

## PARACETAMOL AND PREGNANCY FACTSHEET

### THE FACTS

- There is no evidence that taking paracetamol during pregnancy causes autism in children.
- A major study conducted in Sweden in 2024, involving 2.4 million children found no evidence that paracetamol causes autism in pregnancy.
- Untreated pain and fever can pose real risks to the unborn baby, so it is crucial to manage these symptoms with the recommended treatment. Paracetamol continues to be the recommended pain relief option for pregnant women when used as directed.
- Patients should not swap to alternatives such as ibuprofen, as non-steroidal anti-inflammatory drugs (NSAIDs) are generally not recommended during pregnancy

### THE EVIDENCE

The largest study to date was conducted last year in Jama Psychiatry by a team from the Karolinska Institute near Stockholm, which found no link between siblings exposed to paracetamol during pregnancy.

2.4 million children born between 1995 and 2019 were part of the study, with their data used along with reports from their midwives during their pregnancy to find 186,000 children whose mothers were treated with paracetamol during pregnancy.

These children were then compared with their own brothers and sisters in cases where the mother had not taken paracetamol when she was pregnant with them. They concluded that there was no evidence of a link between maternal paracetamol use and autism.

### MHRA's COMMENT ON PARACETEMOL FOR PREGNANCY

#### **Dr Alison Cave, Chief Safety Officer at the MHRA, said:**

"Patient safety is our top priority. There is no evidence that taking paracetamol during pregnancy causes autism in children.

"Paracetamol remains the recommended pain relief option for pregnant women when used as directed. Pregnant women should 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 to manage these symptoms with the recommended treatment.

"Our 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.

“We continuously monitor the safety of all medicines, including those used during pregnancy, through robust monitoring and surveillance. We encourage anyone to report any suspected side effects to us via the Yellow Card scheme.”

## **Q&As**

### **Is paracetamol safe to use during pregnancy?**

Yes. Current evidence supports the safe use of paracetamol during pregnancy when used as directed. This advice has been consistent for many years.

The MHRA regularly reviews the safety of paracetamol during pregnancy to ensure that the benefits to the parent and unborn baby outweigh any risks.

Paracetamol is recommended by [NHS guidance](#) as the first-choice painkiller for pregnant women, to be used at the lowest dose and for the shortest duration. If pain does not resolve then patients are advised to seek advice from their healthcare professional.

### **Should pregnant women stop taking paracetamol?**

No. Pregnant women should continue to follow current medical guidance. Paracetamol remains a recommended painkiller during pregnancy when used as directed. Women with concerns should speak to their healthcare professional rather than stopping medication without medical advice.

### **Will the MHRA review its guidance following the US announcement?**

No. The MHRA carefully monitors new evidence on the safety of medicines and takes action when evidence shows a potential risk to patients.

In the case of paracetamol use in pregnancy, recent studies, including the one published in August, have not established a direct relationship between paracetamol use during pregnancy and an increased risk of autism.

### **Does the MHRA only act when a causal link is proven?**

No. The MHRA carefully monitors new evidence on the safety of medicines and takes regulatory action when evidence shows a potential risk to patients, which exceeds the potential benefits.

It continuously monitors emerging data and will introduce safety measures when warranted to protect public health.

### **How does the MHRA monitor medicine safety in pregnancy?**

The MHRA has comprehensive systems including the Yellow Card Scheme for reporting suspected side effects, analysis of healthcare databases, and review of international evidence. MHRA works closely with healthcare professionals and regularly update guidance when new evidence emerges.