Generic Name:
Hydroxyprogesterone caproate injection
Trade Name:
Makena
Company:
Ther-Rx
Notes:

FDA originally approved hydroxyprogesterone caproate under the trade name Delalutin in 1956 for use in pregnant women; however, the original manufacturer requested withdrawal of the product from the market in 2000 for reasons unrelated to safety. This newly available synthetic progestin is given as a 250-mg intramuscular injection once weekly by a health professional beginning between 16 weeks, 0 days, and 20 weeks, 6 days gestation, and continuing until week 37 of gestation or delivery, whichever occurs first. Approval was based on data showing that women treated with weekly hydroxyprogesterone caproate injections were less likely to deliver babies before 32, 35, and 37 weeks of gestation compared with those given a vehicle injection. Injection site reactions, urticaria, pruritus, nausea, and diarrhea occurred more commonly with active therapy.
Medication Monitor Categories:
New Drug Approvals
Use:

Reduce the risk of preterm birth in women with a singleton pregnancy and a history of singleton spontaneous preterm birth