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Health Care  
Plans**



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**TO: ALL FHCP PROVIDERS**

**FROM: CAROL COOPER, L.P.N. / PROVIDER RELATIONS COORDINATOR**

**DATE: APRIL 7, 2011**

**SUBJECT: BENZOCAINE TOPICAL FDA - MEDWATCH**



**The FDA Safety Information and  
Adverse Event Reporting Program**

## **Benzocaine Topical Products: Sprays, Gels and Liquids: Risk of Methemoglobinemia**

**AUDIENCE:** Family Practice, Pharmacy, Consumers

**ISSUE:** FDA notified healthcare professionals and patients that FDA continues to receive reports of methemoglobinemia, a serious and potentially fatal adverse effect, associated with benzocaine products both as a spray, used during medical procedures to numb the mucous membranes of the mouth and throat, and benzocaine gels and liquids sold over-the-counter and used to relieve pain from a variety of conditions, such as teething, canker sores, and irritation of the mouth and gums.

**BACKGROUND:** Methemoglobinemia is a rare, but serious condition in which the amount of oxygen carried through the blood stream is greatly reduced. In the most severe cases, methemoglobinemia can result in death. Patients who develop methemoglobinemia may experience signs and symptoms such as pale, gray or blue colored skin, lips, and nail beds; headache; lightheadedness; shortness of breath; fatigue; and rapid heart rate. Methemoglobinemia has been reported with all strengths of benzocaine gels and liquids, and cases occurred mainly in children aged two years or younger who were treated with benzocaine gel for teething. The signs and symptoms usually appear within minutes to hours of applying benzocaine and may occur with the first application of benzocaine or after additional use. The development of methemoglobinemia after treatment with benzocaine sprays may not be related to the amount applied. In many cases, methemoglobinemia was reported following the administration of a single benzocaine spray.

### **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.

FDA is continuing to evaluate the safety of benzocaine products and the Agency will update the public when it has additional information. FDA will take appropriate regulatory actions as warranted.

Healthcare professionals and patients are encouraged to report adverse events, side effects, or product quality problems related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: [www.fda.gov/MedWatch/report.htm](http://www.fda.gov/MedWatch/report.htm)
- [Download form](#) or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

Read the Medwatch safety alert, including links to the Drug Safety Communications and Q&As, at:

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm250264.htm>

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You are encouraged to report all serious adverse events and product quality problems to FDA MedWatch at [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm)



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