

Risk of methemoglobinemia in the medicine cabinet

Patients need to know about benzocaine

Benzocaine-containing products may cause a rare but serious and possibly fatal condition called methemoglobinemia. Methemoglobinemia is a condition where too much of the hemoglobin in red blood cells becomes unable to bind and carry oxygen. Labels of OTC benzocaine products do not contain warnings about methemoglobinemia. FDA is particularly concerned about the use of OTC benzocaine products in children for relief of teething pain because parents or caregivers may not be aware of or watch for signs and symptoms of this condition when using the products.

Background

Benzocaine is the main ingredient in many OTC gels and liquids applied to the gums or mouth to relieve pain from a variety of conditions, such as teething, canker sores, and irritation of the mouth and gums. Benzocaine gels and liquids are sold under different brand names such as Anbesol, HurriCaine, Orajel, Baby Orajel, Orabase, and store brands.

Benzocaine is also sold in other forms such as lozenges and spray solutions. The spray solutions are marketed under different brand names such as HurriCaine, Cetacaine, Exactacain, and Topex and are used during medical procedures to numb the mucous membranes of the mouth and throat.

FDA data

A search of FDA's Adverse Event Reporting System database through March 16, 2011, identified 21 cases of methemoglobinemia associated with the use of OTC benzocaine gel or liquid products. Methemoglobinemia has been reported across a range of benzocaine gels and liquids, even at the lowest concentrations.

Of the 21 cases, 10 were categorized as life threatening, defined as those patients with a reported methemoglobin level greater than 55%. Six cases were categorized as serious, defined as those

patients with a reported methemoglobin level of 30% to 55% or who were administered methylene blue regardless of the level of methemoglobin. One death was reported, but it is unclear from the information provided whether the use of benzocaine gel contributed to the outcome. Most of the cases involved pediatric patients, particularly children aged 2 years or younger who were administered benzocaine gel for teething pain.

In 2006, FDA issued a Public Health Advisory about methemoglobinemia with the use of benzocaine sprays during medical procedures. Since then, FDA has received reports of 72 new cases of methemoglobinemia associated with the use of benzocaine sprays, including 3 resulting in death, bringing the total to 319 cases as of March 16, 2011. Of the 319 cases, 7 were deaths, 32 cases were categorized as life threatening, and 216 were categorized as serious.

A review of the 319 cases indicated that 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. In other cases, methemoglobinemia resulted after excessive amounts were applied.

The amount of benzocaine contained in a single spray varies across the different products 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. Symptoms may appear within minutes to 1 or 2 hours after using benzocaine.

Counseling tips

As members of the health care team most often available at the point of purchase, pharmacists have an opportunity to help patients and caregivers select an appropriate OTC product. Pharmacists should

provide the following information when counseling patients and caregivers seeking products containing benzocaine:

- Children younger than 2 years should not receive benzocaine products except under the advice and supervision of a health professional.
- Use alternative methods for reducing pain from teething. The American Academy of Pediatrics recommends using a teething ring chilled in the refrigerator, gently rubbing the child's gums with your finger, or contacting a health professional to identify other treatments if these methods do not provide relief.
- Use benzocaine gels and liquids sparingly and only when needed—not more than four times a day.
- Keep benzocaine products out of the reach of children.
- Discuss the signs and symptoms of methemoglobinemia, including pale, gray, or blue-colored skin, lips, and nail beds; headache; lightheadedness; shortness of breath; fatigue; and tachycardia.
- Symptoms may appear within minutes to 1 or 2 hours after using benzocaine. Symptoms may occur with the first or subsequent applications of benzocaine. Seek medical attention immediately if methemoglobinemia is suspected.
- Patients who have breathing problems such as asthma, bronchitis, or emphysema, patients with heart disease, and patients who smoke are at greater risk for complications related to methemoglobinemia.

Pharmacists are encouraged to report adverse events related to the use of these products to FDA's MedWatch Safety Information and Adverse Event Reporting Program at www.fda.gov/MedWatch/report.htm.

For more information, visit <http://apha.us/uQZOzp>.

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