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Use of paracetamol during pregnancy unchanged in the EU

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Paracetamol medicines can be used in pregnancy, in accordance with official recommendations

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In the EU, paracetamol (also known as acetaminophen) can be used for reducing pain or fever during pregnancy if clinically needed. 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.[1][2]

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.

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[1] "The European Network of Teratology Information Services, ENTIS: Position statement on acetaminophen (paracetamol) in pregnancy", October 3, 2021, https://www.entis-org.eu/entis-news/official-entis-position-statement-paracetamol-acetaminophen-apap-use-in-pregnancy.

[2] Ahlqvist VH, Sjöqvist H, Dalman C, et al. "Acetaminophen use during pregnancy and children's risk of autism, ADHD, and intellectual disability" JAMA, 2024;331(14):1205–1214. doi:10.1001/jama.2024.3172

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Adopted

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Contact point

Media enquiries

Tel. +31 (0)88 781 8427
E-mail: press@ema.europa.eu

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1083 HS Amsterdam The Netherlands

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