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IN BRIEF

New Warnings on NSAID Use in Pregnancy

The FDA has required a new warning in the labels of prescription and over-the-counter products containing nonsteroidal anti-inflammatory drugs (NSAIDs) advising against their use during pregnancy beginning at 20 weeks' gestation because of a risk of renal dysfunction in the fetus that could lead to low amniotic fluid levels (oligohydramnios) and neonatal renal impairment.¹ NSAID labels previously warned against use of the drugs beginning at 30 weeks' gestation because of a risk for premature closure of the ductus arteriosus and persistent neonatal pulmonary hypertension.

Beginning at ~20 weeks' gestation, most amniotic fluid is produced by the fetal kidneys. NSAIDs inhibit renal prostaglandins and decrease renal blood flow. Maternal NSAID use can cause fetal renal dysfunction and a decrease in amniotic fluid production, which can impair pulmonary, digestive, and muscular development and lead to malformations, growth restriction, and preterm birth.²

An FDA review found that most published oligohydramnios cases associated with NSAID use occurred during the third trimester after several days to weeks of treatment, but some appear to have occurred as early as 20 weeks' gestation and after

as little as 48 hours of treatment. Oligohydramnios was usually reversible within 3-6 days after NSAID discontinuation. Among the cases identified by the review were 20 published reports of neonatal renal dysfunction following *in utero* NSAID exposure and 35 instances of serious oligohydramnios or neonatal renal dysfunction associated with maternal NSAID use that were reported to the FDA Adverse Event Reporting System (AERS). Neonatal death resulting from renal failure or dialysis complications occurred in 8 of the published cases.¹

Except for ophthalmic formulations and low-dose aspirin (81 mg/day), NSAIDs should not be taken during pregnancy after 30 weeks' gestation, and they should be avoided if possible between 20 and 30 weeks. If an NSAID must be used after 20 weeks' gestation, it should be taken at the lowest effective dose for the shortest possible duration. Ultrasound monitoring of the amniotic fluid should be considered if NSAID use for >48 hours is necessary. ■

1. FDA drug safety communication: FDA recommends avoiding use of NSAIDs in pregnancy at 20 weeks or later because they can result in low amniotic fluid. October 15, 2020. Available at: <https://bit.ly/31npNbS>. Accessed October 22, 2020.
2. LN Petrozella et al. Clinical significance of borderline amniotic fluid index and oligohydramnios in preterm pregnancy. *Obstet Gynecol* 2011; 117:338.

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