DOCTORS HEALTHCARE PLANS, INC.

FDA Drug Withdrawal from Market

FDA approval of medicine Makena and its generics hydroxyprogesterone caproate injection is withdrawn due to safety concerns

4/06/2023

Dear Prescriber:

The FDA has announced their decision to withdraw approval of Makena—a drug that had been approved under the accelerated approval pathway. This drug was approved to reduce the risk of preterm birth in women pregnant with one baby who have a history of spontaneous preterm birth. The decision was issued jointly by the FDA Commissioner and Chief Scientist. Effective 04/06/2023, Makena and its generics are no longer approved and cannot lawfully be distributed in interstate commerce.

The FDA approved Makena under the accelerated approval pathway in 2011 based on a determination that the sponsor had demonstrated a drug effect on an intermediate clinical endpoint that was reasonably likely to predict clinical benefit. The agency's approval included a requirement that the sponsor conduct a post marketing confirmatory study. The resultant confirmatory study did not verify clinical benefit and the FDA's Center for Drug Evaluation and Research (CDER) proposed withdrawing the drug's approval in 2020. The sponsor requested a hearing, which was held in October 2022.

Based on that review, the FDA Commissioner and Chief Scientist have decided to withdraw approval of Makena and generic versions of Makena.

The following are the affected NDCs:

Product	NDC #
Hydroxyprogesterone Caproate Injection	0517-1767-01
Hydroxyprogesterone Caproate Injection	0517-1791-01
Hydroxyprogesterone Caproate Injection	55150-0309-01
Hydroxyprogesterone Caproate Injection	55150-0310-01
Makena (hydroxyprogesterone caproate injection)	64011-0243-01
Makena (hydroxyprogesterone caproate injection)	64011-0247-02
Makena (hydroxyprogesterone caproate injection)	64011-0301-03
Hydroxyprogesterone Caproate Injection	66993-0039-01
Hydroxyprogesterone Caproate Injection	67457-0886-05
Hydroxyprogesterone Caproate Injection	67457-0967-01
Hydroxyprogesterone Caproate Injection	69238-1797-01
Hydroxyprogesterone Caproate Injection	71225-0104-01
Hydroxyprogesterone Caproate Injection	71225-0105-01

While the approvals of Makena and its generics have been withdrawn, the FDA recognizes that there is a supply of product that has already been distributed. Approvals of these drugs have been withdrawn because the drugs

are no longer shown to be effective, and the benefits do not outweigh the risks for the indication for which they were approved. For additional information, see Makena Information on FDA.gov.
https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/makena-hydroxyprogesterone-caproate-injection-information

For more information, please review the following press release: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts

Doctors HealthCare Plans has taken the following actions in response to this information:

Effective 04/06/2023, a HARD Point of Service (at the Pharmacy) alert message will be set to fire for the NDCs above as follows: "DRUG'S FDA APPROVAL WITHDRAWN. CONTACT PHYSICIAN."

Source: https://www.fda.gov/news-events/press-announcements/fda-commissioner-and-chief-scientist-announce-decision-withdraw-approval-makena