

Oral Over-the-Counter Benzocaine Products: Drug Safety Communication - Risk of Serious and Potentially Fatal Blood Disorder

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AUDIENCE: Pediatrics, Dentistry, Consumer, Health Professional, Pharmacy

ISSUE: The FDA is warning that over-the-counter (OTC) oral drug products containing benzocaine should not be used to treat infants and children younger than 2 years. We are also warning that benzocaine oral drug products should only be used in adults and children 2 years and older if they contain certain warnings on the drug label. These products carry serious risks and provide little to no benefits for treating oral pain, including sore gums in infants due to teething. Benzocaine, a local anesthetic, can cause a condition in which the amount of oxygen carried through the blood is greatly reduced. This condition, called methemoglobinemia, can be life-threatening and result in death. Due to the significant safety risk of methemoglobinemia, we have urged manufacturers that they should stop marketing OTC oral drug products for treating teething in infants and children younger than 2 years. If companies do not comply, we will take action to remove these products from the market.

We have also urged manufacturers of OTC oral drug products containing benzocaine for adults and children 2 years and older to make the following changes to the labels of their products:

- Adding a warning about methemoglobinemia;
- Adding contraindications, FDA's strongest warnings, directing parents and caregivers not to use the product for teething and not to use in infants and children younger than 2 years; and
- Revising the directions to direct parents and caregivers not to use the product in infants and children younger than 2 years.

BACKGROUND: Benzocaine is a local anesthetic contained in some OTC products for the temporary relief of pain due to minor irritation, soreness, or injury of the mouth and throat. Benzocaine products are marketed as gels, sprays, ointments, solutions, and lozenges under brand names such as Anbesol, Orabase, Orajel, Baby Orajel, Hurracaine, and Topex, as well as store brands and generics. Prescription local anesthetics include articaine, bupivacaine, chloroprocaine, lidocaine, mepivacaine, prilocaine, ropivacaine, and tetracaine.

RECOMMENDATION: We continue to monitor the safety and effectiveness of OTC benzocaine products and intend to take additional actions in the future as needed. We will notify the public about any updates. In addition to our recent actions regarding OTC benzocaine products, we are also requiring a standardized methemoglobinemia warning to be included in the prescribing information of all prescription local anesthetics.

Parents and caregivers should follow the [American Academy of Pediatrics' recommendations \(https://www.healthychildren.org/English/ages-stages/baby/teething-tooth-care/pages/Teething-4-to-7-Months.aspx\)](https://www.healthychildren.org/English/ages-stages/baby/teething-tooth-care/pages/Teething-4-to-7-Months.aspx) for treating teething. <http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm>

- Gently rub or massage the child's gums with one of your fingers.
- Use a firm rubber teething ring.

Topical pain relievers and medications that are rubbed on the gums are not useful because they wash out of a baby's mouth within minutes. FDA has previously cautioned parents and caregivers to **not give certain homeopathic teething tablets** (</NewsEvents/Newsroom/PressAnnouncements/ucm538684.htm>) to children. Alternative treatments for adults who experience mouth pain may include dilute salt water mouth rinse and OTC pain relief medications. Adults should follow the **American Dental Association's recommendations** (https://www.ada.org/~/media/ADA/Publications/Files/ADA_PatientSmart_Mouth_Sores.pdf) (<http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm>) for mouth sores:

- Schedule regular oral health checkups
- Keep a diary of what you eat and drink
- Keep a list of oral hygiene products you have been using
- Avoid all tobacco products
- If you drink alcoholic beverages, do so in moderation
- See your dentist if you notice any change in your mouth.

Consumers using benzocaine products to treat mouth pain should seek medical attention immediately for signs and symptoms of methemoglobinemia. These include pale, gray or blue-colored skin, lips, and nail beds; shortness of breath; fatigue; confusion; headache; lightheadedness; and fast heart rate. Signs and symptoms of methemoglobinemia may appear within minutes to one to two hours after using benzocaine. Symptoms may occur after using benzocaine for the first time, as well as after prior uses.

Health care professionals should warn patients of the possibility of methemoglobinemia and advise them of the signs and symptoms when recommending or prescribing local anesthetic products. Some patients are at greater risk for complications related to methemoglobinemia. This includes those with breathing problems such as asthma, bronchitis, or emphysema; heart disease, and the elderly. Health care professionals using local anesthetics during medical procedures should take steps to minimize the risk for methemoglobinemia. These include monitoring patients for signs and symptoms suggestive of methemoglobinemia; using co-oximetry when possible; and having resuscitation equipment and medications readily available, including methylene blue.

Healthcare professionals and patients are encouraged to report adverse events or side effects 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 (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting_home)
- **Download form** (</Safety/MedWatch/HowToReport/DownloadForms/ucm2007307.htm>) 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

[05/23/2018 - **Drug Safety Communication** (</Drugs/DrugSafety/ucm608265.htm>) - FDA]

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