

Nonsteroidal Anti-Inflammatory Drugs (NSAIDs) – Safety update

- On October 15, 2020, the [FDA announced](#) the requirement of safety related changes to drug labels for both prescription and over-the-counter (OTC) NSAIDs stating that use during pregnancy may cause rare but serious kidney problems in an unborn baby. Use of NSAIDs during pregnancy can cause low levels of amniotic fluid surrounding the baby and possible complications.
 - This issue does not affect NSAIDs administered directly to the eye.
- NSAIDs are commonly used to relieve pain and reduce fevers. They include medicines such as aspirin, ibuprofen, naproxen, diclofenac, and celecoxib.
- Although this safety concern is well known among certain medical specialties, the FDA wants to communicate their recommendations more widely to educate other health care professionals and pregnant women.
- For prescription NSAIDs, the label updates will describe the risk of kidney problems in unborn babies that result in low amniotic fluid.
 - NSAIDs should be avoided in pregnant women at 20 weeks or later in pregnancy rather than the 30 weeks currently described in NSAID prescribing information.
 - At around 30 weeks, NSAIDs can cause a problem that may result in heart issues in the unborn baby. If deemed necessary by a health care professional, use of NSAIDs between 20 and 30 weeks of pregnancy should be limited to the lowest effective dose for the shortest duration.
 - The label updates will also indicate that health care professionals should consider ultrasound monitoring of amniotic fluid if NSAID treatment extends beyond 48 hours.
- For OTC NSAIDs, the Drug Facts labels will be updated. The existing labels already warn about NSAID use during pregnancy and advise pregnant and breastfeeding women to ask a health care professional before using these medicines.
- Pregnant women are advised to:
 - Not use NSAIDs at 20 weeks or later unless specifically advised to do so by a health care professional.
 - Read the Drug Facts labels of OTC medicines to find out if it contains NSAIDs.
 - Ask a health care provider if they are unsure if a medicine contains NSAIDs.
 - Discuss the benefits and risks of NSAIDs during pregnancy before use.
- Health care providers are advised to:
 - 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, 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.
- One exception to the above recommendations is the use of the low 81 mg dose of the NSAID aspirin for certain pregnancy-related conditions at any point in pregnancy under the direction of a health care professional.

- The safety update is based on the FDA's review of the medical literature and cases reported to the FDA.



OptumRx® specializes in the delivery, clinical management and affordability of prescription medications and consumer health products. We are an Optum® company — a leading provider of integrated health services. Learn more at [optum.com](https://www.optum.com).

All Optum® trademarks and logos are owned by Optum, Inc. All other brand or product names are trademarks or registered marks of their respective owners.

This document contains information that is considered proprietary to OptumRx and should not be reproduced without the express written consent of OptumRx.

RxNews® is published by the OptumRx Clinical Services Department.

©2020 Optum, Inc. All rights reserved.