

Nonsteroidal Anti-Inflammatory Drugs (NSAIDs): Drug Safety Communication - Avoid Use of NSAIDs in Pregnancy at 20 Weeks or Later

AUDIENCE: Consumer, Patient, Health Professional, Pharmacy

ISSUE: FDA is warning that use of NSAIDs around 20 weeks or later in pregnancy may cause rare but serious kidney problems in an unborn baby. This can lead to low levels of amniotic fluid surrounding the baby and possible complications.

For prescription NSAIDs, FDA is requiring changes to the prescribing information to describe the risk of kidney problems in unborn babies that result in low amniotic fluid.

For over-the-counter (OTC) NSAIDs intended for use in adults, FDA will also update the Drug Facts labels (<https://www.fda.gov/drugs/drug-information-consumers/otc-drug-facts-label>). These labels already warn to avoid using NSAIDs during the last 3 months of pregnancy because the medicines may cause problems in the unborn child or complications during delivery. The Drug Facts labels already advise pregnant and breastfeeding women to ask a health care professional before using these medicines.

BACKGROUND:

NSAIDs

- are a class of medicines available by prescription and

OTC. They are some of the most commonly used medicines for pain and fever.

- are used to treat medical conditions such as arthritis, menstrual cramps, headaches, colds, and the flu.
- work by blocking the production of certain chemicals in the body that cause inflammation.
- are available alone and combined with other medicines. Examples of NSAIDs include aspirin, ibuprofen, naproxen, diclofenac, and celecoxib.

Common side effects of NSAIDs include: stomach pain, constipation, diarrhea, gas, heartburn, nausea, vomiting, and dizziness.

RECOMMENDATION:

Consumers/Patients

- If you are pregnant, do not use NSAIDs at 20 weeks or later in pregnancy unless specifically advised to do so by your health care professional because these medicines may cause problems in your unborn baby.
- Many OTC medicines contain NSAIDs, including those used for pain, colds, flu, and insomnia, so it is important to read the Drug Facts labels (<https://www.fda.gov/drugs/drug-information-consumers/otc-drug-facts-label>) to find out if the medicines contain NSAIDs.
- Talk to your health care professional or pharmacist if you have questions or concerns about NSAIDs or which medicines contain them.
- Other medicines, such as acetaminophen, are available to treat pain and fever during pregnancy. Talk to your pharmacist or health care professional for help

deciding which might be best.

Health Care Professionals

- FDA recommends that health care professionals should limit prescribing NSAIDs between 20 to 30 weeks of pregnancy and avoid prescribing them after 30 weeks of pregnancy. If NSAID treatment is determined necessary, limit use to the lowest effective dose and shortest duration possible. Consider ultrasound monitoring of amniotic fluid if NSAID treatment extends beyond 48 hours and discontinue the NSAID if oligohydramnios is found. FDA is warning that use of NSAIDs around 20 weeks gestation or later in pregnancy may cause fetal renal dysfunction leading to oligohydramnios and, in some cases, neonatal renal impairment.
- These adverse outcomes are seen, on average, after days to weeks of treatment, although oligohydramnios has been infrequently reported as soon as 48 hours after NSAID initiation.
- Oligohydramnios is often, but not always, reversible with treatment discontinuation.
- Complications of prolonged oligohydramnios may include limb contractures and delayed lung maturation. In some postmarketing cases of impaired neonatal renal function, invasive procedures such as exchange transfusion or dialysis were required.
- If NSAID treatment is deemed necessary between 20 to 30 weeks of pregnancy, limit use to the lowest effective dose and shortest duration possible. As currently described in the NSAID labels, avoid prescribing NSAIDs at 30 weeks and later in pregnancy because of the additional risk of premature closure of the fetal ductus arteriosus.

- The above recommendations do not apply to low-dose 81 mg aspirin prescribed for certain conditions in pregnancy.
- Consider ultrasound monitoring of amniotic fluid if NSAID treatment extends beyond 48 hours. Discontinue the NSAID if oligohydramnios occurs and follow up according to clinical practice.

Consumers, patients and health care professionals 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 (<https://www.accessdata.fda.gov/scripts/medwatch/index.cfm>).
- Download form (<https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda>) or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the form, or submit by fax to 1-800-FDA-0178.

[10/15/2020] - Drug Safety Communication (<https://www.fda.gov/drugs/drug-safety-and-availability/fda-recommends-avoiding-use-nsaids-pregnancy-20-weeks-or-later-because-they-can-result-low-amniotic>) - FDA]