

# Medical Abortion in the United States: Mifepristone Fact Sheet

# Mifepristone Medical Abortion

Medical abortion regimens using mifepristone continue to gain support worldwide as **safe and effective alternatives** to surgical abortion in the first trimester. Mifepristone medical abortion requires the use of two drugs: mifepristone and misoprostol. Mifepristone, an anti-progestin, blocks receptors of the hormone progesterone, a hormone necessary to sustain a pregnancy. The drug also facilitates cervical dilation. The second drug, the prostaglandin misoprostol, stimulates contractions and further dilates the cervix, completing the abortion.

## Mifepristone Providers in the United States

Mifepristone is distributed only to **qualified healthcare providers**, including private practice physicians (not limited by specialty or type of practice) as well as to doctors in clinics. It is not available at pharmacies.

- In order to provide mifepristone medical abortion, the U.S. Food and Drug Administration (FDA) requires that physicians be able to:
  - o Date the age of the pregnancy,
  - o Diagnose ectopic pregnancy, and
  - o Provide or arrange referral for surgical completion.
- Mifepristone is available in all 50 states, Washington, DC, Guam, and Puerto Rico.

# Mifepristone Regimens in the United States

On September 28, 2000, the FDA approved Mifeprex®, the brand-name for mifepristone in the U.S., for medical abortion up to 49 days from the first day of the last menstrual period (LMP) using a three step regimen:

- Step One Visit to a qualified healthcare provider and administration of 600 mg mifepristone.
- Step Two Two days after taking mifepristone, administer 400 µg oral misoprostol, unless complete termination can be confirmed.
- Step Three Follow-up visit in approximately 14 days to confirm complete termination of pregnancy.

Based on extensive experience and numerous studies, other regimens are common. Currently, the most commonly used regimen in the United States is 200 mg mifepristone, followed in 24 to 48 hours with 800  $\mu$ g vaginal misoprostol up to 63 days LMP. Evidence-based, off-label drug use is common, safe, and standard medical practice.<sup>1</sup>

### Safety

Mifepristone medical abortion is as safe as or safer than alternatives.

- Approximately **400,000 women** in the U.S. have used mifepristone for medical abortion since it was first approved in 2000.
- Discomfort and symptoms such as cramping and vaginal bleeding are associated with and are expected consequences of mifepristone medical abortion.
- Mifepristone has a very low rate of serious adverse events. Out of the 43,153 patients at Planned Parenthood clinics who received mifepristone for medical abortion in 2003, about one in 200 women reported adverse events. Two-thirds of these reports were of continuing pregnancies requiring surgical completion. About one in 6,200 had infection requiring IV antibiotics. Fewer than one in 900 required treatment in an emergency room for heavy bleeding and only one in about 2,225 received a transfusion.<sup>2</sup>
- Mifepristone medical abortion is as safe as surgical abortion and associated with the same risks as a natural miscarriage. Maternal death during and after childbirth is more likely than following mifepristone medical abortion.<sup>3</sup>

### **Benefits**

Mifepristone medical abortion has several advantages over surgical abortion. Mifepristone medical abortion avoids the risks associated with surgical abortion, such as uterine perforation and complications caused by anesthesia.

- Many women prefer medical over surgical abortion because it is **noninvasive**, **more natural**, and more private.<sup>4</sup>
- When given a choice between medical and surgical abortion, the majority of women choose the medical option.<sup>5</sup>
- 96% of women in clinical trials of mifepristone said they would **recommend this method to a friend**.<sup>6</sup>

### For More Information

- Danco Laboratories, Mifeprex website. www.earlyoptionpill.com
- FDA, Center for Drug Evaluation and Research, Mifepristone Information. www.fda.gov/cder/drug/infopage/mifepristone/default.htm
- Richard Hausknecht, "Mifepristone and Misoprostol for Early Medical Abortion: 18 Months Experience in the United States," *Contraception* 67:463-65 (2003).
- National Abortion Federation, Facts About Mifepristone.
   www.prochoice.org/about\_abortion/facts/facts\_mifepristone.html

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<sup>&</sup>lt;sup>1</sup> National Abortion Federation, "Early Medical Abortion with Mifepristone and Other Agents: Overview and Protocol Recommendations," (2002). Available at:

http://www.prochoice.org/pubs\_research/publications/downloads/professional\_education/medical\_abortion/early\_med\_abortion\_overview\_2002.pdf

<sup>&</sup>lt;sup>2</sup> Planned Parenthood / CAPS Medical Abortion Training Program, "Three Years in Review," *Mife Matters,* (Spring 2004). Related publication forthcoming in *Contraception,* (Sept 2005).

<sup>&</sup>lt;sup>3</sup> Grimes D, "Risks of Mifepristone Abortion in Context," *Contraception* 71:161 (2005).

<sup>&</sup>lt;sup>4</sup> Population Council. Mifepristone, At Last, *Momentum,* (Jan 2001). Available at: http://www.popcouncil.org/publications/momentum/momentum1200\_1.html

Sjones R, Henshaw S, "Mifepristone for Early Medical Abortion: Experiences in France, Great Britain and Sweden," *Perspectives on Sexual and Reproductive Health* 34:154-61 (2002), citing Cameron et al., "Impact of the Introduction of New Medical Methods on Therapeutic Abortions at the Royal Infirmary in Edinburgh," *British J. of Obstetrics & Gynaecology*, (1996) and Winikoff B. "Acceptability of Medical Abortion in Early Pregnancy," *Family Planning Perspectives*, (1995).

<sup>&</sup>lt;sup>6</sup> Winikoff B, Ellertson C, Elul B, and Sivin I, "Acceptability and Feasibility of Early Pregnancy Termination by Mifepristone-Misoprostol," *Archives of Family Medicine* 7:360-66 (1998).