U.S. Department of Health and Human Services

Food and Drug Administration

FDA's Information for **Healthcare Professionals**

Topic: ***Benzocaine Sprays*** *(sold under various brand names such as Hurricaine, Cetacaine, Exactacain, and Topex)*

Healthcare professionals are being informed that the U.S. Food and Drug Administration continues to receive reports of methemoglobinemia, a potentially fatal adverse effect, associated with benzocaine sprays used during medical procedures to numb the mucous membranes of the mouth and throat.

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. Conditions such as anemia, heart disease, and lung disease (e.g. emphysema) may exacerbate the toxicity of methemoglobinemia.

In 2006, FDA issued a Public Health Advisory warning about methemoglobinemia with the use of benzocaine sprays during medical procedures. Since then, FDA has received 72 new cases of methemoglobinemia, including three resulting in death, associated with the use of benzocaine sprays, bringing the total to 319 cases.

A review of the cases indicates that the development of methemoglobinemia after treatment with benzocaine sprays may not be related to the amount applied. Methemoglobinemia was reported following the administration of a single benzocaine spray. In other cases, methemoglobinemia resulted after excessive amounts were applied.

Additional information for healthcare professionals:

- Labels of marketed benzocaine sprays are not currently required to warn about the risk of methemoglobinemia although the use of benzocaine can cause this condition.
- Carefully monitor patients who receive benzocaine sprays for signs of methemoglobinemia during the procedure and for at least two hours post-application. Signs include pale, gray or blue colored skin, lips, and nail beds; shortness of breath; decreased blood oxygen saturation levels; and tachycardia. These indicate a moderate to severe level of methemoglobin and a marked reduction in the oxygen-carrying capacity of the blood. A characteristic color of the blood (chocolate-brown rather than blood-red) may indicate methemoglobinemia, but this change is a late sign of the condition.

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Signs and Symptoms

Signs and symptoms usually appear within minutes to hours of using benzocaine and may include:

- pale, gray or blue colored skin, lips and nail beds
- headache
- lightheadedness
- shortness of breath
- fatigue
- rapid heart rate.

Topic: ***Benzocaine Sprays*** *(continued)*

- Be aware that the amount of benzocaine contained in a single spray varies among different manufacturers and depends on the concentration of the solution, the amount of time the actuator is depressed, the residual volume in the can, and the spatial orientation of the can during spraying.
- Methemoglobinemia can cause unreliable oxygen saturation readings on a standard 2-wavelength pulse oximeter when used to assess the amount of oxygen bound to hemoglobin. If blood is drawn to check for methemoglobinemia, an FDA-approved co-oximeter should be used to reliably measure methemoglobin.
- Infants less than four months of age, elderly patients, and patients with certain inborn defects such as glucose-6-phosphodiesterase deficiency, hemoglobin-M disease, NADH-methemoglobin reductase (diaphorase 1) deficiency, and pyruvate-kinase deficiency may also be at greater risk of developing methemoglobinemia.
- Medications, foods, and water containing nitrites and nitrates may also induce methemoglobin formation, which will be additive to that formed by benzocaine products.
- Report adverse events or medication errors involving benzocaine to the FDA MedWatch program using the information in the "Contact Us" box at the bottom of this page.

For more information visit the FDA website at WWW.FDA.GOV/.

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