

## **Announcements on the use of Paracetamol (also known as Acetaminophen) during pregnancy released by the World Health Organization and overseas drug regulatory authorities**

The Department of Health ("DH") noted that the World Health Organization ("WHO") had issued a statement on 24 September 2025 indicating that there is currently insufficient scientific evidence to conclude that paracetamol (also known as acetaminophen) use during pregnancy causes autism or other neurodevelopmental disorders in children, or that there is any association between the two. Furthermore, several drug regulatory authorities, including those in the European Union, the United Kingdom, Australia, and Canada, had also made announcements and emphasised that, based on rigorous assessments of existing scientific data, paracetamol remains an important option for pregnant women to relieve pain or fever when clinically indicated and under medical advice. Some authorities specifically noted that studies suggesting a potential link between the two exhibit significant limitations and in fact failed to establish a causal relationship. Conversely, the medical community has long confirmed through more rigorous large-scale studies that there is no association between paracetamol use during pregnancy and autism or attention deficit/hyperactivity disorder (ADHD).

Based on current scientific evidence, claims that taking paracetamol during pregnancy causes autism or other neurodevelopmental disorders in children lack sufficient supporting evidence.

In this connection, the DH issued a press statement (<http://www.info.gov.hk/gia/general/202509/25/P2025092501333.htm>) on 25 September 2025 to emphasise that all public health policies and medical advice must be based on scientific evidence.

Below please find the announcements on the use of paracetamol during pregnancy issued by the WHO and overseas drug regulatory authorities:

### **i) World Health Organization (WHO) statement on autism-related issues**

The World Health Organization (WHO) announces the following related to autism-related issues:

The World Health Organization emphasizes that there is currently no conclusive scientific evidence confirming a possible link between autism and use of acetaminophen (also known as paracetamol) during pregnancy.

Globally, nearly 62 million people (1 in 127) have autism spectrum disorder, a diverse group of conditions related to development of the brain. Although awareness and diagnosis have improved in recent years, the exact causes of autism have not been established, and it is understood there are multiple factors that can be involved.

Extensive research has been undertaken over the past decade, including large-scale studies, looking into links between acetaminophen use during pregnancy and autism. At this time, no

consistent association has been established.

WHO recommends that all women continue to follow advice of their doctors or health workers, who can help assess individual circumstances and recommend necessary medicines. Any medicine should be used with caution during pregnancy, especially in the first three months, and in line with advice from health professionals.

Please refer to the following website in WHO for details:

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

ii) **European Union: Use of paracetamol during pregnancy unchanged in the European Union**

European Medicines Agency (EMA) announces that in the European Union (EU), paracetamol (also known as acetaminophen) can be used for reducing pain or fever during pregnancy if clinically needed. Paracetamol medicines can be used in pregnancy, in accordance with official recommendations. There is currently no new evidence that would require changes to the current EU recommendations for use.

*"Paracetamol remains an important option to treat pain or fever in pregnant women. Our advice is based on a rigorous assessment of the available scientific data and we have found no evidence that taking paracetamol during pregnancy causes autism in children." - EMA's Chief Medical Officer, Steffen Thirstrup*

As included in the product information for paracetamol in the EU, a large amount of data from pregnant women who used paracetamol during pregnancy indicates no risk of malformations in the developing foetus or in newborns.

In 2019, EMA reviewed available studies that investigated the neurodevelopment of children exposed to paracetamol in utero and found that the results were inconclusive and that no link with neurodevelopmental disorders could be established.

When needed, paracetamol can be used during pregnancy. As with any medicine for acute treatment, it should be used at the lowest effective dose, for the shortest possible time and as infrequently as possible.

Pregnant women should speak to their healthcare professional if they have questions about any medication during pregnancy.

As for all medicines, EMA and the national competent authorities in the EU will continue to monitor the safety of medicines containing paracetamol and promptly evaluate any new data as they emerge. Regulatory actions will be taken as necessary to protect public health.

Please refer to the following website in EMA for details:

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

**iii) The United Kingdom: Paracetamol and pregnancy - reminder that taking paracetamol during pregnancy remains safe**

The Medicines and Healthcare products Regulatory Agency (MHRA) announces that 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

**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) looking at studies on paracetamol use in pregnancy and children later diagnosed with autism or attention deficit hyperactivity disorder (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, 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, 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 United Kingdom.

## **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.

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

Please refer to the following website in MHRA for details:

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

### **iv) Canada: Acetaminophen (paracetamol) is a recommended treatment for fever and pain during pregnancy**

#### **Affected products**

Acetaminophen (also known as paracetamol)

#### **Issue**

Health Canada currently maintains that there is no conclusive evidence that using acetaminophen as directed during pregnancy causes autism or other neurodevelopmental disorders.

Acetaminophen is commonly used to relieve pain and reduce fever. It has been used safely by millions of Canadians for decades, including during pregnancy and while breastfeeding.

Acetaminophen is a recommended treatment of pain or fever in pregnancy when used as directed. It should be used at the lowest effective dose for the shortest duration needed. Untreated fever and pain in pregnant women can pose risks to the unborn child.

