

October 19, 2020

COM-2020-083

DRUG SAFETY NOTIFICATION



DATE: October 15, 2020

DRUG NAME: Non-steroidal Anti-Inflammatory Drugs (NSAIDs)

SAFETY TOPIC: Use of NSAIDs during pregnancy

Dear provider of pharmaceutical services,

PharmPix is committed to our member's health and wellness. The clinical team wants to communicate you with the latest up-to-date information on drug safety. For this reason, we notify you that the U.S. Food and Drug Administration (FDA) issued a warning to avoid the use of Non-steroidal Anti-inflammatory Drugs (NSAIDs) during pregnancy at 20 weeks or later. The use of NSAIDs around 20 weeks or later in pregnancy may cause serious kidney problems in the fetus, low levels of amniotic fluids, and other complications. Previously NSAIDs labels warned to avoid use during the last three (3) months of pregnancy due to the risk of premature closure of the fetal ductus arteriosus. The FDA now requires changes in the prescribing information for both prescription and over the counter (OTC) NSAIDs.

Recommendations for healthcare professionals:

- Advise pregnant women to avoid the use of NSAIDs at 20 weeks of pregnancy or later.
- If NSAIDs are necessary during 20 to 30 weeks of pregnancy, limit treatment to the lowest dose possible and for the shortest duration. Consider ultrasound monitoring of amniotic fluid if treatment extends over 48 hours. If low levels of amniotic fluid are identified, discontinue the NSAID.
- These recommendations do not apply to low dose 81mg aspirin prescribed for certain conditions in pregnancy.
- Report adverse events or side effects at [MedWatch: The FDA Safety Information and Adverse Event Reporting Program](#) by any of the following ways:
 - Complete and submit the [MedWatch Online Voluntary Reporting Form](#) online.
 - [Download](#) FDA Form 3500 or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

Additional information can be found at [MedWatch: The FDA Safety Information and Adverse Event Reporting Program](#) and [FDA's Drug Safety and Availability portal](#).

If you have any questions or wish to have more information regarding this document, you can call us at 787-522-5252, extension 137. In addition, know that you can access our recent communications at our providers' portal: <https://www.pharmpix.com/providers/>.

Regards,

PharmPix Clinical Department

Reference:

- Non-steroidal Anti-inflammatory Drugs (NSAIDs): Drug Safety Communication- Avoid use of NSAIDs in Pregnancy at 20 weeks or later. (2020). Retrieved on October 16, 2020 from https://www.fda.gov/safety/medical-product-safety-information/nonsteroidal-anti-inflammatory-drugs-nsaids-drug-safety-communication-avoid-use-nsaids-pregnancy-20?utm_medium=email&utm_source=govdelivery