Makena® (hydroxyprogesterone caproate) – New formulation

- On February 14, 2018, AMAG Pharmaceuticals announced the FDA approval of Makena (hydroxyprogesterone caproate) subcutaneous (SC) injection, 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 1 mL single-dose vial and a 5 mL multi-dose vial for intramuscular (IM) injection containing 250 mg/mL hydroxyprogesterone caproate.
- About one in 10 babies in the U.S. are born prematurely.
- In a single-dose, bioavailability study in 120 healthy post-menopausal women, comparable systemic exposure of hydroxyprogesterone caproate was seen when Makena was administered SC with the auto-injector (1.1 mL) in the back of the upper arm and when Makena was dosed IM (1 mL) in the upper outer quadrant of the gluteus maximus.
- Makena is contraindicated in patients with current or a history of thrombosis or thromboembolic disorders; known or suspected breast cancer, other hormone-sensitive cancer, or history of these conditions; undiagnosed abnormal vaginal bleeding unrelated to pregnancy; cholestatic jaundice of pregnancy; liver tumors, benign or malignant, or active liver disease; and uncontrolled hypertension.
- Warnings and precautions of Makena include thromboembolic disorders, allergic reactions, decrease in glucose tolerance, fluid retention, depression, jaundice, and hypertension.
- In studies where the Makena SC injection using the auto-injector was compared with Makena IM injection, the most common adverse reaction reported with Makena auto-injector use (and higher than with Makena IM injection) was injection site pain (10% in one study and 34% in another).
- The recommended dosage of the Makena auto-injector is 275 mg (1.1 mL) SC once weekly (every 7 days) in the back of either upper arm by a healthcare provider.
    - The recommended dosage of the Makena single- and multi-dose vials is 250 mg (1 mL) IM once weekly (every 7 days) in the upper outer quadrant of the gluteus maximus by a healthcare provider.
    - Begin treatment between 16 weeks, 0 days and 20 weeks, 6 days of gestation.
    - Continue administration once weekly until week 37 (through 36 weeks, 6 days) of gestation or delivery, whichever occurs first.

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- AMAG Pharmaceuticals plans to launch the Makena auto-injector in the second half of March 2018. The Makena SC injection will be available as a 1.1 mL single-use auto-injector containing 275 mg of hydroxyprogesterone caproate (250 mg/mL).