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## Drugs

### Questions & Answers: Reports of a rare, but serious and potentially fatal adverse effect with the use of over-the-counter (OTC) benzocaine gels and liquids applied to the gums or mouth

On April 7, 2011, the U.S. Food and Drug Administration (FDA) warned the public about the use of over-the-counter (OTC) products containing benzocaine, an ingredient used to reduce pain in the mouth and gums. Benzocaine use may cause a rare, but serious condition where the amount of oxygen that can be carried through the blood stream is greatly reduced. This condition is called methemoglobinemia. FDA is particularly concerned about the use of OTC benzocaine products in children for relief of pain from teething because of the serious outcomes, including death, that may be associated with methemoglobinemia, as well as the difficulty parents or consumers may have in recognizing the signs and symptoms of methemoglobinemia when using these products at home. Furthermore, symptoms of methemoglobinemia may not always be evident or attributed to the condition.

Parents and caregivers should not use OTC benzocaine products on children under two years of age, except under the advice and supervision of a healthcare professional. If benzocaine products are used, it should be used sparingly and only when needed, but not more than four times a day.

Below is some additional information about benzocaine, methemoglobinemia, and steps consumers can take if they have or recognize an adverse reaction after using an OTC product containing benzocaine.

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#### Q1. What is benzocaine?

**A.** Benzocaine is a local anesthetic and is the active ingredient in many OTC products used to relieve pain in the mouth and gums from a variety of conditions such as teething, canker sores, and irritation of the mouth and gums.

OTC benzocaine products come in the form of gels, sprays, liquids, and lozenges. Many OTC benzocaine products are sold under the brand names listed [here](#). Please note that there may be additional benzocaine products that are not listed. Consumers can look at the Drug Facts label when buying products used to treat pain in the mouth and gums to find out whether benzocaine is listed as the active ingredient.

#### Q2. Why is FDA concerned about the use of benzocaine?

**A.** FDA is concerned about the use of benzocaine products because they may cause a rare, but serious and possibly fatal condition where the amount of oxygen carried through the blood stream is greatly reduced. This condition is called methemoglobinemia. In the most severe cases, methemoglobinemia can result in death. Labels of OTC benzocaine products currently do not contain warnings about methemoglobinemia, therefore, FDA is concerned that consumers may not be aware of and monitor for this condition when using OTC benzocaine products.

Methemoglobinemia with benzocaine use has been reported in adults and children. FDA is particularly concerned about the use of OTC benzocaine products in children aged two years and younger. There have been 21 reported cases of methemoglobinemia after the use of OTC benzocaine gels and liquids. Eleven of the 21 cases occurred in children two years of age or younger who were treated with benzocaine gel for teething.

Given the seriousness of the cases of methemoglobinemia, FDA will continue to evaluate the safety of benzocaine products and will update the public when additional information is available.

#### Q3. What are the signs and symptoms of methemoglobinemia?

**A.** Methemoglobinemia is a rare, but serious condition where the amount of oxygen carried by the blood is greatly reduced. Signs and symptoms of methemoglobinemia may include:

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

Symptoms of methemoglobinemia usually appear within minutes to one or two hours after using benzocaine gels or liquids. Methemoglobinemia can occur after the first time a person uses benzocaine, or after using a benzocaine product multiple times.

#### Q4. What should consumers do if they recognize the signs and symptoms of methemoglobinemia?

**A.** **Stop using the product and seek medical help immediately by calling 911.**

Methemoglobinemia caused by benzocaine may require treatment with medications and may require admission to a hospital. Serious cases of methemoglobinemia should be treated promptly. If left untreated or if treatment is delayed, serious cases of methemoglobinemia may cause permanent injury to the brain and body tissues, and even death, due to an inadequate supply of oxygen.

#### Q5. What should parents and caregivers do if they are currently using OTC benzocaine products on children who are teething?

**A.** Parents, caregivers, and consumers should not use OTC benzocaine products on children under two years of age, except under the advice and supervision of a healthcare professional. Parents and caregivers using OTC benzocaine products on children should closely watch for signs and symptoms of methemoglobinemia. These may include pale, gray or blue colored skin, lips, and nail beds; shortness of breath; fatigue; confusion; headache; lightheadedness; and rapid heart rate. In some cases, symptoms of methemoglobinemia may not always be evident or attributed to the condition. Symptoms usually appear within minutes to one or two hours after using a benzocaine product, and methemoglobinemia can develop after using the product for the first time, as well as after several uses. **Parents and caregivers who suspect a child may have**

**methemoglobinemia should stop using the product and seek medical help immediately by calling 911.**

Parents and caregivers should keep OTC benzocaine products out of reach of children and should not allow children to use these products without supervision. Consumers should follow the directions printed on the product labeling when using OTC benzocaine products.

Parents, caregivers, and consumers should report any reactions, symptoms, or side effects from the use of OTC benzocaine products to the FDA MedWatch program, using the information in the "Contact Us" box at the bottom of the page.

#### Q6. What are alternative methods for reducing pain from teething?

A. The American Academy of Pediatrics' recommends the following for treating teething pain: [1,2](#)

- Give the child a teething ring chilled in the refrigerator.
- Gently rub or massage the child's gums with your finger to relieve the symptoms of teething in children.

If these methods do not provide relief from teething pain, consumers should contact a healthcare professional to identify other treatments.

#### References

1. Markman L. Teething: facts and fiction. *Pediatr Rev.* 2009;30:e59-64.
2. American Academy of Pediatrics. Teething: 4 to 7 Months. Available at: <http://www.healthychildren.org/English/ages-stages/baby/teething-tooth-care/pages/Teething-4-to-7-Months.aspx><sup>1</sup>. Accessed on March 28, 2011.

#### List of OTC Benzocaine Products\*

Americaine	Dent's Maxi-Strength Toothache	Orajel Medicated Toothache
Americaine Hemorrhoidal	Dermoplast Antibacterial	Orajel Mouth Sore
Anbesol	Dermoplast Painrelieving	Orajel Multi-Action Cold Sore
Anbesol Baby	Detane	Orajel PM
Anbesol Cold Sore Therapy	Dry Socket Remedy	Orajel Ultra Mouth Sore
Anbesol Jr.	Exactacain	Oticaine
Anbesol Maximum Strength	Foille	Otocain
Baby Orajel	Freez Eez	Outgro
Banadyne	HDA Toothache	Red Cross Canker Sore
Benzocaine Burn Spray	Hurracaine	Rid-A-Pain Dental Drops
Benzodent	Ivy-Rid	Skeeter Stik
Boil Ease Maximum Strength	Kanka Soft Brush	Sting-Kill
Cepacol Sore Throat	Lanacane	Tanac
Cetacaine	Lanacane Maximum Strength	Thorets
Chiggerex	Mycinettes	Topicale Xtra
Chiggertox	Navogan	Trocaine
Comfort Caine	Orabase with Benzocaine	Walgreens Oral Anesthetic Paste
Dentapaine	Orajel Denture Plus	Walgreens Zilactin-B
Dent's Extra Strength Toothache	Orajel Maximum Strength	Zilactin Toothache and Gum Pain

*\*This list is not all-inclusive*

#### Related Information

- [FDA Drug Safety Communication: Reports of a rare, but serious and potentially fatal adverse effect with the use of over-the-counter \(OTC\) benzocaine gels and liquids applied to the gums or mouth](#)<sup>2</sup>

#### Links on this page:

1. <http://www.healthychildren.org/English/ages-stages/baby/teething-tooth-care/pages/Teething-4-to-7-Months.aspx>
2. </Drugs/DrugSafety/ucm250024.htm>