



FDA Drug Safety Communication: FDA evaluating the risks of using the pain medicine tramadol in children aged 17 and younger

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因進行扁桃腺切除手術後服用止痛藥物 tramadol，可能使 17 歲以下孩童呼吸困難的嚴重副作用發生率提高，FDA 正在調查 17 歲以下孩童 tramadol 服藥情形，待評估所有資訊後，FDA 會整合出結論與建議並進行公告。目前 FDA 尚未核准 tramadol 用於 17 歲以下孩童，但統計資料顯示 tramadol 被以“off-label”的方式使用於兒童族群，醫療人員應處方 FDA 核准用於孩童的止痛藥物供孩童使用。

建議

FDA 建議，家中若有孩童正在服用 tramadol，家長與照顧者應留意孩童是否出現呼吸緩慢、微弱、呼吸困難或不尋常的嗜睡等症狀，如果出現相關症狀必須停用 tramadol 並馬上就醫。家長與照顧者如果對 tramadol 或其他止痛藥物有任何疑慮應與醫療人員討論。

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AUDIENCE: Health Professionals

ISSUE: FDA is investigating the use of the pain medicine tramadol in children aged 17 years and younger, because of the rare but serious risk of slowed or difficult breathing. This risk may be increased in children treated with tramadol for pain after surgery to remove their tonsils and/or adenoids. FDA is evaluating all available information and will communicate final conclusions and recommendations to the public when the review is complete.

Tramadol is not FDA-approved for use in children; however, data show it is being used “off-label” in the pediatric population. Health care professionals should be aware of this and consider prescribing alternative FDA-approved pain medicines for children.

BACKGROUND: In the body, tramadol is converted in the liver to the active form of the opioid, called O-desmethyltramadol. Some people have genetic variations that cause tramadol to be converted to the active form of the opioid faster and more completely than usual. These people, called ultra-rapid metabolizers, are more likely to have higher-than-normal amounts of the active form of the opioid in their blood after taking tramadol, which can result in breathing difficulty that may lead to death. Recently, a 5-year-old child in France experienced severely slowed and difficult breathing requiring emergency intervention and hospitalization after taking a single prescribed dose of tramadol oral solution for pain relief following surgery to remove his tonsils and adenoids. The child was later found to be an ultra-rapid metabolizer and had high levels of O-desmethyltramadol in his body.

RECOMMENDATION: Parents and caregivers of children taking tramadol who notice any signs of slow or shallow breathing, difficult or noisy breathing, confusion, or unusual sleepiness should stop tramadol and seek medical attention immediately by taking their child to the emergency room or calling 911. Parents and caregivers should talk with their child’s health care professional if they have any questions or concerns about tramadol or other pain medicines their child is taking.