

MEDICATION GUIDE

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

Read this information carefully before taking Mifepristone tablets, 200 mg and misoprostol. It will help you understand how the treatment works. This Medication Guide does not take the place of talking with your healthcare provider.

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

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, 200 mg 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 healthcare provider. You can write down your healthcare provider's telephone number here _____.

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 healthcare 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 healthcare provider right away. Fever may be a symptom of a serious infection or another problem.

If you cannot reach your healthcare provider, go to the nearest hospital emergency room.

What to do if you are still pregnant after Mifepristone tablets, 200 mg with misoprostol treatment. If you are still pregnant, your healthcare 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 healthcare provider. Before you take Mifepristone tablets, 200 mg, you should read this Medication Guide and you and your healthcare provider should discuss the benefits and risks of your using Mifepristone tablets, 200 mg.

What is Mifepristone tablets, 200 mg?

Mifepristone tablets, 200 mg 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, 200 mg is not approved for ending pregnancies that are further along. Mifepristone tablets, 200 mg blocks a hormone needed for your pregnancy to continue. When you use Mifepristone tablets, 200 mg on Day 1, you also need to take another medicine called misoprostol 24 to 48 hours after you take Mifepristone tablets, 200 mg, 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, 200 mg 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, 200 mg 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, 200 mg?

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

- Have a pregnancy that is more than 70 days (10 weeks). Your healthcare 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, 200 mg.
- Have been told by your healthcare 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 healthcare provider if you are not sure about all your medical conditions before taking this medicine to find out if you can take Mifepristone tablets, 200 mg.

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

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

- cannot follow-up within approximately 7 to 14 days of your first visit
- are breastfeeding. Mifepristone tablets, 200 mg can pass into your breast milk. The effect of the Mifepristone, tablets, 200 mg 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, 200 mg and certain other medicines may affect each other if they are used together. This can cause side effects.

How should I take Mifepristone tablets, 200 mg?

- Mifepristone tablets, 200 mg will be given to you by a healthcare provider or pharmacy.
- You and your healthcare 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, 200 mg and misoprostol:

Mifepristone tablets, 200 mg (1 tablet) orally + misoprostol (4 tablets) buccally

Day 1:

- Take 1 Mifepristone 200 mg tablet by mouth.

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

- Take 4 misoprostol tablets by placing 2 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.
- The medicines may not work as well if you take misoprostol sooner than 24 hours after Mifepristone tablets, 200 mg or later than 48 hours after Mifepristone tablets, 200 mg.
- Misoprostol often causes cramps, nausea, diarrhea, and other symptoms. Your healthcare provider may send you home with medicines for these symptoms.



Figure A (2 tablets between your left cheek and gum and 2 tablets between your right cheek and gum).

Follow-up Assessment at Day 7 to 14:

- This follow-up assessment is very important. You must follow-up with your healthcare provider about 7 to 14 days after you have taken Mifepristone tablets, 200 mg to be sure you are well and that you have had bleeding and the pregnancy has passed from your uterus.
- Your healthcare 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 has 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, 200 mg 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 healthcare provider about them because they may interfere with the treatment. Ask your healthcare provider about what medicines you can take for pain and other side effects.

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

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

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, 200 mg. See “How should I take Mifepristone tablets, 200 mg?” for more information on your follow-up assessment. If you are not already bleeding after taking Mifepristone tablets, 200 mg, you probably will begin to bleed once you take misoprostol, the medicine you take 24 to 48 hours after Mifepristone tablets, 200 mg. 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, 200 mg 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, 200 mg.

Call your healthcare 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, 200 mg.

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, 200 mg. If you would like more information, talk with your healthcare provider. You may ask your healthcare provider for information about Mifepristone tablets, 200 mg that is written for healthcare professionals.

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

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This Medication Guide has been approved by the U.S. Food and Drug Administration.
Approval 01/2023