



MEDICATION GUIDE

Mifepristone (MIF-eh-pris-tone) tablets, 200mg, for oral use

Read this information carefully before taking Mifepristone tablets, 200mg, 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.



GenBioPro

PUTTING ACCESS INTO PRACTICE

What is the most important information I should know about Mifepristone tablets, 200mg?

What symptoms should I be concerned with? Although cramping and bleeding are an expected part of ending a pregnancy, rarely, serious and potentially life-threatening bleeding, infections, or other problems can occur following a miscarriage, surgical abortion, medical abortion, or childbirth. Seeking medical attention as soon as possible is needed in these circumstances. Serious infection has resulted in death in a very small number of cases. There is no information that use of Mifepristone tablets, 200mg, and misoprostol caused these deaths. If you have any questions, concerns, or problems, or if you are worried about any side effects or symptoms, you should contact your health care provider. You can write down your health care provider's telephone number here:

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Be sure to contact your healthcare provider promptly if you have any of the following:

- **Heavy Bleeding.** Contact your healthcare provider 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. In about 1 out of 100 women, bleeding can be so heavy that it requires a surgical procedure (surgical aspiration or D&C).

- **Abdominal Pain or "Feeling Sick."** If you have abdominal pain or discomfort, or you are "feeling sick," including weakness, nausea, vomiting, or diarrhea, with or without fever, more than 24 hours after taking misoprostol, you should contact your health care provider without delay. These symptoms may be a sign of a serious infection or another problem (including an ectopic pregnancy, a pregnancy outside the womb).
- **Fever.** In the days after treatment, if you have a fever of 100.4°F or higher that lasts for more than 4 hours, you should contact your health care provider right away. Fever may be a symptom of a serious infection or another problem.

If you cannot reach your health care provider, go to the nearest hospital emergency room. Take this Medication Guide with you.

When you visit an emergency room or a health care provider who did not give you your Mifepristone tablets, 200mg, you should give them your Medication Guide so that they understand that you are having a medical abortion with Mifepristone tablets, 200mg.

What to do if you are still pregnant after Mifepristone tablets, 200mg, with misoprostol treatment.

If you are still pregnant, your health care provider will talk with you about a surgical procedure to end your pregnancy. In many cases, this surgical procedure can be done in the office/clinic. The chance of birth defects if the pregnancy is not ended is unknown.

Talk with your health care provider. Before you take Mifepristone tablets, 200mg, you should read this Medication Guide and you and your health care provider should discuss the benefits and risks of your using Mifepristone tablets, 200mg.

What is Mifepristone tablets, 200mg?

Mifepristone tablets, 200mg, is used in a regimen with another prescription medicine called misoprostol to end an early pregnancy.

Early pregnancy means it is 70 days (10 weeks) or less since your last menstrual period began. Mifepristone tablets, 200mg, is not approved for ending pregnancies that are further along. Mifepristone tablets, 200mg, blocks a hormone needed for your pregnancy to continue. When you use Mifepristone tablets, 200mg, on Day 1, you also need to take another medicine called misoprostol 24 to 48 hours after you take Mifepristone tablets, 200mg, to cause the pregnancy to be passed from your uterus.

The pregnancy is likely to be passed from your uterus within 2 to 24 hours after taking Mifepristone tablets, 200mg, and misoprostol. When the pregnancy is passed from the uterus, you will have bleeding and cramping that will likely be heavier than your usual period. About 2 to 7 out of 100 women taking Mifepristone tablets, 200mg, will need a surgical procedure because the pregnancy did not completely pass from the uterus or to stop bleeding.

Who should not take Mifepristone tablets, 200mg?

Some women should not take Mifepristone tablets, 200mg. Do not take Mifepristone tablets, 200mg, if you:

- Have a pregnancy that is more than 70 days (10 weeks). Your health care provider may do a clinical examination, an ultrasound examination, or other testing to determine how far along you are in pregnancy.
- Are using an IUD (intrauterine device or system). It must be taken out before you take Mifepristone tablets, 200mg.
- Have been told by your health care provider that you have a pregnancy outside the uterus (ectopic pregnancy).
- Have problems with your adrenal glands (chronic adrenal failure).
- Take a medicine to thin your blood.
- Have a bleeding problem.
- Have porphyria.
- Take certain steroid medicines.
- Are allergic to mifepristone, misoprostol, or medicines that contain misoprostol, such as Cytotec or Arthrotec.

Ask your health care provider if you are not sure about all your medical conditions before taking this medicine to find out if you can take Mifepristone tablets, 200mg.

What should I tell my health care provider before taking Mifepristone tablets, 200mg?

Before you take Mifepristone tablets, 200mg, tell your health care provider if you:

- Cannot follow up within approximately 7 to 14 days of your first visit.
- Are breastfeeding. Mifepristone tablets, 200mg, can pass into your breast milk. The effect of the Mifepristone tablets, 200mg, and misoprostol regimen on the breastfed infant or on milk production is unknown.
- Are taking medicines, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Mifepristone tablets, 200mg, and certain other medicines may affect each other if they are used together. This can cause side effects.

