



Health Santé
Canada Canada

Health Products and Food Branch
Direction générale des produits de santé et des aliments

The Health Products and Food Branch (HPFB) posts on the Health Canada web site safety alerts, public health advisories, press releases and other notices as a service to health professionals, consumers, and other interested parties. These advisories may be prepared with Directorates in the HPFB which includes pre-market and post-market areas as well as market authorization holders and other stakeholders. Although the HPFB grants market authorizations or licenses for therapeutic products, we do not endorse either the product or the company. Any questions regarding product information should be discussed with your health professional.

NOTICE TO HOSPITALS
Health Canada Issued Important Safety Information on
Benzocaine Sprays

November 23, 2006

To: Hospital Chief of Medical Staff

Please distribute to the relevant Departments of Surgery, Emergency Medicine, Pharmacy, Pediatrics, Anesthesia, Internal Medicine, Nursing, Dentistry, Otolaryngology, Gastroenterology and other involved professional staff and **post this NOTICE** in your institution.

Subject: Association of Benzocaine Sprays with Methemoglobinemia

Benzocaine sprays are indicated for use during surgical, dental and other medical procedures to topically anesthetize mucous membranes and help obtund the pharyngeal and tracheal reflexes.

Methemoglobinemia (MHb) is an uncommon adverse reaction known to be associated with benzocaine. MHb results in an impaired ability of red blood cells to bind and carry oxygen and may lead to cyanosis, weakness and coma. Benzocaine products are available in many different topical forms, but almost all reported cases of benzocaine-induced MHb have been associated with higher concentration (14-20% benzocaine) spray products used in the mouth and on other mucous membranes.

Although this potentially life-threatening reaction is well established, cases continue to be reported to Health Canada, and the number of cases reported in the medical literature also appears to be increasing. Accordingly, Health Canada reminds health care professionals that benzocaine sprays must be used judiciously to minimize the risk of acquired MHb.

Recommendations:

1. Carefully evaluate patients for pre-disposing risk factors for benzocaine-induced MHb. Risk factors include mucosal damage or inflammation at the application site, use in infants, concomitant use of other oxidizing agents, heart disease, malnutrition and deficiencies in certain enzymes such as glucose-6-phosphate dehydrogenase or hemoglobin reductase. Alternatives to benzocaine sprays, such as topical lidocaine preparations, are available and should be considered for patients with MHb risk factors.
2. Record and pay special attention to the number of sprays administered and the length of each spray. Use the minimum quantity of spray needed to achieve the desired effect.
3. Monitor patients for signs and symptoms of MHb such as pallor, cyanosis, nausea, muscle weakness, dizziness, confusion, agitation, dyspnea and tachycardia.
4. Even when the classic clinical finding of chocolate brown-coloured arterial blood is present, confirm suspected cases of MHb by way of co-oximetry as this will give a direct and accurate measure of methemoglobin levels. Do not rely on standard pulse oximetry readings or arterial blood gas values as they can yield misleadingly near-normal results in such cases. To reduce the risk of morbidity, treat clinically significant cases of MHb immediately.

Managing marketed health product-related adverse reactions depends on health care professionals and consumers reporting them. Reporting rates determined on the basis of spontaneously reported post-marketing adverse reactions are generally presumed to underestimate the risks associated with health product treatments. Any cases of MHb or other serious or unexpected adverse reactions in patients receiving benzocaine should be reported to the manufacturer or to Health Canada at the following address:

Canadian Adverse Drug Reaction Monitoring Program (CADRMP)
Marketed Health Products Directorate
HEALTH CANADA
Address Locator: 0701C
OTTAWA, Ontario, K1A 0K9
Tel: (613) 957-0337 or Fax: (613) 957-0335
To report an Adverse Reaction, consumers and health professionals may call toll free:
Tel: 866 234-2345
Fax: 866 678-6789
cadrmp@hc-sc.gc.ca

The [AR Reporting Form](#) and the [AR Guidelines](#) can be found on the Health Canada web site or in *The Canadian Compendium of Pharmaceuticals and Specialties*.

http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/form/ar-ei_form_e.html
http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/guide/ar-ei_guide-ldir_e.html

For other inquiries related to this communication, please contact Health Canada at:

Marketed Health Products Directorate (MHPD)
MHPD_DPSC@hc-sc.gc.ca
Tel: (613) 954-6522
Fax: (613) 952-7738

References:

Moore TJ, Walsh CS, Cohen MR. Reported Adverse Event Cases of Methemoglobin Associated With Benzocaine Products. *Arch Intern Med* 2004;164:1192-1196.

Armstrong C, Burak KW, Beck PL. Benzocaine-induced methemoglobinemia: A condition of which all endoscopists should be aware. *Can J Gastroenterol* 2004;18(10):625-629.