

Mifepristone Reporting Guide



Audits and Reporting

Comply with audits to ensure all processes and procedures are completed.

- Maintain all records of Prescriber Agreement Forms, dispensing and shipping, and compliance with processes and procedures for audit purposes.
- Train all relevant staff on the Mifepristone REMS Program requirements.
- Maintain confidentiality except when needed to appropriately dispense and as necessary for payment/insurance purposes.
- Do not distribute, transfer, loan, or sell mifepristone except to certified prescribers or other locations of the pharmacy.
- Report any patient deaths to the prescriber, including NDC and lot number.
 - Remind the prescriber of their obligation to report deaths to the appropriate Mifepristone Sponsor.
 - Notify the Mifepristone Sponsor that the pharmacy submitted a report of death to the prescriber, including the name and contact information for the prescriber and the NDC and lot number of the dispensed product.



Mifepristone Sponsor Links

Follow these links for access contact information for the mifepristone manufacturers.

[Mifeprex® \(mifepristone\) from Danco](#)

[Mifepristone tablets from GenBioPro](#)



FDA Resource Links

[Approved Mifepristone Risk Evaluation and Mitigation Strategy \(REMS\)](#)

[Information about Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation](#)

[Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation](#)