

April 20, 2017

FDA RESTRICTS USE OF CODEINE AND TRAMADOL MEDICINES IN CHILDREN, RECOMMENDS AGAINST USE IN BREASTFEEDING MOTHERS

The Issue:

The Food and Drug Administration (FDA) today [announced](#) that it is restricting the use of codeine and tramadol medicines in children, as well as recommending against using codeine and tramadol medicines in breastfeeding mothers due to possible harm to their infants.

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, and should not be used in these children. These medicines also should be limited in some older children.

The FDA is requiring several changes to the labels of all prescription medicines containing these drugs. These new actions further limit the use of these medicines beyond FDA's 2013 restriction of codeine use in children younger than 18 years to treat pain after surgery to remove the tonsils and/or adenoids. The agency is now adding:

- FDA's strongest warning, called a *Contraindication*, to the drug labels of codeine and tramadol alerting that codeine should not be used to treat pain or cough and tramadol should not be used to treat pain in children younger than 12 years.
- A new *Contraindication* to the tramadol label warning against its use in children younger than 18 years to treat pain after surgery to remove the tonsils and/or adenoids.
- A new *Warning* to the drug labels of codeine and tramadol to recommend against their use in adolescents between 12 and 18 years who are obese or have conditions such as obstructive sleep apnea or severe lung disease, which may increase the risk of serious breathing problems.
- A strengthened *Warning* to mothers that breastfeeding is not recommended when taking codeine or tramadol medicines due to the risk of serious adverse reactions in breastfed infants. These can include excess

sleepiness, difficulty breastfeeding or serious breathing problems that could result in death.

The FDA is urging health care professionals and patients to report side effects involving codeine-and tramadol-containing medicines to the FDA MedWatch program, through its [online form](#).

What You Can Do:

Please share this advisory with medical and nursing staff leadership, pediatrics, obstetrics, emergency department, family medicine, surgery, pharmacy and risk management.

Further Questions:

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