



California Drug Safety Notification



Notification Name

U. S. FDA Warns Prescription Oral Lidocaine Should Not Be Used for Teething Pain

Notification Date	Notification Warning	Notification Reason
06/26/14	<p>The U.S. Food and Drug Administration (FDA) is warning health care professionals and caregivers for infants that prescription oral viscous lidocaine should not be used to treat children and infants with teething pain.</p> <p>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:</p> <ul style="list-style-type: none"> • 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. 	<p><i>In 2014, FDA reviewed 22 case reports of serious adverse reactions, <u>including deaths</u>, 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.</i></p> <p><i>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.</i></p> <p><i>Oral viscous lidocaine solution is not approved to treat teething pain and use in young children can cause serious harm, including death.</i></p>

FOR ADDITIONAL INFORMATION, PLEASE VISIT:

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm402790.htm>