

May 30, 2017



**Drug Safety Communication: Risks of Codeine and Tramadol Use in Children**

Codeine is approved to treat pain and cough, and tramadol is approved to treat pain. These medicines carry serious risks, including slowed or difficult breathing and death, which appear to be a greater risk in children younger than 12 years of age.

On April 20, 2017, the United States Food and Drug Administration (FDA) announced they are restricting the use of codeine and tramadol medicines in children. They are also recommending against the use of codeine and tramadol medicines in breastfeeding mothers due to possible harm to their infants.

Health care providers should be aware that tramadol and single-ingredient codeine medicines are FDA-approved only for use in adults. Over-the-counter (OTC) or other FDA-approved prescription medicines should be considered for pain management in children younger than 12 years of age and in adolescents younger than 18 years of age, especially those with certain genetic factors, obesity, or obstructive sleep apnea and other breathing problems.

Cough is often secondary to infection, not serious, and usually will get better on its own, so treatment may not be necessary. OTC cough and cold medications should not be used in children under 2 years of age because of the risk of serious, life-threatening adverse events.

To read the full MedWatch safety alert, refer to the “FDA Drug Safety Communication: FDA restricts use of prescription codeine pain and cough medicines and tramadol pain medicines in children; recommends against use in breastfeeding women” article found on the [Drug Safety and Availability](#) Web page of the FDA website.