



## Makena<sup>®</sup> (hydroxyprogesterone caproate) – First-time generic

- On June 25, 2018, [American Regent](#) launched an [AP-rated](#) generic version of AMAG Pharmaceuticals' [Makena \(hydroxyprogesterone caproate\)](#) 250 mg/mL preservative-free injection.
  - Prasco has also launched an authorized generic of Makena.
- Makena is approved to reduce the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth. The effectiveness of Makena is based on improvement in the proportion of women who delivered < 37 weeks of gestation. There are no controlled trials demonstrating a direct clinical benefit, such as improvement in neonatal mortality and morbidity.
  - While there are many risk factors for preterm birth, safety and efficacy of Makena has been demonstrated only in women with a prior spontaneous singleton preterm birth. It is not intended for use in women with multiple gestations or other risk factors for preterm birth.
- Makena is also available as a branded 1,250 mg/5 mL with preservative injection and a 275 mg/1.1 mL auto-injector.
  - All Makena products carry the same indication.



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