

EXHIBIT 69

Information about Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation

Mifeprex (mifepristone) and its generic, Mifepristone Tablets, 200 mg (collectively mifepristone) are approved, in a regimen with misoprostol, to end an intrauterine pregnancy through ten weeks gestation (70 days or less since the first day of a patient's last menstrual period). The FDA first approved Mifeprex in 2000 and approved a generic version of Mifeprex, Mifepristone Tablets, 200 mg, in 2019.

Risk Evaluation and Mitigation Strategy (REMS) Information

Mifeprex and its generic, Mifepristone Tablets, 200 mg, are available under a single, shared system risk evaluation and mitigation strategy (REMS), known as the Mifepristone REMS Program, which sets forth the requirements that must be followed for prescribing and dispensing mifepristone for medical termination of pregnancy through ten weeks gestation.

Under the Mifepristone REMS Program, mifepristone must be prescribed by certified prescribers and must be dispensed by or under the supervision of a certified prescriber or by a certified pharmacy on a prescription issued by a certified prescriber. Under the Mifepristone REMS Program, mifepristone may be dispensed in person or by mail.

Mifeprex was first approved in 2000 with restrictions to assure its safe use. Mifeprex was deemed to have in effect an approved REMS under the Food and Drug Administration Amendments Act of 2007. In 2019, at the same time the FDA approved the generic version of Mifeprex, the agency approved the Mifepristone REMS Program, a single, shared system REMS for mifepristone products for the medical termination of intrauterine pregnancy through 70 days gestation.

In 2021, after conducting a review of the Mifepristone REMS Program, the FDA determined that the available data and information support modification of the REMS to reduce burden on the health care delivery system and to ensure the benefits of the product outweigh the risks. After reviewing supplemental applications from the applicants for Mifeprex and the approved generic, the FDA approved a modification to the Mifepristone REMS Program on January 3, 2023. As modified, the Mifepristone REMS Program includes the following requirements, among others:

- Mifepristone must be prescribed by a health care provider that meets certain qualifications and is certified under the Mifepristone REMS Program.
- In order to become certified to prescribe mifepristone, health care providers must complete a Prescriber Agreement Form.
- The Patient Agreement Form must be reviewed with and signed by the patient and the health care provider, and the risks of the mifepristone treatment regimen must be fully explained to the patient before mifepristone is prescribed.
- The patient must be provided with a copy of the Patient Agreement Form and mifepristone Medication Guide (FDA-approved information for patients).
- Mifepristone may only be dispensed by or under the supervision of a certified prescriber, or by a certified pharmacy on a prescription issued by a certified prescriber.
- To become certified to dispense mifepristone, pharmacies must complete a Pharmacy Agreement Form.
- Certified pharmacies must be able to ship mifepristone using a shipping service that provides tracking information.
- Certified pharmacies must ensure mifepristone is dispensed to the patient in a timely manner.

To learn more, please see [Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation \(/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation\)](https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation).

FDA Does Not Recommend Buying Mifepristone Online

Mifepristone prescribed under the Mifepristone REMS Program will be dispensed to you by your health care provider (or someone under the supervision of your health care provider), or by a pharmacy to which your health care provider has submitted your prescription. You can ask your health care provider whether they are certified in the Mifepristone REMS Program (or working under the supervision of someone who is). The FDA does not recommend purchasing mifepristone outside of the Mifepristone REMS Program – e.g. buying it online or personally transporting it from a foreign country. If a person does so, they would be bypassing important safeguards specifically designed to protect their health. Prescription medicines that are approved for use in the United States have been reviewed for safety, effectiveness, and quality by the FDA, and are subject to FDA-regulated manufacturing controls, including inspection of manufacturing facilities. Generally, prescription medicines purchased from foreign sources are not the FDA-approved versions. The FDA does not have regulatory oversight of prescription medicines from outside the legitimate U.S. drug supply chain; therefore, the FDA cannot ensure the safety, effectiveness, or quality of those medications.

To learn more about buying drugs safely, please see [BeSafeRx: Your Source for Online Pharmacy Information \(/drugs/buying-using-medicine-safely/besaferrx-your-source-online-pharmacy-information\)](#)

Related Information

- [Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation \(/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifeprex\)](#)
- Previous REMS
 - [REMS Approved in 2011 \(/media/164648/download?attachment\)](#)
 - [REMS Approved in 2016 \(/media/164649/download?attachment\)](#)
 - [REMS Approved in 2019 \(/media/164650/download?attachment\)](#)
 - [REMS Approved in 2021 \(/media/164651/download?attachment\)](#)
- [Historical Information on Mifepristone \(marketed as Mifeprex\) \(http://wayback.archive-it.org/7993/20161022205309/http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm111334.htm\)](#)
[↗ \(http://www.fda.gov/about-fda/website-policies/website-disclaimer\)](#)

Labeling and Other Important Information

Mifeprex (mifepristone)

- [Mifeprex Prescribing Information \(https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/020687Orig1s0251bl.pdf\)](#)
- [Mifeprex Medication Guide \(https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/020687Orig1s0251bl.pdf#page=16\)](#)
- [Mifeprex Patient Agreement Form \(https://www.accessdata.fda.gov/drugsatfda_docs/remis/Mifepristone_2023_01_03_Patient_Agreement_Form.pdf\)](#)
- [Mifeprex Prescriber Agreement Form \(https://www.accessdata.fda.gov/drugsatfda_docs/remis/Mifepristone_2023_03_23_Prescriber_Agreement_Form_for_Danco_Laboratories_LLC.pdf\)](#)
- [Mifeprex Pharmacy Agreement Form \(https://www.accessdata.fda.gov/drugsatfda_docs/remis/Mifepristone_2023_01_03_Pharmacy_Agreement_Form_Danco_Laboratories.pdf\)](#)

Mifepristone Tablets, 200 mg

- [Mifepristone Tablets, 200 mg Prescribing Information \(/media/164653/download?attachment\)](#)
- [Mifepristone Tablets, 200 mg Medication Guide \(/media/164654/download?attachment\)](#)
- [Mifepristone Tablets, 200 mg Patient Agreement Form \(https://www.accessdata.fda.gov/drugsatfda_docs/remis/Mifepristone_2023_01_03_Patient_Agreement_Form.pdf\)](#)
- [Mifepristone Tablets, 200 mg Prescriber Agreement Form \(https://www.accessdata.fda.gov/drugsatfda_docs/remis/Mifepristone_2023_03_23_Prescriber_Agreement_Form_for_GenBioPro_Inc..pdf\)](#)
- [Mifepristone Tablets, 200 mg Pharmacy Agreement Form \(https://www.accessdata.fda.gov/drugsatfda_docs/remis/Mifepristone_2023_01_03_Pharmacy_Agreement_Form_GenBioPro_Inc.pdf\)](#)

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