



## **Information for Patients Selecting Medical Management of Early Pregnancy Loss**

### **Prior to starting the medication:**

- You should feel completely certain that this pregnancy has no chance for survival. We feel confident and have diagnosed a miscarriage by one of the following;
  - Crown Rump length of 7mm or greater and no heartbeat.
  - Mean sac diameter of 25mm or greater and no embryo.
  - Absence of embryo with heartbeat 2 weeks or more after a scan that showed a gestational sac without a yolk sac.
  - Absence of embryo with heartbeat 11 days or more after a scan that showed a gestational sac with a yolk sac.
- Have at home over the counter ibuprofen (Motrin, Advil) and acetaminophen (Tylenol)
- Received prescriptions
  - Mifeprex (mifepristone): makes Cytotec more effective, blocks progesterone
  - Cytotec (Misoprostol): makes the uterus contract and expel the tissue
  - Oxycodone (or another narcotic): pain medicine for more intense pain
- If using Mifeprex the prescription for Mifeprex and Cytotec need to be sent to the same pharmacy. We will also fax the “Patient Agreement” and the “Physicians Agreement” with your prescriptions. You will need to pick up the medications within 4 calendar days of being sent. Prescriptions sent to

CVS East Lansing  
240 M.A.C. Ave,  
East Lansing, MI 48823

### **How to take the medication:**

1. If taking Mifeprex, you would take the 1 pill by mouth 24 hours prior to starting Cytotec
2. On the day of taking Cytotec, place four (4) tablets of 200mcg Cytotec (800mcg total) INTO THE VAGINA as far you can get them and lie flat for 30 minutes.
3. Start taking ibuprofen and acetaminophen for pain control. These medications work in different ways and are safe to take together. Continue to repeat these medications as you need them

Ibuprofen (Motrin, Advil) 600mg by mouth every 6 hours

Acetaminophen (Tylenol) 1000mg by mouth every 6 hours

4. Add the narcotic medication as prescribed if you need additional pain control.
5. Expect moderate to heavy bleeding and cramping. You will pass tissue and clots. This typically starts within 6 hours after the medication and will last for about 2 - 4 hours. Every person's body and process is different. Once the uterus is empty, the bleeding and cramping will rapidly taper off and you will feel tired but well.
6. If you do not have significant cramping and bleeding a second dose of Cytotec can be taken

Call Alliance or go to the University of Michigan - Sparrow Emergency Room if you experience severe pain, fever greater than 100.4 or symptoms that concern you. Some people will run a low grade fever or have diarrhea and nausea from the medicine and this is okay. If you are having excessive bleeding go directly to the University of Michigan - Sparrow Emergency Room. Excessive bleeding is soaking 1 pad per half-hour for 2 hours.

### **After taking the medication:**

Once the miscarriage has passed, we will repeat an ultrasound to make sure the uterus is empty. After the ultrasound we will start weekly blood draws to follow the beta HCG pregnancy hormone down to less than 5. Bleeding may last up to 10 days, but should not be heavy or painful. Expect your first period to begin 3 - 6 weeks after the medication. Once the miscarriage has passed, it is okay to start trying immediately for pregnancy or we can start you on birth control.

Mifeprex<sup>®</sup> (Mifepristone) Tablets, 200 mg, is indicated, in a regimen with misoprostol, for the medical termination of intrauterine pregnancy through 70 days gestation. Please see Prescribing Information and Medication Guide for complete safety information.

**TO BECOME A CERTIFIED PRESCRIBER, YOU MUST:**

**If you submit Mifeprex prescriptions for dispensing from certified pharmacies:**

- Submit this form to each certified pharmacy to which you intend to submit Mifeprex prescriptions. The form must be received by the certified pharmacy before any prescriptions are dispensed by that pharmacy.

**If you order Mifeprex for dispensing by you or healthcare providers under your supervision:**

- Submit this form to the distributor. This form must be received by the distributor before the first order will be shipped to the healthcare setting.
- Healthcare settings, such as medical offices, clinics, and hospitals, where Mifeprex will be dispensed by or under the supervision of a certified prescriber in the Mifepristone REMS Program do not require pharmacy certification.

**Prescriber Agreement:** By signing this form, you agree that you meet the qualifications below and will follow the guidelines for use. You are responsible for overseeing implementation and compliance with the Mifepristone REMS Program. You also understand that if the guidelines below are not followed, the distributor may stop shipping mifepristone to the locations that you identify and certified pharmacies may stop accepting your mifepristone prescriptions.

***Mifepristone must be provided by or under the supervision of a certified prescriber who meets the following qualifications:***

- Ability to assess the 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, and be able to assure patient access to medical facilities equipped to provide blood transfusions and resuscitation, if necessary.
- Has read and understood the Prescribing Information for mifepristone. The Prescribing Information is available by calling 1-877-4 Early Option (1-877-432-7596), or by visiting [www.earlyoptionpill.com](http://www.earlyoptionpill.com).

