



Advisory

Labelling update regarding the use of non-steroidal anti-inflammatory drugs (NSAIDs) beyond 20 weeks of pregnancy and risk of kidney damage to unborn babies leading to low amniotic fluid

Tweet: #HealthCanada advises pregnant women not use NSAIDs from 20 to 28 weeks of pregnancy, unless advised by a healthcare professional, due to risk of kidney damage and low amniotic fluid. [\[LINK to PA\]](#)

June 8, 2021
For immediate release

Summary

Products: Prescription and non-prescription non-steroidal anti-inflammatory drugs (NSAIDs)

Issue: The use of non-steroid anti-inflammatory drugs (NSAIDs), starting from approximately 20 weeks of pregnancy or later, may cause rare but serious kidney problems in an unborn baby. This can lead to low levels of amniotic fluid and possible complications.

What to do: Do not use NSAIDs from approximately 20 to 28 weeks of pregnancy, unless advised to do so by your healthcare professional. The use of NSAIDs remains contraindicated (must not be used) in the last trimester of pregnancy (i.e., beyond 28 weeks to the end of pregnancy).

Issue

Health Canada has completed a safety review confirming that the use of non-steroid anti-inflammatory drugs (NSAIDs)—such as acetylsalicylic acid (aspirin), ibuprofen, naproxen, diclofenac and celecoxib—starting from approximately 20 weeks of pregnancy or later, may cause rare but serious kidney problems in an unborn baby. This can lead to low levels of amniotic fluid and possible complications, such as impaired lung maturation and loss of joint movement (limb contractures) in the newborn baby.

As a result of its findings, Health Canada is advising that pregnant women not use NSAIDs from approximately 20 to 28 weeks of pregnancy, unless advised to do so by their healthcare professional. Prescription and non-prescription NSAID product labels will be updated with this new information.

If a healthcare professional decides that the use of NSAIDs between 20 and 28 weeks of pregnancy is necessary, Health Canada recommends that they use the lowest effective dose for the shortest duration possible, and that they consider monitoring amniotic fluid levels via ultrasound if treatment extends beyond 48 hours. These recommendations do not apply to the use of low-dose (81 mg) aspirin, pediatric-only formulations (i.e., those only indicated for children less than 12 years of age) or NSAIDs administered directly to the eye.

Health Canada continues to monitor the situation closely and will take further action to help protect the health and safety of Canadians, if necessary. This includes continuing to work with Canadian manufacturers of NSAID products to take appropriate action in Canada in light of this new evidence.

What consumers should do

- Do not use NSAIDs starting from around 20 to 28 weeks of pregnancy, unless advised to do so by your healthcare professional.
- The use of NSAIDs remains contraindicated (must not be used) in the last trimester of pregnancy (i.e., beyond 28 weeks to the end of pregnancy).





Health Canada Santé Canada

- Consult your healthcare professional if you are pregnant and have used NSAIDs and have health concerns.
- Report any health product [side effects](#) or [complaints](#) to Health Canada.

Related Links

- [Recalls and safety alerts](#)
- [October 30, 2020: Use of Non-Steroidal Anti-Inflammatory Drugs \(NSAIDs\) beyond 20 weeks of pregnancy and risk of kidney damage in unborn babies, leading to low amniotic fluid](#)

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