

FDA Recommends Not Using Lidocaine to Treat Teething Pain, Now Requires Box Warning

On June 26, 2014, the U.S Food and Drug Administration (FDA) released a safety announcement warning that prescription 2% oral lidocaine solution should not be used to treat teething pain in infants and children. The FDA has also decided to require a Black Boxed Warning for the product, requiring the label to include information against its use for that indication. The decision comes amidst the results of 22 case reports of serious adverse reactions, including death, in children aged 5 months to 3.5 years of age who were either prescribed lidocaine 2% solution to treat mouth pain from teething and stomatitis, or had accidental ingestions. Of the 22 cases reviewed, 6 resulted in death, 3 were classified as life-threatening, and another 11 required hospitalization. The FDA goes on to list the American Academy of Pediatrics' recommendations for treating teething pain, including a refrigerator chilled teething ring or massaging the child's gums with a finger to relieve symptoms.

Teething pain in a child can be a difficult symptom to treat, as often times the child cannot express the degree of pain they are experiencing. Clinical presentation of discomfort includes mild pain, irritation, reddening, excessive drooling, mouth biting, gum rubbing, low-grade fever, swelling, and occasional eruption cysts (3). Treatment of teething discomfort should err on the side of caution. Nonpharmacologic treatment options include the FDA recommendations listed above as well as having the child chew a cold rag, or if the child is old enough to tolerate food, they may be given food such as dry toast to chew.

Pharmacologic options include topical and systemic analgesics. Benzocaine in concentrations of 5-20% and phenol at 0.5% are generally accepted preparations. However, the FDA warns about the rare but serious condition of methemoglobinemia associated with the use of benzocaine concentrations as low as 7.5% to treat teething pain (4). Methemoglobinemia refers to the oxidation of ferrous iron (Fe^{++}) to ferric iron (Fe^{+++}) within the hemoglobin molecule (5). This reaction impairs the ability of hemoglobin to transport oxygen and carbon dioxide, leading to tissue hypoxemia and in severe cases, death. Systemic analgesic (e.g. acetaminophen, ibuprofen) can also be used to treat teething pain.

Resources:

1. FDA Drug Safety Communication: FDA recommends not using lidocaine to treat teething pain and requires new Boxed Warning. FDA. Available at: <http://www.fda.gov/Drugs/DrugSafety/ucm402240.htm>
2. Lidocaine In: Clinical Pharmacology [Internet database] Gold Standard, Inc., 2007. Available at <http://www.clinicalpharmacology.com>. Accessed September 5, 2014.
3. Albanese NP. Oral Pain and Discomfort In: Krinsky DL, et al. Handbook of Nonprescription Drugs: An interactive approach to self-care (17th Ed.); Washington, D.C.: American Pharmacists Association; 2012 p. 592-593

4. 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. FDA. Available at:
<http://www.fda.gov/Drugs/DrugSafety/ucm250024.htm>
5. Shamriz O, Cohen-Glickman I, Reif S, Shteyer E. Methemoglobinemia induced by lidocaine-prilocaine cream. Isr Med Assoc J. 2014 Apr;16(4):250-4. Review. PubMed PMID: 24834764.

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