**In addition to having these qualifications, you also agree to follow these guidelines for use:**

- Ensure that the *Patient Agreement Form* is reviewed with the patient and the risks of the mifepristone treatment regimen are fully explained. Ensure any questions the patient may have prior to receiving mifepristone are answered.
- Ensure the healthcare provider and patient sign the *Patient Agreement Form*.
- Ensure that the patient is provided with a copy of the *Patient Agreement Form* and Medication Guide.
- Ensure that the signed *Patient Agreement Form* is placed in the patient's medical record.
- Ensure that any deaths of patients who received Mifeprex are reported to Danco Laboratories, LLC, identifying the patient by a non-identifiable reference and including the NDC and lot number from the package of Mifeprex that was dispensed to the patient.

**Ensure that healthcare providers under your supervision follow the guidelines listed above.**

**If Mifeprex will be dispensed through a certified pharmacy:**

- Assess appropriateness of dispensing Mifeprex when contacted by a certified pharmacy about patients who will receive Mifeprex more than 4 calendar days after the prescription was received by the certified pharmacy.
- Obtain the NDC and lot number of the package of Mifeprex the patient received in the event the prescriber becomes aware of the death of a patient.

**If Mifeprex will be dispensed by you or by healthcare providers under your supervision:**

- Ensure the NDC and lot number from each package of Mifeprex are recorded in the patient's record.

I understand that a certified pharmacy may dispense mifepristone made by a different manufacturer than that stated on this Prescriber Agreement Form.

Print Name: \_\_\_\_\_ Title: \_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Medical License # \_\_\_\_\_ State \_\_\_\_\_

NPI # \_\_\_\_\_

Practice Name(s): \_\_\_\_\_

Practice Setting Address: \_\_\_\_\_

Email: \_\_\_\_\_ Phone: \_\_\_\_\_ Preferred  email  phone

Return completed form to: [Mifeprex@dancodistributor.com](mailto:Mifeprex@dancodistributor.com)  
or fax to 1-866-227-3343.

*Mifeprex*   
(Mifepristone)  
Tablets, 200 mg

**THE ORIGINAL EARLY OPTION PILL.**



\*MIFEPREX IS A REGISTERED TRADEMARK OF DANCO LABORATORIES, LLC.  
P.O. BOX 4816 · NEW YORK, NY 10185 1-877-4-EARLY-OPTION · (1-877-432-7596)  
[WWW.EARLYOPTIONPILL.COM](http://WWW.EARLYOPTIONPILL.COM)

**PATIENT AGREEMENT FORM**

**Mifepristone**  
Tablets, 200 mg

**Healthcare Providers:** *Counsel the patient on the risks of mifepristone. Both you and the patient must provide a written or electronic signature on this form.*

**Patient Agreement:**

1. I have decided to take mifepristone and misoprostol to end my pregnancy and will follow my healthcare provider's advice about when to take each drug and what to do in an emergency.
2. I understand:
  - a. I will take mifepristone on Day 1.
  - b. I will take the misoprostol tablets 24 to 48 hours after I take mifepristone.
3. My healthcare provider has talked with me about the risks, including:
  - heavy bleeding
  - infection
4. I will contact the clinic/office/provider right away if in the days after treatment I have:
  - a fever of 100.4°F or higher that lasts for more than four hours
  - heavy bleeding (soaking through two thick full-size sanitary pads per hour for two hours in a row)
  - severe stomach area (abdominal) pain or discomfort, or I am "feeling sick," including weakness, nausea, vomiting, or diarrhea, more than 24 hours after taking misoprostol — these symptoms may be a sign of a serious infection or another problem (including an ectopic pregnancy, a pregnancy outside the womb).

My healthcare provider has told me that these symptoms could require emergency care. If I cannot reach the clinic or office right away my healthcare provider has told me who to call and what to do.
5. I should follow up with my healthcare provider about 7 to 14 days after I take mifepristone to be sure that my pregnancy has ended and that I am well.
6. I know that, in some cases, the treatment will not work. This happens in about 2 to 7 out of 100 women who use this treatment. If my pregnancy continues after treatment with mifepristone and misoprostol, I will talk with my provider about a surgical procedure to end my pregnancy.
7. If I need a surgical procedure because the medicines did not end my pregnancy or to stop heavy bleeding, my healthcare provider has told me whether they will do the procedure or refer me to another healthcare provider who will.
8. I have the MEDICATION GUIDE for mifepristone.
9. My healthcare provider has answered all my questions.

**Patient Signature:** \_\_\_\_\_ **Patient Name (print):** \_\_\_\_\_ **Date:** \_\_\_\_\_

**Provider Signature:** \_\_\_\_\_ **Provider Name (print):** \_\_\_\_\_ **Date:** \_\_\_\_\_

*Patient Agreement Forms may be provided, completed, signed, and transmitted in paper or electronically.*