

ACCESSING MIFEPRISTONE FOR MISCARRIAGE MANAGEMENT IN YOUR PRACTICE

Why use it? What makes it hard?

How to start prescribing?

Clinical protocols

FAQ

Connect

Why use mifepristone?

- ▶ To provide the most optimal care to women
- ▶ To be a model for practices across the country



Mifepristone in EPL: success with combined regimen 25% higher than with misoprostol alone by day 3

		Misoprostol	Combine	
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Women receiving combined treatment are 63% less likely to need a procedure (Number needed to treat=7)

Day 8	(81.8%)	(74.5%)	(89.2%)	1.33)
Success by Day 30	248 (83.5%)	113 (75.8%)	135 (91.2%)	1.2 (1.08, 1.33)
Required Procedure	48 (16.2%)	35 (23.5%)	13 (8.8%)	0.37 (0.21, 0.68)

*All successes by day 5 were with 1 dose and no additional interventions (primary outcome for the trial).

**All p-values are $\leq .001$

Data are presented as n (%).

Relative risks (RR) adjusted for site via the Mantel-Haenszel method.

How to start

- ▶ Provider certification
- ▶ Work with your pharmacy to order medication
- ▶ Storage and dispensation requirements
- ▶ Mifepristone Provider Agreement
- ▶ Mifepristone patient agreement



Mifepristone REMS restrictions

- ▶ Healthcare providers who prescribe Mifeprex® must be certified.
 - ▶ Review the prescribing information
 - ▶ Complete the prescriber agreement form
 - ▶ Have pre-specified qualifications.
- ▶ Review and sign Patient Agreement Form with patients
- ▶ Patient receives copy of Patient Agreement Form and Medication Guide
- ▶ Record serial number from each package in each patient's record
- ▶ Report any deaths to the manufacturer, Danco Laboratories



Provider certification requirements for mifepristone

- ▶ Review the prescribing information
- ▶ Complete the prescriber agreement form
- ▶ Have pre-specified qualifications
 - ▶ Ability to assess duration of pregnancy accurately
 - ▶ Ability to diagnose ectopic pregnancies
 - ▶ Ability to provide surgical intervention in cases of incomplete abortion or severe bleeding, or have made plans to provide such care through others
 - ▶ Ability to assure access to facilities equipped to provide blood transfusion and resuscitation if necessary



Administrative requirements

- ▶ Providers sign Provider Agreement
- ▶ All patients who receive mifepristone sign Patient Agreement
- ▶ Serial number for medication logged for each encounter
- ▶ Providers who are certified or under supervision of certified providers may administer



Mifepristone: shipping, storage, and dispensation

- ▶ Medication is shipped to outpatient pharmacy, and delivered to clinic for storage.
- ▶ Federal regulations allow for dispensation or administration



Protocol: medical management of EPL

- ▶ Mifepristone 200 mg orally
- ▶ Misoprostol 800 mcg vaginally approximately 24h afterward
- ▶ May repeat misoprostol dosing in 24h if no passage of POC



FAQ (refer back to website for these)

- ▶ Can I dispense mifepristone for patients to take at home?
- ▶ If a patient starts bleeding after mifepristone, should they receive misoprostol?
- ▶ Will I be on a public provider list if I become certified to provide mifepristone?
- ▶ Can I prescribe mifepristone if I am not certified?
- ▶ Does a patient require a second dose of mifepristone if they need a second dose of misoprostol?

