Questions and Answers on Mifeprex

Updated 3/30/2016

1. **What is Mifeprex and how does it work?**
   Mifeprex (mifepristone) is a drug that blocks a hormone called progesterone that is needed for a pregnancy to continue. Mifeprex, when used together with another medicine called misoprostol, is used to end an early pregnancy (70 days or less since the first day of the last menstrual period).

2. **Who should not take Mifeprex?**
   Some women should not take Mifeprex. A woman should not take Mifeprex if it has been more than 70 days since the first day of her last menstrual period, or if she:
   - has an ectopic pregnancy (a pregnancy outside of the uterus)
   - has problems with the adrenal glands (the glands near the kidneys)
   - is currently being treated with long-term corticosteroid therapy (medications)
   - has had an allergic reaction to mifepristone, misoprostol or similar drugs
   - has bleeding problems or is taking anticoagulant (blood thinning) drug products
   - has inherited porphyria
   - has an intrauterine device (IUD) in place (it must be removed before taking Mifeprex)

3. **What changes to the Mifeprex application did the FDA approve on March 29, 2016?**
   The FDA first approved Mifeprex in 2000. In 2016, the agency approved a supplemental application submitted by the drug company that markets Mifeprex. This approval includes changes in the dose of Mifeprex and the dosing regimen for taking Mifeprex and misoprostol (including the dose of misoprostol and a change in the route of misoprostol administration from oral to buccal (in the cheek pouch), the interval between taking Mifeprex and misoprostol, and the location at which the woman may take misoprostol). The approval also modifies the gestational age up to which Mifeprex has been shown to be safe and effective, as well as the process for follow-up after administration of the drug. In addition, the labeling has been revised to meet the current labeling requirements in the FDA’s regulations. The FDA also approved changes to the existing Risk Evaluation and Mitigation Strategy (REMS) to reflect the changes approved in the supplemental application, and to make the Mifeprex REMS consistent with more recently approved REMS.
   Find more information here: [Mifeprex (mifepristone) Information](/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm111323.htm)

4. **Where can women get Mifeprex?**
   Mifeprex is supplied directly to healthcare providers who meet certain qualifications. It is only available to be dispensed in certain healthcare settings, specifically, clinics, medical offices and hospitals, by or under the supervision of a certified prescriber. It is not available in retail pharmacies, and it is not legally available over the Internet.
5. **What qualifications must healthcare providers have to obtain and dispense Mifeprex?**

Healthcare providers who would like to become certified to prescribe Mifeprex must have the ability to date pregnancies accurately and to diagnose ectopic pregnancies. Healthcare providers must also be able to provide any necessary surgical intervention, or have made arrangements for others to provide for such care. Healthcare providers must be able to ensure that women have access to medical facilities for emergency care, and must agree to other responsibilities, including reviewing and signing the Patient Agreement Form with the patient and providing each patient with a copy of the signed Patient Agreement Form and the Medication Guide.

Healthcare providers who prescribe and who meet certain qualifications are authorized to order and dispense Mifeprex. Some states allow healthcare providers other than physicians to prescribe medications. Healthcare providers should check their individual state laws.

6. **Are there restrictions on the distribution of this drug?**

Yes. When the agency reviewed and approved the original new drug application for Mifeprex, it concluded that certain distribution restrictions were necessary to ensure the safe use of the drug. After reviewing the data and information submitted by the drug company that markets Mifeprex, and after taking into consideration the safety data that have become available since the initial approval of Mifeprex in 2000, the FDA concluded that certain restrictions continue to be necessary to ensure the safe use of the drug.

7. **What are the possible side effects of using Mifeprex?**

Cramping and vaginal bleeding are expected effects of the treatment regimen. In some cases very heavy vaginal bleeding will need to be stopped by a surgical procedure, which can often be performed in the office. Other common side effects of the treatment regimen include nausea, weakness, fever/chills, vomiting, headache, diarrhea, and dizziness in the first day or two after taking the two medicines.

The possible side effects are described in the Adverse Reactions section of the labeling and in the Medication Guide for Mifeprex.

8. **What serious adverse events have been reported after Mifeprex use?**

It is not uncommon for the FDA to receive reports of serious adverse events for prescription drugs after they are approved. The FDA has received reports of serious adverse events in women who took Mifeprex. The reports in women who took Mifeprex include one case of ectopic pregnancy resulting in death; several cases of severe systemic infection (also called sepsis), including some that were fatal; and a single case of non-fatal heart attack. At this time, it is unknown whether there is a causal relationship between any of these adverse events and the use of Mifeprex and misoprostol.

As with all approved drugs, when the FDA receives new information regarding adverse events, the agency reviews the new information and, as appropriate, provides updates to doctors and their patients so that they have information on how to use the drug safely.

9. **What should healthcare providers watch for in women who have taken Mifeprex?**

All providers of medical abortion and emergency room healthcare practitioners should investigate the possibility of sepsis in women who are undergoing medical abortion and present with nausea, vomiting, or diarrhea and weakness with or without abdominal pain. These symptoms, even without a fever, may indicate a serious infection. Strong consideration should be given to obtaining a complete blood count in these patients. Significant leukocytosis with a marked left shift and hemoconcentration may be indicative of sepsis.
10. **When can a woman become pregnant again if she takes Mifeprex?**
A woman can become pregnant again right after a pregnancy ends. If a woman does not want to become pregnant, she should start using a birth control method after the pregnancy ends and before she resumes sexual activity.

11. **How much does Mifeprex cost?**
The FDA does not have the authority to regulate the prices of drug products in the United States. Manufacturers, distributors, and retailers establish the prices. Additionally, the FDA has no input into or legal control over whether an insurance company does or does not cover the cost of a drug. Insurance coverage is a decision made by an insurance provider.

12. **Is Mifeprex approved in any other countries?**
Yes, mifepristone has been approved in France since 1998, and also is approved in the United Kingdom, Sweden and approximately 60 other countries.

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