COMMUNICATION

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2023

PLEASE REVIEW

Drug Information

PharmPix Clinical Department

PharmPix is committed to the health and wellness of our members.

The clinical team wants to communicate the latest up-to-date drug information.

Drug Information:

Remember that medical literature is dynamic and is continuously changing as new scientific knowledge is developed. We exhort the frequent revision of treatment guidelines to assure that your recommendations are consistent with the most updated information.

It is our priority to offer high-quality services and support practices for health promotion and diseases prevention. If you have any questions or wish to have more information regarding this document, you can call us directly or view PharmPix communications online.

QUESTIONS

Call us at 787-522-5252, ext. 220

Access our recent communications at our providers' portal: https://www.pharmpix.com/providers/.

FDA Withdraws Approval of the Only Preterm Birth Medication

On April 6 the U.S. Food and Drug Administration (FDA) officially withdrew the approval of Makena™ (hydroxyprogesterone caproate), the only preterm birth medication.

FDA Withdraws Makena's Approval

Back in October 2022 the FDA Obstetrics, Reproductive and Urologic Drugs Advisory Committee held a hearing on the possible withdrawal of Makena™, and it voted to recommend that FDA pursue withdrawal of approval of the only FDA-approved treatment to reduce the risk of preterm birth in pregnant women who have had a prior spontaneous preterm birth. Covis Pharma Goup, the drug's manufacturer, submitted a response noting that safety and efficacy data continue to support the approval of Makena™, at least in a higher-risk patient population. The company also stated that it respected the Committee's recommendations and was seeking to voluntarily withdraw the Makena NDA.

On April 6 the FDA announced the final decision to withdraw approval of this medication. The decision was issued jointly by the FDA Commissioner and Chief Scientist. This withdrawal means that both the brand and generic products are no longer approved and cannot lawfully be distributed in interstate commerce.

The FDA had previously approved Makena™ under the accelerated approval pathway in 2011 to reduce the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth. The approval included a requirement that the sponsor conduct a post marketing confirmatory study, which did not verify clinical benefit.

The agency recognizes that there is a supply of product that has already been distributed. Patients who have questions should talk to their healthcare provider.

Additional information can be found at:

- FDA News Release: FDA Commissioner and Chief Scientist Announce Decision to Withdraw Approval of Makena
- Formulary Watch: FDA Officially Withdraws Makena, the Only Preterm Birth Med

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REFERENCES:
1. U.S. Food and Drug Administration. (2023, April 6). FDA Commissioner and Chief Scientist Announce Decision to Withdraw Approval of Makena. https://www.fda.gov/news-events/press-announcements/fda-commissioner-and-chief-scientist-announce-decision-withdraw-approval-makena
2. Blank, C. (2023, April 7). FDA officially withdraws Makena, the only preterm birth med. Formulary Watch. https://www.formularywatch.com/view/fda-officially-withdraws-makena-the-only-preterm-birth-med

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