#### **What you should do**

- Continue to use acetaminophen for pain and/or fever during pregnancy, as directed. Always follow the directions on the label.

- Do not take more than the recommended dose. Taking too much acetaminophen can cause harms including serious harm to your liver.
- If you are pregnant or breastfeeding, talk to your health care provider if you have questions about the use of any medications.
- Contact a health care provider if:
  - pain lasts more than 5 days; or
  - fever lasts more than 3 days.

### **What Health Canada is doing**

- Health Canada's advice is based on robust, rigorous assessments of the available scientific evidence. Any new evidence that could affect our recommendations will be carefully evaluated.
- Health Canada monitors the safety of all medicines authorized for use in Canada, including acetaminophen. All Canadian non-prescription acetaminophen products already carry clear warnings about safe use during pregnancy and breastfeeding, as well as the risk of serious liver injury if too much is taken.
- If new scientific evidence demonstrates a risk, Health Canada would take action to update labels, inform health care professionals, and provide advice to Canadians.

Please refer to the following website in Health Canada for details:

<http://recalls-rappels.canada.ca/en/alert-recall/acetaminophen-recommended-treatment-fever-and-pain-during-pregnancy>

### **v) Australia: Paracetamol use in pregnancy**

The Therapeutic Goods Administration (TGA) announces the following in relation to use of paracetamol in pregnancy:

- Australia's Chief Medical Officer and the TGA join with other global medicines regulators, leading clinicians and scientists worldwide in rejecting claims regarding the use of paracetamol in pregnancy, and the subsequent risk of development of ADHD or autism in children.
- Robust scientific evidence shows no causal link between the use of paracetamol in pregnancy and autism or ADHD, with several large and reliable studies directly contradicting these claims.
- Paracetamol remains the recommended treatment option for pain or fever in pregnant women when used as directed. Importantly, untreated fever and pain can pose risks to the unborn baby, highlighting the importance of managing these symptoms with recommended treatment. Pregnant women should speak to their healthcare professionals if they have questions about any medication during pregnancy.
- Paracetamol remains pregnancy category A in Australia, meaning that it is considered safe for use in pregnancy when used according to directions in TGA-approved Product Information (PI) and Consumer Medicines Information (CMI) documents.
- This means that a medicine has been taken by a large number of pregnant women and women of childbearing age without any proven increase in the frequency of malformations or other harmful effects on the fetus having been observed. As with the use of any medicine during

pregnancy, people who are pregnant should seek medical advice tailored to their specific circumstances before taking paracetamol.

- The TGA is responsible for ensuring the safety, quality and efficacy of medicines on the Australian Register of Therapeutic Goods (ARTG), with safety in pregnancy a key consideration for all products on the ARTG.
- The TGA undertakes evaluation of clinical, scientific and toxicological data prior to registration of a medicine, and this information is summarised in TGA-approved PI and CMI documents, targeted at healthcare professionals and consumers respectively, to help support safe use of a medicine in the community. These documents include information relating to use of a medicine in pregnancy.
- The TGA is aware of announcements by the US Food and Drug Administration that use of paracetamol in pregnancy may be associated with an increased risk of autism and ADHD in children, though a causal association has not been established.
- TGA advice on medicines in pregnancy is based on rigorous assessment of the best available scientific evidence. Any new evidence that could affect our recommendations would be carefully evaluated by our independent scientific experts.
- Whilst there are published articles suggesting an association between maternal paracetamol use and childhood autism, they had methodological limitations. More recent and robust studies have refuted these claims, supporting the weight of other scientific evidence that does not support a causal link between paracetamol and autism or ADHD.
- The TGA maintains robust post-market safety surveillance and pharmacovigilance processes for all medicines registered in Australia, including paracetamol. This includes detailed analysis of adverse event reports made by medicine consumers, clinicians and pharmaceutical companies, review of published medical literature, and close liaison with international medicines regulators. If a safety issue is confirmed prompt regulatory action is taken to mitigate risks.
- International peer regulators including the Medicine and Healthcare products Regulatory Agency (MHRA) in the United Kingdom have reiterated that paracetamol should continue to be used in line with product information documents. Following evaluation in 2019, the European Medicines Agency (EMA) found that scientific evidence regarding effects of paracetamol on childhood neurodevelopment was inconclusive.
- People who have concerns and are pregnant, or considering pregnancy, are advised to consult their healthcare professionals in the first instance to discuss this issue.

Please refer to the following website in TGA for details:

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

### **Local Situation in Hong Kong**

In Hong Kong, there are 707 registered pharmaceutical products containing paracetamol (acetaminophen). So far, with regard to paracetamol, the Department of Health (DH) has received 59 cases of adverse drug reaction, but these cases were not related to autism and ADHD in children associated with pregnancy use.

In light of the above announcements issued by the overseas drug regulatory authorities and the World Health Organization (WHO), letters to inform local healthcare professionals will be issued, and the DH will continue to closely monitor safety recommendations and research findings from other international health authorities and drug regulatory authorities regarding the use of paracetamol containing products, and to take appropriate follow-up actions as necessary.

Ends/Friday, Sep 26, 2025

Issued at HKT 15:30