

SFDA Safety Communication

[24/02/2021]

The SFDA Advises to Avoid Using NSAIDs in Pregnancy at 20 Weeks or Later

The Saudi Food & Drug Authority (SFDA) advises health care providers to avoid using of Nonsteroidal Anti-Inflammatory Drugs (NSAIDs) in pregnancy at 20 weeks or later due to risk of rare but serious fetal renal dysfunction, which may result in low levels of the amniotic fluid surrounding the baby and possible complications.

NSAIDs are commonly used to treat pain and fever from different medical conditions such as arthritis and headaches. They include medicines such as ibuprofen, naproxen, diclofenac aspirin and celecoxib.

The low amniotic fluid levels with use of NSAIDs are identified, on average, after days to weeks of treatment, although oligohydramnios has been infrequently reported as soon as 48 hours after NSAID initiation.

Advice for healthcare providers:

- SFDA advises Healthcare professionals to limit prescribing NSAIDs between 20 to 30 weeks of pregnancy unless necessary with limit use to the lowest effective dose and shortest duration possible.

- Avoid prescribing NSAIDs after 30 weeks of pregnancy.
- Consider ultrasound monitoring the amniotic fluid if NSAIDs treatment extends beyond 48 hours and discontinue if oligohydramnios is found.
- The above recommendations do not apply to low-dose 81 mg aspirin prescribed for certain conditions in pregnancy.
- Instruct your pregnant patients to read the Patient Leaflet before using over the counter drugs to ensure that it does not contain NSAIDs, and to ask the pharmacist if she is unsure.

Call for reporting:

The SFDA urges both healthcare professionals and patients to report ADRs related to use of any medication to the SFDA using the following contact information:

The National Pharmacovigilance Centre (NPC):

Fax: +966-11-205-7662

SFDA Call Center: 19999

E-mail: npc.drug@sfda.gov.sa

Website: <https://ade.sfda.gov.sa>