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Public Health Advisory: Use of Codeine By Some Breastfeeding Mothers May Lead To Life-Threatening Side Effects In Nursing Babies

8/17/2007

FDA has important new information about a very rare, but serious, side effect in nursing infants whose mothers are taking codeine. Differences in drug metabolism among mothers taking codeine may contribute to side effects in nursing infants.

Infants of nursing mothers taking codeine may have an increased risk of morphine overdose if the mother is an ultra-rapid metabolizer of codeine. When codeine enters the body and is metabolized, it changes to morphine, which relieves pain. Many factors affect codeine metabolism, including a person's genetic make-up. Some people have a variation in a liver enzyme and may change codeine to morphine more rapidly and completely than other people. These people are ultra-rapid metabolizers and are more likely to have higher than normal levels of morphine in their blood after taking codeine. Nursing mothers taking codeine may also have higher morphine levels in their breast milk. These higher levels of morphine in breast milk may lead to life-threatening or fatal side effects in nursing babies. In most cases, it is unknown if someone is an ultra-rapid codeine metabolizer.

Codeine has been used safely for many years in nursing mothers. Codeine is an ingredient in many prescription pain relievers and some over-the-counter cough syrups.

Once the body changes codeine to morphine, the morphine relieves the pain or cough and may also be responsible for any side effects people may experience. Infants exposed to very high levels of morphine through breast milk can get a morphine overdose as described below.

Last year, a medical journal described a healthy 13-day-old breastfed baby who died from a morphine overdose. The mother was taking less than the usual amount of codeine normally prescribed for episiotomy pain (Koren, et al, Lancet, vol 368 p. 704, Aug 2006). Laboratory tests showed high levels of morphine in the baby's blood, and genetic testing showed that the baby's mother was an ultra-rapid metabolizer of codeine.

FDA is issuing this public health advisory to inform healthcare professionals and nursing mothers about the following important safety information:

- **When prescribing codeine for a nursing mother**, doctors should prescribe the lowest dose for the shortest amount of time to relieve pain or cough. Doctors need to tell their nursing patients how to recognize signs of high morphine levels in themselves and their babies.
- **If you are a nursing mother taking codeine**, call your doctor if you become extremely sleepy and have trouble caring for your baby.
- **Breastfed babies usually nurse every two to three hours and should not sleep more than four hours at a time.** If your baby shows signs of increased sleepiness (more than usual), difficulty breastfeeding, breathing difficulties, or limpness, talk to the baby's doctor immediately. If you cannot reach the doctor right away, take the baby to an emergency room or call 911 (or local emergency services).
- **Nursing mothers should talk to their doctors** if they have any questions about taking codeine.

The estimated number of ultra-rapid metabolizers varies among different population groups from less than 1 per 100 people up to 28 per 100 people. For people who are ultra-rapid metabolizers, the risk of having an adverse event when taking codeine is not known.

Anyone can be an ultra-rapid metabolizer without knowing it. The only way to find out is with a genetic test. There is a FDA-cleared test to determine whether a patient is an ultra-rapid metabolizer, but there is limited information about using this test for codeine metabolism. At this time, the test result alone may not correctly predict if a mother's breast milk will have too much morphine if she uses codeine to treat pain. This test isn't

a substitute for a doctor's judgment.

Among pain relievers, ultra-rapid metabolism has only been reported as a problem with codeine, although it has the potential to affect other narcotics. All narcotics can cause the same serious side effects in breastfed babies if the levels of drug in breast milk are too high.

FDA has asked the makers of prescription codeine-containing products to include information about differences in codeine metabolism and concerns with breastfeeding in the drug label. Use of codeine products to manage pain after birth is common, but reports of serious side effects in nursing infants are very rare. Doctors who prescribe codeine need to be aware of the potential for the increased risks to breastfeeding babies of mothers who are ultra-rapid metabolizers of codeine.

The FDA urges healthcare providers and nursing mothers to report side effects that occur while using codeine to the FDA's MedWatch Adverse Event Reporting program

Related Information

- [Codeine Side-Effects in Nursing Infants - Overview](#)¹ [ARCHIVED]
Podcast - August 17, 2007
- [Codeine Side-Effects in Nursing Infants - Full Version](#)² [ARCHIVED]
Podcast - August 17, 2007

Contact FDA

1-800-332-1088

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Regular Mail: Use postage-paid [FDA Form 3500](#)⁴

Mail to: MedWatch 5600 Fishers Lane
Rockville, MD 20857

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