

# Use of artemether–lumefantrine to treat malaria during pregnancy: what do we know and need to know?

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## Abstract

Artemether–lumefantrine is a fixed-dose combination containing 20 mg artemether/120 mg lumefantrine per tablet, used for treating uncomplicated malaria in patients weighing 5 kg. It is the first artemisinin-based combination registered in some European countries and in the USA. It is marketed in Europe as Riamet<sup>®</sup> (Novartis, Basel, Switzerland) and in malaria-endemic countries as Coartem<sup>®</sup> (Novartis). Safety concerns prevent early pregnancy usage, while limited post marketing surveillance has delayed safety assessment and policy development. Large clinical studies, post marketing surveillance and pharmacovigilance ongoing in some countries may soon bridge safety issues. Fatty diet requirements for optimal absorption, pregnancy-induced changes in pharmacokinetics, pregnancy-related anorexia and food taboos, and emerging reduced parasite sensitivity to artemisinin, challenges optimal artemether–lumefantrine dosing and efficacy during pregnancy. This evaluation addresses drug usage, safety concerns following early exposure, implications for changed pharmacokinetics and reduced parasite susceptibility. Clinical-use updates and strategies to address some knowledge gaps including key operational research are discussed.

Keywords: Artemether-lumefantrine, artemether-lumefantrine pregnancy, artemisinin resistance, deranged, pharmacokinetics, pharmacovigilance, post marketing safety.