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Mifeprex®: FDA Approves Modifications to Mifepristone REMS Program

Danco Laboratories is pleased to announce that on January 3, 2023, the FDA approved Risk Evaluation and Mitigation Strategy (REMS) modifications to the Mifepristone REMS Program.

Key changes include:

- Pharmacies who become certified in the Mifepristone REMS Program may dispense Mifeprex® directly to patients upon receipt of a prescription from a certified Mifeprex® prescriber, provided a Prescriber agreement is provided or on file with the certified pharmacy;

- The "in-person" requirement (that patients see healthcare providers in physical locations) which was temporarily removed during the Public Health Emergency (PHE), is now permanently removed.

To implement these modifications, changes were made to the REMS and the REMS materials including the Prescriber Agreement and the Patient Agreement. A new Pharmacy Agreement was also added to allow the certification of pharmacies. Conforming changes were also made to the Prescribing Information and the Medication Guide. ***The revised Mifepristone REMS Program materials can be found by visiting our website at www.earlyoptionpill.com.***

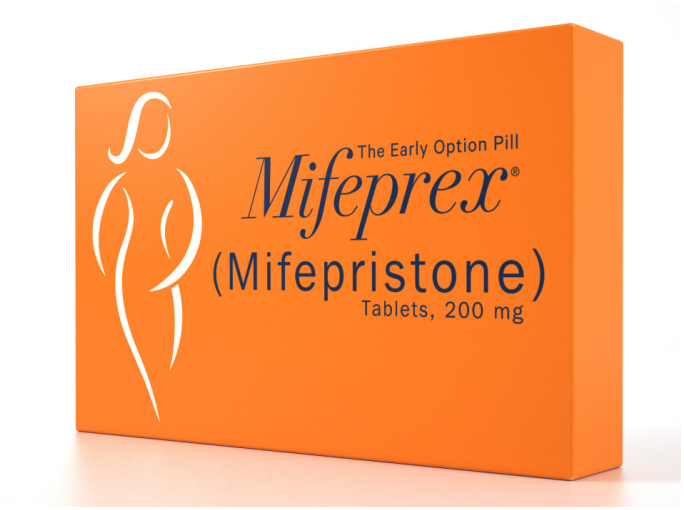
Danco has worked to ensure that the REMS modifications will not disrupt the medication abortion services that are currently being provided by existing Mifeprex providers whether through clinics, medical offices, hospitals or telehealth utilizing our mail order pharmacies, **American Mail Order Pharmacy** (AMOP) and **Manifest Pharmacy**. We expect that there may be an adjustment period for Mifeprex® providers as we implement the changes to the REMS. Current providers will be able to continue provision of Mifeprex under their current Prescriber Agreements for a number of months before an updated Prescriber Agreement must be put in place.

At a time when people across the country are struggling to obtain abortion care services this modification is critically important to expanding access to medication abortion services and will provide healthcare providers with an additional method for providing their patients with a safe and effective option for ending early pregnancy. Danco is proud and honored to continue the work with Mifeprex® providers and the reproductive rights community that has spanned more than two decades.

Mifeprex® was approved for the termination of early pregnancy by FDA on September 28, 2000. In the last 20+ years it has been used by more than 4 million women in the United States. Mifeprex® is 97% effective in terminating early pregnancy, approximately 3% of women will require surgical intervention for ongoing pregnancy, heavy bleeding, incomplete expulsion or other reasons such as patient request.

More Information About Mifeprex®

Mifeprex® is a pill that blocks progesterone, a naturally produced hormone that prepares the lining of the uterus for a fertilized egg and helps maintain pregnancy. Without progesterone the pregnancy cannot continue and the lining of the uterus softens, breaks down and bleeding begins. Mifeprex® is used in a regimen with a prostaglandin, misoprostol, which causes the uterus to contract and helps complete the process.



Serious and sometimes fatal infections and bleeding occur very rarely following spontaneous, surgical, and medical abortions, including following Mifeprex® use. No causal relationship between the use of Mifeprex® and misoprostol and these events has been established. A high index of suspicion is needed to rule out serious and rarely fatal infections (*e.g. Clostridium sordellii*) and sepsis that can present without fever, bacteremia or significant findings on a pelvic exam, with or without abdominal pain, but with leukocytosis with a marked left shift, tachycardia, hemoconcentration, and general malaise.

Danco Laboratories, LLC is a women's health pharmaceutical company that manufactures, markets and distributes Mifeprex® in the United States.

For Prescribing Information, or more information about Mifeprex®, please access the Mifeprex® web site at www.earlyoptionpill.com, or call the Mifeprex® hotline at 1-877-4 Early Option (1-877-432-7596).

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