

September 26th, 2025

In response to the recent FDA press release suggesting an association between paracetamol (acetaminophen) use during pregnancy and the risk of autism¹, the International Society of Pharmacovigilance (ISoP) wishes to provide the following clarifications:

- Current scientific evidence is insufficient to establish a causal link between antenatal exposure to paracetamol and the development of autistic spectrum disorders. While several studies have explored this potential association, the results remain inconsistent, ambiguous and subject to methodological limitations.
- Our understanding of autism has advanced to show that this term covers a spectrum of disorders and so we suggest that research and dissemination of evidence should always be done in partnership with recognized autism groups and the relevant families.
- As highlighted by the European Medicines Agency (EMA) and other regulatory bodies worldwide^{2,3,4} and the World Health Organisation⁵, the scientific evidence available to date does not justify any updates to the recommendations for use of paracetamol in pregnancy.
- Paracetamol remains the analgesic and antipyretic of first choice during pregnancy, and untreated high fever itself can cause harm to a fetus. Paracetamol's safety profile is well established as described in the label. As with any medication taken in pregnancy, paracetamol should be used at the lowest dose for the shortest duration. Any questions or concerns should be discussed with the relevant healthcare provider.

ISoP calls for responsible communication on this topic, grounded in scientific evidence and clinical consensus with the interests of those with autism and their families first and foremost.

1. <https://www.fda.gov/news-events/press-announcements/fda-responds-evidence-possible-association-between-autism-and-acetaminophen-use-during-pregnancy>

2. <https://www.ema.europa.eu/en/news/use-paracetamol-during-pregnancy-unchanged-eu>

3. <https://www.gov.uk/drug-safety-update/paracetamol-and-pregnancy-reminder-that-taking-paracetamol-during-pregnancy-remains-safe>

4. <https://www.tga.gov.au/news/media-releases/paracetamol-use-pregnancy>

5. <https://www.who.int/news/item/24-09-2025-who-statement-on-autism-related-issues>