



Use of paracetamol during pregnancy: European recommendations confirmed

The Italian Medicines Agency (AIFA) reports that, in light of the latest scientific assessments carried out at European level, there is no new evidence requiring changes to the current recommendations on the use of paracetamol during pregnancy.

Paracetamol (acetaminophen), widely used for the treatment of fever and pain, can be used during pregnancy if clinically necessary. The available data show no association with an increased risk of autism or malformations in the foetus or newborn.

A review conducted in 2019 by the Pharmacovigilance Risk Assessment Committee (PRAC) of the European Medicines Agency (EMA) on the effects of paracetamol on neurodevelopmental outcomes in children exposed in utero concluded that the available evidence is inconclusive and does not support changes to the current recommendations on use during pregnancy. Experience of use in large cohorts of pregnant women also confirms the absence of malformative or toxic risks.

However, it is recommended that paracetamol be used during pregnancy at the lowest effective dose, for the shortest possible period of time and with the minimum frequency compatible with treatment.

The EMA, in collaboration with the regulatory authorities of other European Union Member States, will continue to monitor the safety of medicines containing paracetamol and update the available information if new data emerge.