest effective dose should be used in this group.<sup>2</sup>

Promethazine is used as an antihistamine, sedative, or 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).

National Drug Event Monitoring Centre  
Medicines Control Council  
Cape Town

1. Sweetman SC, ed. *Martindale: The Complete Drug Reference*. 34th ed. London: Pharmaceutical Press, 2005: 439-440.
2. Starke PR, Weaver J, Badrul A. Comment from FDA. Boxed warning added to promethazine labelling for paediatric use. *N Engl J Med* 2005; 352 (25): 2653.
3. Hickson GB, Altemeier WA, Clayton EW. Should promethazine in liquid form be available without prescription? *Pediatrics* 1990; 86: 221-225 (Abstract).

### Roche recalls Viracept due to chemical impurity

Roche, in agreement and co-operation with health authorities (EMA and Swissmedic), is recalling all batches of Viracept powder and tablets in Europe and some other regions of the world. The USA, Canada and Japan are not affected by this recall.

Roche has received several reports that some batches of Viracept 250 mg tablets have a strange odour. A detailed chemical analysis of the affected tablets showed they contain higher than normal levels of methane sulfonic acid ethyl ester. In the interests of patient safety Roche has decided to recall all batches of Viracept tablets and powder currently on the market.

In South Africa, Roche is working closely with the Medicines Control Council in the process of recalling the products.

Roche has also proactively frozen all stock of the powder and tablets at distributor and wholesaler levels, and is in the process of extending this to pharmacy level.

In South Africa it is estimated that less than 200 patients received Virecept therapy in the last year. Patients are requested to contact their doctors to discuss alternative therapies.

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