

# Mifeprex (mifepristone) Information

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Mifeprex (mifepristone) is used, together with another medication called misoprostol, to end an early pregnancy. FDA first approved Mifeprex in 2000. In 2016, the agency approved a supplemental application for Mifeprex based on data and information submitted by the drug manufacturer. After reviewing the supplemental application, the agency determined that Mifeprex is safe and effective when used to terminate a pregnancy in accordance with the revised labeling. In 2019, FDA approved a generic version of Mifeprex, Mifepristone Tablets, 200 mg.

Content current as of:  
12/16/2021

Regulated Product(s)  
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## FDA-Approved Regimen (2016)

Mifepristone is approved, in a regimen with misoprostol, to end a pregnancy through 70 days gestation (70 days or less since the first day of a woman’s last menstrual period). The approved mifepristone dosing regimen is:

- On Day One: 200 mg of Mifeprex taken by mouth
- 24 to 48 hours after taking Mifeprex: 800 mcg of misoprostol taken buccally (in the cheek pouch), at a location appropriate for the patient
- About seven to fourteen days after taking Mifeprex: follow-up with the healthcare provider

## Risk Evaluation and Mitigation Strategy (REMS)

FDA previously approved a REMS for Mifeprex. In 2019, at the same time FDA approved the generic version of Mifeprex, the agency approved a single, shared system REMS for mifepristone products for the medical termination of intrauterine pregnancy through 70 days gestation (the Mifepristone REMS Program). Under the 2019 REMS:

- Mifeprex must be ordered, prescribed and dispensed by or under the supervision of a healthcare provider who prescribes and who meets certain qualifications;
- Healthcare providers who wish to prescribe Mifeprex must complete a Prescriber Agreement Form prior to ordering and dispensing Mifeprex;
- Mifeprex may only be dispensed in clinics, medical offices, and hospitals by or under the supervision of a certified healthcare provider;
- The healthcare provider must obtain a signed Patient Agreement Form before dispensing Mifeprex.

Healthcare providers who prescribe Mifeprex are required under FDA regulations to provide the patient with a copy of the Mifeprex Medication Guide (FDA-approved information for patients).

In 2021 FDA undertook a full review of the Mifepristone REMS Program. Based on that review, FDA has determined that the REMS will include the following elements:

- Mifepristone must be prescribed by or under the supervision of a certified healthcare provider who meets certain qualifications, including signing a Prescriber Agreement Form;
- The healthcare provider must obtain a signed Patient Agreement Form from the patient after counseling and prior to prescribing Mifeprex.
- Pharmacies that dispense mifepristone must be certified.

In accordance with the typical process for REMS modifications, FDA has sent REMS Modification notification letters to the applicants for Mifeprex and the approved generic version of Mifeprex, Mifepristone Tablets, 200 mg. Following receipt of these letters, the applicants prepare proposed REMS modifications and submit them to FDA. Once those submissions are reviewed and approved, the REMS modifications will be effective. The revised REMS document and materials will be available within one day after approval on the FDA website at

<http://www.accessdata.fda.gov/scripts/cder/remis/index.cfm>.

To learn more, including new information added on Dec. 16, 2021, please see [Mifeprex \(mifepristone\) Questions and Answers](#).

### Do Not Buy Mifeprex or its Approved Generic Over the Internet

You should not buy Mifeprex or its approved generic over the Internet because you will bypass important safeguards designed to protect your health.

Mifeprex and its approved generic have special safety restrictions on how it is distributed to the public. Also, drugs purchased from foreign Internet sources are not the FDA-approved versions of the drugs, and they are not subject to FDA-regulated manufacturing controls or FDA inspection of manufacturing facilities.

To learn more about buying drugs safely, please see [BeSafeRx: Your Source for Online Pharmacy Information](#)

## Related Information

- [Questions and Answers on Mifeprex](#)
- [Historical Information on Mifepristone \(marketed as Mifeprex\)](#)

## Labeling and Regulatory History from Drugs@FDA

[Mifeprex \(mifepristone\)](#)

- [Mifepristone \(marketed as Mifeprex\) Prescribing and Label Information](#)
- [Mifeprex label, 2016](#)
- [Mifeprex Medication Guide](#)
- [Mifeprex \(mifepristone\) Patient Agreement Form](#)
- [Mifeprex \(mifepristone\) Prescriber Agreement Form](#)

[Mifepristone Tablets, 200 mg](#)

- [Mifepristone Tablets, 200 mg Medication Guide](#)
- [Mifepristone Tablets, 200 mg Patient Agreement Form](#)
- [Mifepristone Tablets, 200 mg Prescriber Agreement Form](#)

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