

Consumer Update

Nov 2021

NSAID and the risk of oligohydramnios in the second trimester

EDA performs label update to include the following:

Warning and precautions

Oligohydramnios and Neonatal Renal Impairment

Use of NSAIDs from about 20 weeks' gestation may cause foetal 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.

Background

Oligohydramnios/Neonatal Renal Impairment Use of NSAIDs, , at about 20 weeks' gestation or later in pregnancy may cause fetal renal dysfunction leading to oligohydramnios and, in some cases, neonatal renal impairment.

Oligohydramnios/Neonatal Renal Impairment: Published studies and postmarketing reports describe maternal NSAID use at about 20 weeks' gestation or later in pregnancy associated with fetal renal dysfunction leading to oligohydramnios, and in some cases, neonatal renal impairment.

References: FDA (Click here)