U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Drug Safety Communications

FDA recommends not using lidocaine to treat teething pain and requires new *Boxed Warning*

Safety Announcement

[6-26-2014] The U.S. Food and Drug Administration (FDA) warns that prescription oral viscous lidocaine 2 percent solution should not be used to treat infants and children with teething pain. We are requiring a new *Boxed Warning*, FDA's strongest warning, to be added to the drug label to highlight this information. Oral viscous lidocaine solution is not approved to treat teething pain, and use in infants and young children can cause serious harm, including death.

Health care professionals should not prescribe or recommend this product for teething pain. Parents and caregivers should follow the American Academy of Pediatrics' recommendations for treating teething pain:[1]

- Use a teething ring chilled in the refrigerator (not frozen).
- Gently rub or massage the child's gums with your finger to relieve the symptoms.

Topical pain relievers and medications that are rubbed on the gums are not necessary or even useful because they wash out of the baby's mouth within minutes. When too much viscous lidocaine is given to infants and young children or they accidentally swallow too much, it can result in seizures, severe brain injury, and problems with the heart. Cases of overdose due to wrong dosing or accidental ingestion have resulted in infants and children being hospitalized or dying.

In 2014, FDA reviewed 22 case reports of serious adverse reactions, including deaths, in infants and young children 5 months to 3.5 years of age who were given oral viscous lidocaine 2 percent solution for the treatment of mouth pain, including teething and stomatitis, or who had accidental ingestions. In addition to the *Boxed Warning*, we are requiring revisions to the *Warnings* and *Dosage and Administration* sections of the drug label to describe the risk of severe adverse events and to include additional instructions for dosing when the drug is prescribed for approved uses.

FDA is also encouraging parents and caregivers not to use topical medications for teething pain that are available over the counter (OTC) because some of them can be harmful. We advise following the American Academy of Pediatrics' recommendations listed above to help lessen teething pain.

FDA previously communicated about safety concerns related to use of OTC topical benzocaine teething preparations. In 2011, we warned that using OTC benzocaine gels for teething or mouth pain can cause a rare but serious condition called methemoglobinemia. This condition results in a large decrease in the amount of oxygen carried through the blood. It is life-threatening and can result in death (see Drug Safety Communication on OTC benzocaine gels and liquids). FDA has continued to receive reports of methemoglobinemia in infants and children associated with OTC benzocaine gels and liquids since the 2011 warning was issued. OTC benzocaine gels and liquids are sold under different brand names such as Anbesol, Hurricaine, Orajel, Baby Orajel, Orabase, and various store brands.

Facts about prescription viscous lidocaine solution

- Should NOT be given to treat teething pain in infants and young children.
- Is NOT approved by FDA to treat teething pain.
- Is FDA-approved to numb irritated or inflamed mucous membranes of the mouth and throat, or pharynx, under the supervision of a health care professional.

Additional Information for Consumers and Parents/Caregivers

- Parents and caregivers should follow the American Academy of Pediatrics' recommendations for treating teething pain:[1]
    - Use a teething ring chilled in the refrigerator (not frozen).
    - Gently rub or massage the child's gums with your finger to relieve the symptoms.
    - Topical pain relievers and medications that are rubbed on the gums are not necessary or even useful because they wash out of the baby's mouth within minutes, and they can be harmful.
- Prescription oral viscous lidocaine solution should NOT be used to treat teething pain. This product can cause serious harm or death in infants and young children.
- In addition to causing death, problems with the heart, or severe brain injury, oral viscous lidocaine solution can cause seizures in infants and young children when too much is applied or it is accidentally swallowed. Seizures involve rapid and uncontrollable shaking of the body. If your child has a seizure after using this product, seek immediate medical attention.
- FDA previously communicated about how over-the-counter (OTC) benzocaine teething preparations can cause methemoglobinemia, a rare but serious blood condition. Methemoglobinemia may result in pale, gray- or blue-colored skin, lips, and nail beds; shortness of breath; tiredness or fatigue; confusion; headache; lightheadedness; and a fast heart rate.
- If viscous lidocaine solution or benzocaine gels and liquids are in the home, they should be stored securely and out of the reach of children to prevent accidental ingestion.
- Report side effects or medication errors to the FDA MedWatch program, using the information in the "Contact FDA" box at the bottom of the page.

