



**Lidocaine Viscous: Drug Safety Communication - Boxed Warning Required –  
Should Not Be Used to Treat Teething Pain**

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FDA 提醒：口服 viscous lidocaine 2% 溶液不應用於治療嬰幼兒牙痛。FDA 要求仿單新增此警示。口服 viscous lidocaine 溶液未被核准用於牙痛，嬰幼兒使用可能造成嚴重傷害甚至死亡。不應將外用止痛藥物擦在牙齦上，即使有效也沒有必要，因為藥物在幼兒口內數分鐘就會洗掉。若嬰幼兒不小心吞下過多 viscous lidocaine，可能導致癲癇或重度腦損傷，及心臟問題。使用過量、劑量錯誤、誤服的案例已經導致嬰幼兒住院或死亡。

**建議**

醫療人員不應處方或建議該品項治療牙痛。父母和照護者應遵循小兒科的建議。

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**AUDIENCE:** Consumer, Pediatrics, Family Practice

**ISSUE:** FDA notified health professionals, their provider organizations and caregivers for infants, that prescription oral viscous lidocaine 2% solution should not be used to treat infants and children with teething pain. FDA is requiring a Boxed Warning to be added to the prescribing information (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.

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.

**BACKGROUND:** 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. See further details in the FDA Drug Safety Communication.

**RECOMMENDATION:** 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.