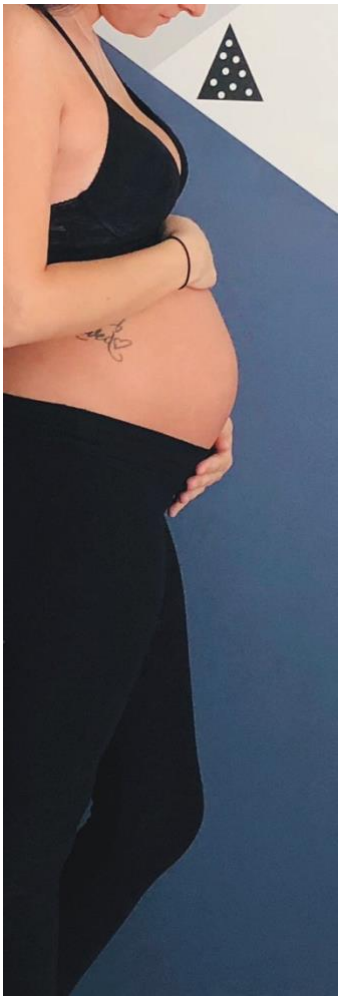
Indian Health Service
National Pharmacy and Therapeutics Committee

Pharmacovigilance Drug Safety Communication

NSAID Use During Pregnancy May Cause Fetal Renal Dysfunction Resulting in Low Amniotic Fluid

The FDA has issued a Drug Safety Communication (DSC) to alert clinicians about risks of NSAID use in pregnant women. The use of nonsteroidal anti-inflammatory drugs (NSAIDs) around 20 weeks or later in pregnancy may cause rare but serious kidney problems in an unborn baby.



After around 20 weeks of pregnancy, the unborn babies' kidneys produce most of the amniotic fluid. Amniotic fluid provides a protective cushion and helps the unborn babies' lungs, digestive system, and muscles develop. Kidney problems can lead to oligohydramnios (low levels of this amniotic fluid surrounding the baby).

Complications of prolonged oligohydramnios may include limb contractures and delayed lung maturation.

Oligohydramnios is often, but not always, reversible with treatment discontinuation. In some post marketing cases of impaired neonatal renal function, invasive procedures such as exchange transfusion or dialysis were required.

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.

FDA recommends that health care professionals 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 (e.g., the use of 81 mg aspirin for certain pregnancy-related conditions), 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.

The complete Drug Safety Communication can be viewed on the FDA website.

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To help the FDA track safety issues with medicines, please report adverse events involving NSAIDS or other medicines to the MedWatch program as recommended in the Indian Health Manual. Instructions for reporting can be found online at the NPTC Pharmacovigilance website.

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