



Facts about Mifepristone (RU-486)

The FDA has issued a public health advisory about mifepristone. Read it at <http://www.fda.gov/cder/drug/infopage/mifepristone/default.htm>.

What is Mifepristone?

Mifepristone (formerly known as RU-486) is a medication that blocks the action of the hormone progesterone. Progesterone is needed to sustain a pregnancy. Mifepristone has been used, in combination with other medications called prostaglandins, for medical abortion since 1988 in France and China, and since the early 1990's in the United Kingdom and Sweden. It has been licensed for use in 37 countries including the United States where it was approved in September 2000. Millions of women worldwide have safely used mifepristone regimens to end their pregnancies.

How mifepristone works to end pregnancy

Mifepristone blocks the action of progesterone, which is needed to sustain a pregnancy. This results in:

- Changes in the uterine lining and detachment of the pregnancy
- Softening and opening of the cervix
- Increased uterine sensitivity to prostaglandin

In the U.S., mifepristone is used in combination with another medication, a synthetic prostaglandin called misoprostol. Misoprostol causes the uterus to contract, and helps the pregnancy tissue to expel.

How effective is the combination of mifepristone and misoprostol in terminating an early pregnancy?

Depending on the prescribing physician's protocols, mifepristone and misoprostol can be used for early abortion up to 63 days after the start of the last menstrual period. Approximately 95-98% of women will have a complete abortion when using mifepristone/misoprostol. Success rates may depend on the treatment regimen and the duration of the pregnancy. The remaining women will need a suction procedure, either because of ongoing or excessive bleeding, an incomplete abortion (tissue remains in the uterus but there is no growing embryo), or an ongoing pregnancy (a viable growing pregnancy, which occurs in less than 1% of cases).

Treatment regimen with mifepristone/misoprostol

Clinical studies have shown that several variations in mifepristone/misoprostol treatment regimens are safe and effective. Generally, however, once a woman has decided to have a medical abortion, there are three steps in the process of a medical abortion:

Step One (at the medical office or clinic)

- A medical history is taken and a clinical exam and lab tests are performed.
- Counseling is completed and informed consent is obtained.
- If eligible for medical abortion, the woman swallows the mifepristone pill(s).

Step Two (at the office/clinic or at home depending on the treatment regimen)

- This step takes place within about 2 days of step one.
- Unless abortion has occurred and has been confirmed by the clinician, the woman uses misoprostol. Misoprostol tablets

may be swallowed, placed between cheek and gum, or inserted into the vagina, depending on the treatment regimen.

Step Three (at the office or clinic)

- This step takes place within about 2 weeks of step two.
- The clinician evaluates the woman to confirm a complete abortion. It is essential for women to return to the office/clinic to confirm that the abortion is complete.
- If there is an ongoing pregnancy, a suction abortion should be provided.
- If there is an incomplete abortion, the clinician will discuss possible treatment options with the woman. These may include waiting and re-evaluating for complete abortion in a number of days or performing a suction procedure.

Possible side effects of a mifepristone abortion

Side effects, such as pain, cramping and vaginal bleeding, result from the abortion process itself, and are therefore expected with a medical abortion. Other side effects may include nausea, vomiting, diarrhea, chills, or fever. Complications are rare, but may include infection, excessive vaginal bleeding requiring transfusion (occurs in approximately 1 in 500 cases), incomplete abortion or ongoing pregnancy which requires a suction abortion (see above). In exceedingly rare instances, as with miscarriage, suction abortion and childbirth, death may occur. Reports of death after medical abortion are very rare – less than 1 in 100,000 cases – a rate comparable to that for early surgical abortion and for miscarriage.¹

What women can expect from a mifepristone abortion

- Medical abortion with mifepristone/misoprostol requires at least two visits to a medical office or clinic.
- Following established treatment regimens, approximately 95-98% of women using mifepristone/misoprostol will have a complete medical abortion.
- Complete abortion generally occurs more quickly when misoprostol is used vaginally rather than orally.
- In most cases, bleeding will begin within several hours of using vaginal misoprostol.
- Approximately two-thirds of women will have a complete medical abortion within 4 hours of using oral misoprostol.
- Approximately 90% of women will have a complete medical abortion within 24 hours of using oral misoprostol.
- On average, women may expect to have bleeding and/or spotting for 9-16 days.
- Women may pass clots, ranging in size.
- Some women may see whitish pregnancy tissue.
- If the medications fail to end the pregnancy, a suction abortion should be provided. For this reason, a woman who chooses medical abortion must be willing to have a suction abortion if needed.

References

¹ Grimes, DA. Risk of mifepristone abortion in context. *Contraception*. 2005;71:161.

For More Information

For information or referrals to qualified abortion providers, call the National Abortion Federation's toll-free hotline: 1-800-772-9100.

Weekdays: 8:00A.M.- 9:00P.M.

Saturdays: 9:00A.M.- 5:00P.M. Eastern time.

For more information on Medical Abortion, please visit www.earlyoptions.org.

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