Additional Information for Health Care Professionals

- Do not prescribe viscous lidocaine solution or recommend benzocaine gels and liquids to treat teething pain, due to the risk of serious harm, including seizures, methemoglobinemia, and death (see Drug Safety Communication on OTC benzocaine gels and liquids).
- Prescription viscous lidocaine solution is NOT approved by FDA to treat teething pain.
- Advise parents and caregivers to follow the American Academy of Pediatrics' recommendations for treating teething pain:[1]
    - Use a teething ring chilled in the refrigerator (not frozen).
    - Gently rub or massage the child's gums with your finger to relieve the symptoms.
    - Some medications you rub on your child's gums can be harmful if too much is used and the child swallows an excessive amount.
- Report side effects or medication errors to the FDA MedWatch program, using the information in the "Contact FDA" box at the bottom of the page.

Data Summary

FDA continues to monitor reports of toxicity with the use of prescription oral viscous lidocaine and over-the-counter (OTC) benzocaine to treat teething pain in infants and young children.

A search of FDA's Adverse Event Reporting System (FAERS) database and the medical literature through December 2013 identified 22 cases of toxicity with the use of prescription oral viscous lidocaine 2 percent solution in infants and young children 5 months to 3.5 years of age. Fifteen cases were identified in FAERS and seven additional cases were noted in the literature.[2-7]

Of the 22 cases, 6 cases resulted in death, 3 were categorized as life-threatening, 11 required hospitalization, and 2 required medical intervention without hospitalization.

The root cause of the overdose in 7 of the 22 cases was the administration technique by caregivers, who did not follow prescriber directions for application of the product or gave additional doses beyond what was prescribed. Accidental ingestion occurred in seven additional cases, and four cases involved overdose due to a prescribing error. The root cause of the error could not be identified in the remaining four cases.

The reported reasons for use of lidocaine in these 22 cases were teething pain (n=5), oral stomatitis (n=6), fever blister (n=1), thrush (n=2), oral ulcer/lesion (n=3), and sore throat due to croup (n=1). In four cases, the reason for use was not reported.

Of the 22 cases, multiple doses of lidocaine taken prior to the onset of the adverse event occurred in 11 cases. In six cases, the toxicity manifested following the accidental

ingestion of a single dose. In five cases, it was not reported whether a single dose or multiple doses were taken prior to the onset of symptoms.

Viscous lidocaine solution continues to be dispensed for infants and young children 2 years and younger (see Table). In 2012, infants and young children 2 years and younger accounted for approximately 4 percent of all patients who received dispensed prescriptions in the outpatient retail setting for oral viscous lidocaine solution. The number of patients aged 2 years and younger decreased by approximately 28 percent between 2008 and 2012 as shown in the following table:[8]

Nationally estimated number of total patients and patients aged 0-2 years receiving dispensed prescriptions for lidocaine 2 percent oral viscous products from U.S. outpatient retail pharmacies[8]

	Year 2008		Year 2009		Year 2010		Year 2011		Year 2012	
	N	%	N	%	N	%	N	%	N	%
Total Patients	901,902	100 %	953,535	100 %	1,010,243	100 %	1,009,232	100 %	899,047	100 %
0-2 years	50,970	5.7 %	46,903	4.9 %	44,385	4.4 %	40,002	4.0 %	36,557	4.1 %
Source: IMS Health, Vector One®: Total Patient Tracker (TPT). Years 2008-2012. Data extracted December 2013.										

On April 7, 2011, FDA issued a Drug Safety Communication (DSC) warning that use of OTC benzocaine gels and liquids applied to the gums or mouth to reduce pain was associated with methemoglobinemia, mainly in children aged two years and younger. Since the issuance of that DSC, FDA has received reports of 6 new cases of methemoglobinemia in infants and young children, 2 years and younger, associated with OTC benzocaine gels and liquids, bringing the total to 27 cases. Hospitalization was required in all six new methemoglobinemia cases, and three were categorized as life-threatening. No new cases were identified in the literature.

References

1. 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. Accessed on January 14, 2014.
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3. Rothstein P, Dornbusch J, Shaywitz B. Prolonged seizures associated with the use of viscous lidocaine. J Pediatr 1982;101:461-3.
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7. Mofensen H, Caraccio T. Lidocaine toxicity from topical mucosal application. Clin Pediatr (Phila) 1983;22:190-2.
8. IMS Health, Vector One®: Total Patient Tracker (TPT). Years 2008-2012. Data Extracted December 2013.