



## SAFETY OF PRESCRIPTION AND OTC PAIN MEDICATIONS DURING PREGNANCY

This special issue of *New Drug FAX Sheet* provides information from the FDA regarding concerns over the safety of prescription and OTC pain medications use during pregnancy. Limited information suggests that health care professionals should evaluate the risk:benefit profile to pregnant patients before administering these agents. If you need further information please contact the Samford University Global Drug Information Service at (205) 726-2659.

**AUDIENCE:** OBGYN, Consumer

**ISSUE:** FDA is aware of and understands the concerns arising from recent reports questioning the safety of prescription and over-the-counter (OTC) pain medicines when used during pregnancy. As a result, FDA evaluated research studies published in the medical literature and determined they are too limited to make any recommendations based on these studies at this time. Because of this uncertainty, the use of pain medicines during pregnancy should be carefully considered. FDA urges pregnant women to always discuss all medicines with their health care professionals before using them.

Severe and persistent pain that is not effectively treated during pregnancy can result in depression, anxiety, and high blood pressure in the mother. Medicines including nonsteroidal anti-inflammatory drugs (NSAIDs), opioids, and acetaminophen can help treat severe and persistent pain. However, it is important to carefully weigh the benefits and risks of using prescription and OTC pain medicines during pregnancy.

**BACKGROUND:** The published studies FDA reviewed reported on the potential risks associated with the following three types of pain medicines used during pregnancy. See the [FDA Drug Safety Communication](#) Data Summary section for more information about these studies.

**RECOMMENDATION:** Healthcare professionals should talk with each patient about the benefits and risks of analgesic use during pregnancy, which may differ among patients and by treatment indication. Continue to follow the existing recommendations in current drug labels regarding the use of analgesics during pregnancy.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: [www.fda.gov/MedWatch/report.htm](http://www.fda.gov/MedWatch/report.htm)
- [Download form](#) or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

Read the MedWatch safety alert, including a link to the FDA Drug Safety Communication, at:

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm429604.htm>