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

Drug Safety Communications

FDA evaluating the risks of using the pain medicine tramadol in children aged 17 and younger

Safety Announcement

[9-21-2015] The U.S. Food and Drug Administration (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. We are evaluating all available information and will communicate our final conclusions and recommendations to the public when our 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.

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.

Treating pain in children is important because it can lead to faster recoveries and fewer complications. Untreated pain can potentially result in long-term physical and psychological consequences. There are other pain medicines available that do not have this side effect of slowed or difficult breathing associated with tramadol and are FDA-approved for use in children.

Tramadol is a specific type of narcotic medicine called an opioid that is approved to treat moderate to moderately severe pain in adults. It is available under the brand names Ultram, Ultram ER, Conzip, and also as generics. Tramadol is also available in combination with the pain reliever acetaminophen under the brand name Ultracet and as generics.

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.[1] The child was later found to be an ultra-rapid metabolizer and had high levels of O-desmethyltramadol in his body.

We urge health care professionals, parents, and caregivers to report side effects involving tramadol to the FDA MedWatch program, using the information in the "Contact FDA" box at the bottom of the page.

References

1. Orliaguet G, Hamza J, Couloigner V, Denoyelle F, Loriot MA, Broly F, Garabedian EN. A case of respiratory depression in a child with ultrarapid CYP2D6 metabolism after tramadol. Pediatrics 2015;135:e753-5.