How should I take Mifepristone tablets, 200mg?

- Mifepristone tablets, 200mg, will be given to you by a health care provider in a clinic, medical office, or hospital.
- You and your health care provider will plan the most appropriate location for you to take the misoprostol, because it may cause bleeding, cramps, nausea, diarrhea, and other symptoms that usually begin within 2 to 24 hours after taking it.
- Most women will pass the pregnancy within 2 to 24 hours after taking the misoprostol tablets.

Follow the instruction below on how to take Mifepristone tablets, 200mg, and misoprostol: Mifepristone tablets, 200mg, (1 tablet) orally + misoprostol (4 tablets) buccally

Day 1:

- Take 1 Mifepristone 200mg tablet by mouth.
- Your health care provider will either give you or prescribe for you 4 misoprostol tablets to take 24 to 48 hours later.

24 to 48 hours after taking Mifepristone tablets, 200mg:

- Place 2 misoprostol tablets in each cheek pouch (the area between your teeth and cheek—see Figure A) for 30 minutes and then swallow anything left over with a drink of water or another liquid.

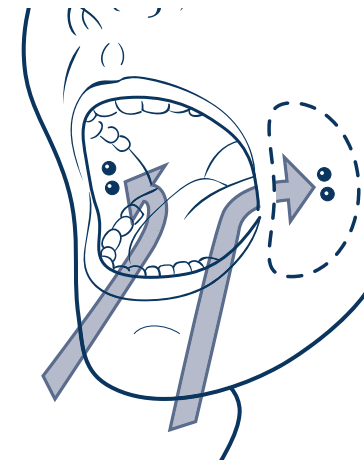


Figure A

*2 tablets between your left cheek and gum and
2 tablets between your right cheek and gum.*

- The medicines may not work as well if you take misoprostol sooner than 24 hours after Mifepristone tablets, 200mg, or later than 48 hours after Mifepristone tablets, 200mg.
- Misoprostol often causes cramps, nausea, diarrhea, and other symptoms. Your health care provider may send you home with medicines for these symptoms.

Follow-up Assessment at Day 7 to 14:

- This follow-up assessment is very important. You must follow up with your health care provider about 7 to 14 days after you have taken Mifepristone tablets, 200mg, to be sure you are well, that you have had bleeding, and the pregnancy has passed from your uterus.
- Your health care provider will assess whether your pregnancy has passed from your uterus. If your pregnancy continues, the chance that there may be birth defects is unknown. If you are still pregnant, your healthcare provider will talk with you about a surgical procedure to end your pregnancy.
- If your pregnancy has ended, but not yet completely passed from your uterus, your provider will talk with you about other choices you have, including waiting, taking another dose of misoprostol, or having a surgical procedure to empty your uterus.

When should I begin birth control?

You can become pregnant again right after your pregnancy ends. If you do not want to become pregnant again, start using birth control as soon as your pregnancy ends or before you start having sexual intercourse again.

What should I avoid while taking Mifepristone tablets, 200mg, and misoprostol?

Do not take any other prescription or over-the-counter medicines (including herbal medicines or supplements) at any time during the treatment period without first asking your health care provider about them because they may interfere with the treatment. Ask your health care provider about what medicines you can take for pain and other side effects.

What are the possible side effects of Mifepristone tablets, 200mg, and misoprostol?

Mifepristone tablets, 200mg, may cause serious side effects. See “What is the most important information I should know about Mifepristone tablets, 200mg?”

Cramping and bleeding. Cramping and vaginal bleeding are expected with this treatment. Usually, these symptoms mean that the treatment is working. But sometimes you can get cramping and bleeding and still be pregnant. This is why you must follow up with your healthcare provider approximately 7 to 14 days after taking Mifepristone tablets, 200mg. See “How should I take Mifepristone tablets, 200mg?” for more information on your follow-up assessment. If you are not already bleeding after taking Mifepristone tablets, 200mg, you probably will begin to bleed once you take misoprostol, the medicine you take 24 to 48 hours after Mifepristone tablets, 200mg. Bleeding or spotting can be expected for an average of 9 to 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. This is an expected part of passing the pregnancy.

The most common side effects of Mifepristone tablets, 200mg, treatment include: nausea, weakness, fever/chills, vomiting, headache, diarrhea, and dizziness. Your provider will tell you how to manage any pain or other side effects. These are not all the possible side effects of Mifepristone tablets, 200mg.

Call your health care provider for medical advice about any side effects that bother you or do not go away. You may report side effects to FDA at 1-800-FDA-1088.

General information about the safe and effective use of Mifepristone tablets, 200mg.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. This Medication Guide summarizes the most important information about Mifepristone tablets, 200mg. If you would like more information, talk with your health care provider. You may ask your health care provider for information about Mifepristone tablets, 200mg, that is written for health care professionals.

For more information about
Mifepristone tablets, 200mg, go to
www.MIFEINFO.com
or call
1-855-MIFEINFO
(1- 855-643-3463).