

Put FDA's New Acetaminophen Pregnancy Warning in Perspective

Clinicians are asking **how to answer questions about whether acetaminophen use during pregnancy increases the risk of autism in kids.**

Parents are concerned about FDA's recent announcement that acetaminophen's labeling will soon say its use in pregnancy is associated with increased risk of pediatric neurological issues...autism, ADHD, etc.

But know that this change isn't based on new, groundbreaking data.

Explain that some past studies suggest a very small association of these conditions with chronic acetaminophen use (over 1 month, etc)...but NOT with short-term prn admin.

Clarify that results are conflicting...some studies found NO link with ANY duration. And most of the concerning data are from animals or observational studies that only show an association...NOT causation.

Plus these studies have a higher risk of bias and confounding. For example, many relied on moms to recall acetaminophen use from months ago.

Emphasize that there is NO evidence that taking acetaminophen during lactation increases these neurological risks. Similarly, several studies failed to show a link in young kids given acetaminophen after delivery.

Reassure expectant mothers that these warnings don't change our current approach in pregnancy: acetaminophen should only be used when needed...at the lowest dose and shortest duration necessary.

Point out that FDA's statement even says acetaminophen is still the safest analgesic in pregnancy when one is needed.

For example, we know oral and topical NSAIDs are generally NOT alternatives due to their fetal risks...miscarriage, kidney defects, premature ductus arteriosus closure, etc.

Continue to use a stepwise pain management approach in pregnancy, when possible...to minimize systemic exposure to meds and fetal risks.

Recommend nondrug measures first, such as hot or cold packs, physical therapy, stretching, etc.

As a next step, consider OTC topicals with menthol and/or lidocaine. But avoid topical salicylates due to their absorption and fetal risks.

Then advise acetaminophen as a prn option for continued mild or moderate pain. For fever, it's okay to use acetaminophen carefully for temps over 102°F...high fevers in mom can be risky to the fetus.

Take a deeper look at the evidence using our *Analgesics in Pregnancy and Lactation* chart to help balance benefits and risks.

Key References:

- FDA. FDA Responds to Evidence of Possible Association Between Autism and Acetaminophen Use During Pregnancy. September 22, 2025. <https://www.fda.gov/news-events/press-announcements/fda-responds-evidence-possible-association-between-autism-and-acetaminophen-use-during-pregnancy> (Accessed September 24, 2025).
- Gustavson K, Ystrom E, Ask H, et al. Acetaminophen use during pregnancy and offspring attention deficit hyperactivity disorder - a longitudinal sibling control study. *JCPP Adv.* 2021 Jun 22;1(2):e12020.

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- Okubo Y, Hayakawa I, Sugitate R, Nariai H. Maternal Acetaminophen Use and Offspring's Neurodevelopmental Outcome: A Nationwide Birth Cohort Study. *Paediatr Perinat Epidemiol*. 2025 Sep 2. doi: 10.1111/ppe.70071.
- Ahlqvist VH, Sjöqvist H, Dalman C, et al. Acetaminophen Use During Pregnancy and Children's Risk of Autism, ADHD, and Intellectual Disability. *JAMA*. 2024 Apr 9;331(14):1205-1214.
- Damkier P, Gram EB, Ceulemans M, et al. Acetaminophen in Pregnancy and Attention-Deficit and Hyperactivity Disorder and Autism Spectrum Disorder. *Obstet Gynecol*. 2025 Feb 1;145(2):168-176.
- Alemany S, Avella-García C, Liew Z, et al. Prenatal and postnatal exposure to acetaminophen in relation to autism spectrum and attention-deficit and hyperactivity symptoms in childhood: Meta-analysis in six European population-based cohorts. *Eur J Epidemiol*. 2021 Oct;36(10):993-1004.
- American College of Obstetricians and Gynecologists. ACOG Affirms Safety and Benefits of Acetaminophen during Pregnancy. September 22, 2025. <https://www.acog.org/news/news-releases/2025/09/acog-affirms-safety-benefits-acetaminophen-pregnancy> (Accessed October 16, 2025).
- Society for Maternal-Fetal Medicine. SMFM Statement on Acetaminophen Use During Pregnancy and Autism. September 5, 2025. <https://www.smfm.org/news/smfm-statement-on-acetaminophen-use-during-pregnancy-and-autism> (Accessed October 16, 2025).

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