Medicines & Healthcare products Regulatory Agency

DRUG SAFETY UPDATE (DSU)

Paracetamol and pregnancy – reminder that taking paracetamol during pregnancy remains safe

Specialisms: *General Practice, Pain management and palliation, Pregnancy, Obstetrics, gynaecology and fertility, Dentistry, Anaesthesia and intensive care, Cancer, Cardiovascular disease and lipidology, Care home staff, Cosmetic surgery, Critical care, Dermatology, Dispensing GP practices, Ear, nose and throat, Emergency medicine, Endocrinology, diabetology and metabolism, General surgery, GI, hepatology and pancreatic disorders, Haematology and oncology, Immunology and vaccination, Immunosuppression and transplantation, Infection prevention, Infectious disease, Neurology, Ophthalmology, Orthopaedics, Paediatrics and neonatology, Pharmacy, Physiotherapy and occupational therapy, Radiology and imaging, Renal medicine, Respiratory disease and allergy, Rheumatology, Urology and nephrology, Vascular and cardiac surgery*

Summary

Patients should be reminded and reassured that there is no evidence that taking paracetamol during pregnancy causes autism in children. Paracetamol is recommended as the first-choice pain reliever for pregnant women, used at the lowest dose and for the shortest duration. It also acts as an antipyretic and is therefore used to treat fever. Patients should not stop taking their pain medicines as untreated pain and fever can pose risks to the unborn child.

Advice for Healthcare Professionals:

- there is no evidence that taking paracetamol during pregnancy causes autism in children
- pregnant women should be advised to continue to follow existing NHS guidance and speak to their healthcare professional if they have questions about any medication during pregnancy
- untreated pain and fever can pose risks to the unborn baby, so it is important that patients continue to manage these symptoms with the recommended treatment. If pain or fever does not resolve, patients are advised to seek advice from their healthcare professional

- patients should not swap to alternatives such as ibuprofen. Non-steroidal anti-inflammatory drugs (NSAIDs), such as ibuprofen, are generally not recommended during pregnancy
- the MHRA regularly reviews the safety of paracetamol including during pregnancy to ensure that the benefits to the patient and unborn baby outweigh any risks
- recent existing studies do not show a causal association between paracetamol use during pregnancy and autism. There are many potential contributing factors in the development of autism, including but not limited to concomitant diseases and family inheritance
- members of the public and healthcare professionals are encouraged to report any suspected side effects from medicines, including paracetamol, to the MHRA's Yellow Card scheme

Advice for Healthcare Professionals to Provide to Patients:

- paracetamol is recommended as the first-choice pain reliever for pregnant women, used at the lowest dose and for the shortest duration. It can also be used to treat fever
- pregnant women should be advised to continue to follow existing NHS guidance and speak to their healthcare professional if they have questions about any medication during pregnancy
- untreated pain and fever can pose risks to the unborn baby, so it is important that patients continue to manage these symptoms with the recommended treatment
- patients should not swap to alternatives such as ibuprofen, as non-steroidal anti-inflammatory drugs (NSAIDs) are generally not recommended during pregnancy

Background

Recent announcement

A recent US announcement suggested a link between paracetamol use in pregnancy and autism. However, there is no robust evidence to support this claim. The current evidence is outlined below.

The US announcement included a literature review published in *Environmental Health* (August 2025)[1] looking at studies on paracetamol use in pregnancy and children later diagnosed with autism or ADHD. The review considered a potential association between the use of paracetamol and the risk of autism; however, explicitly acknowledged that the evidence did not support that paracetamol caused autism. There were significant limitations to this review:

- Observational studies – these studies could not rule out alternative explanations for an association, such as confounding factors.
- Confounding factors – women taking paracetamol for fever, infection or pain, which themselves are risk factors for adverse pregnancy outcomes and risks to the child (this is known as confounding by indication).
- Self-reported use of paracetamol by mothers – many studies relied on mothers remembering if they took paracetamol years earlier, which is unreliable and prone to error (this is known as recall bias).
- Inconsistent methods – studies measured exposure and outcomes differently, making results hard to compare (misclassification bias).
- Small effect sizes – even where associations are seen, they were small and could easily be explained by other factors.

Other studies and reviews

There are other more rigorous systematic reviews and studies using national population-based registries which have found no association between paracetamol and autism.

One of the largest studies on this topic, published in 2024, used registry data for 2.4 million children born in Sweden,[2] and compared 185,909 children exposed to paracetamol during pregnancy with their own brothers and sisters in cases where the mother had not taken paracetamol when she was pregnant with them. It showed no evidence that paracetamol used during pregnancy causes autism, nor that taking more paracetamol increases risk. Similarly, there was no evidence of a dose-response pattern. The authors highlighted that associations observed in other studies may have been confounded.

A world-wide review of the scientific literature published February 2025,[3] of patients with well documented diagnosis of ADHD or autism, indicated that there was no evidence to support a link between the use of paracetamol during pregnancy and autism.

Review by the Pharmacovigilance Risk Assessment Committee (PRAC) of the European Medicines Agency

Regulators have also repeatedly assessed evidence. In 2019, the Pharmacovigilance Risk Assessment Committee (PRAC) of the European Medicines Agency's (EMA) reviewed studies on paracetamol and possible effects on both the urinary and reproductive systems, as well as on brain development. It concluded that the evidence was inconclusive (not strong enough to prove or disprove a risk) but recommended that product information should be updated to reflect the state of knowledge. These updates were also adopted in the UK (see example SmPC).

Review by the UK Commission on Human Medicines (CHM)

In 2022, the UK Commission for Human Medicines (CHM) reviewed the use of non-prescription pain medicines during pregnancy. The CHM advised that there was no need to change the advice on paracetamol. However, an update to warnings for ibuprofen were included to advise mothers not to use ibuprofen during pregnancy due the risk of heart

and kidney disorders in the unborn child. Non-steroidal anti-inflammatory drugs (NSAIDs): potential risks following prolonged use after 20 weeks of pregnancy - GOV.UK

Paracetamol therefore remains the preferred pain and fever medicine in pregnancy, when used at the lowest effective dose for the shortest necessary time.

Reporting advice

Healthcare professionals, patients, and caregivers are asked to submit reports using the Yellow Card scheme electronically using:

- the Yellow Card website.
- the Yellow Card app; download from the Apple App Store or Google Play Store
- some clinical IT systems for healthcare professionals (EMIS, SystmOne, Vision, MiDatabank, and Ulysses)

When reporting suspected adverse drug reactions, please provide as much information as possible, including information about medical history, any concomitant medication, onset timing, and treatment dates.

Additional information

You can sign up to receive email notifications for Drug Safety Updates.

You can sign up to receive our monthly roundup of safety communications.

For any enquiries, please contact info@mhra.gov.uk

References

1. Prada D and others. Evaluation of the evidence on acetaminophen use and neurodevelopmental disorders using the Navigation Guide methodology. Environmental Health 24, 2025: article number 56
2. Ahlqvist VH and others. Acetaminophen Use During Pregnancy and Children's Risk of Autism, ADHD, and Intellectual Disability. JAMA 2024: volume 331, issue 14, pages 1205-1214
3. Damkier, Per MD, and others. Acetaminophen in Pregnancy and Attention-Deficit and Hyperactivity Disorder and Autism Spectrum Disorder. Obstetrics & Gynecology 2025: volume 145, issue 2, pages 168-176

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