

Topical Benzocaine Sprays (4/06)

For **UPDATE**, [click here](#).

Recently several agencies, including the US Food and Drug Administration (FDA) and the DoD Patient Safety Program, have published information about possible adverse events, including methemoglobinemia (MHb), associated with the use of topical benzocaine spray (e.g., Hurracaine Spray [benzocaine 20%], Cetacaine Spray [benzocaine 14%], Topex Spray [benzocaine 20%]). The FDA issued a Public Health Advisory, and is reviewing available safety data, but is not planning on removing it from the market at this time. In February 2006, the Veterans Health Administration (VA) announced a decision to stop using benzocaine sprays when locally numbing mucous membranes of the mouth and throat for minor surgical procedures or when a tube must be inserted into the stomach or airway. The FDA has concluded that the number of reported cases is low and when properly used the use of topical benzocaine has value. The alerts appear to be directed towards using benzocaine spray for more invasive procedures (e.g., procedures requiring a tube be inserted down the throat or windpipe) than what is typically performed in a dental setting. Also, problems have occurred with incorrect use, such as longer duration or more frequent sprays than recommended. The FDA Advisory applies only to *benzocaine sprays* used in the mouth and throat, *not* to other benzocaine products or to benzocaine sprays applied to exterior skin. Nonetheless, it is very important to follow the directions and not spray the benzocaine for a time longer than recommended by the manufacturer, which is generally about one second.

On 27 March 2006, the DoD Patient Safety Program recommended:

1. Facilities insure their provider staffs are aware of the proper dosing and issues surrounding the use of topical benzocaine spray used in the surface anesthesia of the nasopharynx, oropharynx, laryngotracheal region and airways.
2. Local Pharmacy and Therapeutics (P&T) Committees consider the removal of benzocaine topical anesthetic sprays used in the surface anesthesia of the mouth and throat from their formularies. Alternative products containing lidocaine are available and have not been shown to contribute to the development of MHb.

USAF Dental clinics should be aware that they may be asked to discontinue using topical benzocaine sprays and may need to seek alternate products.

References

- Institute of Safe Medication Practices. (2002). *Benzocaine Containing Topical Sprays and Methemoglobinemia*. Huntingdon Valley, PA. Available at www.ismp.org/newsletters/acutecare/articles/20021003.asp.
- U.S. Food and Drug Administration, Center for Drug Evaluation and Research. (2006). FDA Public Health Advisory Benzocaine Sprays marketed under different names, including Hurracaine, Topex, and Cetacaine. Rockville, MD.
- Patient Safety Alert. 2006. *Cessation of topical Benzocaine Usage to Anesthetize the Surfaces of Nasopharynx, Oropharynx, Laryngotracheal Region and Airway*. Washington, D.C.
- Medical Material Quality Control Message, MMQC-06-1074. (2006). *Benzocaine Sprays Marketed Under the Names Hurracaine, Topex, and Cetacaine/FDA Public Health Advisory*. Ft Detrick, MD.

UPDATE (5/11)

The US Food and Drug Administration (FDA) recently reported that it continues to receive reports of methemoglobinemia associated with benzocaine products (see above) and has made the following recommendations:

- Benzocaine products should not be used on children less than two years of age, except under the advice and supervision of a healthcare professional.
- Adult consumers who use benzocaine gels or liquids to relieve pain in the mouth should follow the recommendations in the product label. Consumers should store benzocaine products out of reach of children. FDA encourages consumers to talk to their healthcare professional about using benzocaine.
- Read the two Drug Safety Communications below for other specific recommendations for Healthcare Professionals, for Consumers and Caregivers and the Data Summary which supports these recommendations.

For additional information from the FDA, [click here](#).