

Medication Guide Mifeprex (MIF-eh-prex) (Mifepristone)

Read this information carefully before taking Mifeprex and misoprostol. It will help you understand how the treatment works. This Medication Guide does not take the place of talking with your health care provider (Family Planning Associates)

What is the most important information I should know about Mifeprex?

Mifeprex is used to end an early pregnancy. It is not approved for ending later pregnancies. Early pregnancy means it is 63 days (9 weeks) or less since your last menstrual period began. By using Mifeprex, you probably will not need a surgical procedure to end your pregnancy.

When you use Mifeprex, you also need to take another medicine called misoprostol. You insert misoprostol 12 to 48 hours after you take Mifeprex.

You need to sign a statement (PATIENT AGREEMENT). Before you get Mifeprex, you will need to read and understand the information in this Medication Guide. Then you will need to sign a statement that you have decided to end your pregnancy.

You must visit Family Planning Associates on Day 1, and about Day 14. See the section called "How should I take Mifeprex?" for information about what happens at each visit. If you do not follow all the steps in "How should I take Mifeprex?" you will not know if your pregnancy has ended.

What to do if you are still pregnant after Mifeprex or Mifeprex with misoprostol treatment. If you are still pregnant, your counselor will talk to you about the other choices you have, including a surgical procedure to end your pregnancy. There is a chance that there may be birth defects if the pregnancy is not ended.

Symptoms to expect. This treatment causes cramping and bleeding. Usually, the symptoms mean that the treatment is working. But sometimes you can get cramping and bleeding and still be pregnant. This is why you **must return** to Family Planning Associates on or about Day 14.

If you are not already bleeding after taking Mifeprex, you probably will begin to bleed once you insert misoprostol. This is a medicine you take 12 to 48 hours after the Mifeprex. Bleeding and spotting can be expected for an average of 9-16 days and may last for up to 30 days. Your bleeding may be similar to, or greater than, a normal heavy period. You may see blood clots and tissue that come from your uterus. This is an expected part of ending the pregnancy.

Heavy bleeding and the need for surgery. In about 1 out of 100 women, bleeding can be so heavy that it requires a surgical procedure (curettage) to stop it. This is why you must talk with your counselor about what to do if you need emergency care to stop heavy and possibly dangerous bleeding.

Before you take Mifeprex. You will be given a 24 hour telephone number to call if you have any questions, concerns, or problems. You will also be given the name and phone number of the person who will handle emergencies.

Talk to your counselor. You and your counselor should discuss the benefits and risks for you of using Mifeprex.

What is Mifeprex?

Mifeprex blocks a hormone needed for your pregnancy to continue. When used together with another medicine called misoprostol, Mifeprex ends your pregnancy. About 5-8 out of 100 women taking Mifeprex will need a surgical procedure to end the pregnancy or to stop too much bleeding.

Who should not take Mifeprex?

Some women should not take Mifeprex. Do not take it if:

- It has been more than 63 days (9 weeks) since your last menstrual period began.
- You have an IUD. It must be taken out before you take Mifeprex.
- You have been told that you have a pregnancy outside the uterus (ectopic pregnancy).
- You have problems with your adrenal glands (chronic adrenal failure).
- You take a medicine to thin your blood.
- You have a bleeding problem.
- You take certain steroid medicines.
- You cannot return for the next visit in 2 weeks.
- You cannot easily get emergency medical help in the 2 weeks after you take Mifeprex.
- You are allergic to mifepristone, misoprostol, or medicines that contain misoprostol, such as Cytotec or Arthrotec.

You must tell Family Planning Associates about all your medical conditions to find out if you can take Mifeprex. Also, tell us if you smoke 10 cigarettes a day or more.

How should I take Mifeprex?

- Day 1 at Family Planning Associates:
 - Read this Medication Guide
 - Discuss the benefits and risks of using Mifeprex to end your pregnancy
 - If you decide Mifeprex is right for you, sign the Patient Agreement and Consent forms
 - After having an ultrasound and lab work, swallow 1 tablet of Mifeprex which will be given to you by Family Planning Associates personnel
- At home, 12 to 48 hours after taking the Mifeprex:
 - You will insert the 4 misoprostol tablets you were given into your vagina.
 - Misoprostol may cause cramps, nausea, diarrhea, and other symptoms. You may call the office if you feel you need medications for these symptoms.
- About Day 14 at Family Planning Associates:
 - This follow-up visit is very important. You must return to Family Planning Associates about 2 weeks after you take Mifeprex to be sure you are well and that you are not pregnant.
 - Family Planning Associates staff will check whether your pregnancy has completely ended. If it has not ended, there is a chance that there may be birth defects. If you are still pregnant, your counselor will talk with you about the other choices you have, including a surgical procedure to end your pregnancy.

What should I avoid while taking Mifeprex and misoprostol?

You should not take certain other medicines, because they may interfere with the treatment. Ask your counselor about what medicines you can take for pain. Do not take any other prescription or non-prescription medicines (including herbal medicines or supplements) at any time during the treatment period without first asking the doctor or nurse at Family Planning Asociates about them.

If you are breastfeeding at the time you take Mifeprex and misoprostol, discuss whether you should stop using your breast milk for a few days.

What are the possible side effects of using Mifeprex?

See the section "What is the most important information I should know about Mifeprex?" for symptoms to expect.

In some cases, bleeding can be very heavy. In a few cases, this bleeding will need to be stopped by a surgical procedure. Contact Family Planning Associates right away if you bleed enough to soak through two thick full-size sanitary pads per hour for two consecutive hours, or if you are concerned about heavy bleeding.

Other side effects of the treatment include diarrhea, nausea, vomiting, headache, dizziness, back pain, and tiredness. These side effects lessen after Day 3 and are usually gone by Day 14. You will be given instructions on how to manage any pain and/or side effects.

If you are worried about any side effects you have, talk with your counselor about them.

If you have any questions, concerns, or problems, please call 24 hours a day. Our number is 602.553.0440.

When should I begin birth control?

You can become pregnant again right after your pregnancy ends. You may discuss birth control options and instructions on starting with your counselor and/or physician.