What is this medicine?

MIFEPRISTONE (mi FE pri stone) is a hormone-like drug. It is used in combination with other medicines to end an early pregnancy (usually during the first 7 weeks). This medicine is only available in a doctor’s office, health clinic, or hospital.

This medicine may be used for other purposes; ask your health care provider or pharmacist if you have questions.

How should I use this medicine?

Take this medicine by mouth with a glass of water. Follow the directions on the prescription label. Before you take this medicine, read the information your doctor or health care provider gives you. Talk to your doctor about any questions you have. Take your medicine exactly as directed. Do not take your medicine more often than directed. Do not stop taking except on your doctor’s advice.

A special MedGuide will be given to you by the pharmacist with each prescription and refill. Be sure to read this information carefully each time.

Talk to your pediatrician regarding the use of this medicine in children. This medicine is not approved for use in children.

Overdosage: If you think you have taken too much of this medicine contact a poison control center or emergency room at once.

NOTE: This medicine is only for you. Do not share this medicine with others.

What should I tell my health care provider before I take this medicine?

They need to know if you have any of these conditions:

- Adrenal gland problems
- Bleeding problems
- Cannot easily get emergency medical help in the 2 weeks after you take this medicine
- Cannot return for follow up appointments after you take this medicine
- Have intrauterine device (IUD)
- It has been more than 49 days (7 weeks) since your last menstrual period began
- Other medical problem
- Porphyria
- Take medicines that treat or prevent blood clots like enoxaparin, warfarin
- Take steroid medicines like prednisone or cortisone
- Tubal or ectopic pregnancy
- An unusual or allergic reaction to mifepristone, misoprostol, prostaglandins, or other medicines, foods, dyes, or preservatives
- Pregnant or trying to get pregnant
- Breast-feeding

What may interact with this medicine?

Do not take this medicine with any of the following medications:

- Cerivastatin
- Cisapride
- Dofetilide
- Medicines that treat or prevent blood clots like enoxaparin, warfarin
- Pimozide
- Ranolazine
- Steroid medicines like prednisone or cortisone

This medicine may also interact with the following medications:

- Erythromycin
- Grapefruit juice
- Medicines for fungal infections like ketoconazole, itraconazole
- Medicines for seizures like carbamazepine, phenytoin, phenobarbital
- Medicines used in surgery for anesthesia

What if I miss a dose?

This does not apply.
• Rifampin
• St. John’s wort or other herbal products

This list may not describe all possible interactions. Give your health care provider a list of all the medicines, herbs, non-prescription drugs, or dietary supplements you use. Also tell them if you smoke, drink alcohol, or use illegal drugs. Some items may interact with your medicine.

What side effects may I notice from receiving this medicine?

Side effects that you should report to your doctor or health care professional as soon as possible:
• Allergic reactions like skin rash, itching or hives, swelling of the face, lips, or tongue
• Breathing problems
• Fast, irregular heartbeat
• Feeling faint, lightheaded
• Fever
• Stomach pain
• Unusually weak or tired
• Vaginal discharge with bad smell

Side effects that usually do not require medical attention (report to your doctor or health care professional if they continue or are bothersome):
• Back pain
• Diarrhea
• Headache
• Loss of appetite
• Nausea, vomiting
• Stomach cramps
• Vaginal bleeding

This list may not describe all possible side effects. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

What should I watch for while using this medicine?

For your safety, you must visit your doctor as directed after taking this medicine. Report any unusual effects to your doctor. This medicine can cause birth defects. You will need surgery if this medicine fails to cause a full abortion.

After you take this medicine, some vaginal bleeding is normal. Heavy bleeding may be a sign that something is wrong. If you soak through 2 thick full-size sanitary pads each hour for 2 hours, get medical help right away. Tell the health care provider that you have taken this medicine.

Call your doctor if you have a fever, stomach pain or tenderness, nausea, vomiting, diarrhea, or feel weak. This may be a sign that something is wrong. You may have a serious infection or complication and need medical help.

Keep the MedGuide for this medicine. If you need emergency medical care, show your healthcare provider the MedGuide.

Where should I keep my medicine?

This drug is given in a hospital or clinic and will not be stored at home.

NOTE: This sheet is a summary. It may not cover all possible information. If you have questions about this medicine, talk to your doctor, pharmacist, or health care provider.