



Association of
Reproductive
Health
Professionals

What You Need to Know Mifepristone Safety Overview

For over 15 years, medical evidence has indicated that mifepristone (Mifeprex®) is as safe or safer than commonly used medications such as over-the-counter non-steroidal anti-inflammatory drugs and anti-histamines, and is less risky than continuing a pregnancy to term. In 2007, however, anti-choice legislators re-introduced the RU-486 Suspension and Review Act, a bill to halt distribution and sale of mifepristone in the US. Despite mifepristone's established safety record, the bill asserts that mifepristone "has caused a significant number of deaths, near deaths, and adverse reactions."

Mifepristone's Safety Is Well-Established

Worldwide, millions of women have used mifepristone for safe and effective early abortion. It is approved for use in 38 countries and has been used for nearly 20 years in Europe. In the first 18 months after mifepristone approval in the US, an estimated 80,000 women were treated; 139 experienced an adverse event.¹ These events—including rash, elevated liver enzymes, medical conditions unrelated to mifepristone use, the need for an aspiration procedure, as well as one death from ectopic pregnancy—occurred at a rate of less than 1% (0.17%, or 170 per 100,000 women treated; see table). Of the more than 850,000 US women who have used mifepristone for early abortion since its approval nearly eight years ago, seven deaths have occurred, one from a ruptured ectopic pregnancy and the others from overwhelming *Clostridium* infections after women used mifepristone orally and misoprostol vaginally (6 cases) and buccally (1 case). One of these deaths occurred during a clinical trial in Canada. In five of the infection cases, the organism was identified as *Clostridium sordellii*, an organism which has been seen in rare infections associated with both childbirth and abortion. The sixth case involved infection with *Clostridium perfringens*. No causal relationship between

Use of mifepristone (Mifeprex®) has been associated with fewer deaths than Tylenol or Viagra, and is safer than full term pregnancy.

the use of mifepristone and misoprostol and these events has been established.²

Comparing Medical Risks of Other Medications

Mifepristone is safer than acetaminophen (Tylenol®), Aspirin®, and sildenafil (Viagra®). Adverse drug events are not uncommon, even with well-accepted and widely used medications. For example, accidental acetaminophen overdose is the single most common cause of catastrophic liver failure in the US, causing approximately 150 deaths annually.³ The American Association of Poison Control Centers reported 59 deaths from aspirin poisoning in 2003. Estimates of the number of excess deaths due to gastrointestinal bleeding from use of aspirin and other non-steroidal anti-inflammatory drugs (such as ibuprofen) range in the thousands.⁴ From 1993 to 2000, the US Food and Drug Administration received over 4,000 adverse event reports, including 55 reports of death, involving loratadine (Claritin®), a drug which recently gained over-the-counter status.⁵ Among users of sildenafil, there have been approximately five deaths for every 100,000 prescriptions provided.⁶ According to the manufacturer, Pfizer, more than 23 million men worldwide have been prescribed the erectile dysfunction medication Viagra and more than 1 billion prescriptions have been written.

Comparing Medical Risks of Continuing Pregnancy to Term

A medication abortion with mifepristone is safer than a full term pregnancy, which is often associated with complications; full-term pregnancy being most risky. Complications of pregnancy and delivery are common enough that at least 20 to 25% of women require cesarean section, a major surgery. Pregnancy-related deaths, including those at delivery, stillbirth, and ectopic pregnancy, claim the lives of two to three US women every day—with 13 deaths reported for every 100,000 live births in 1999 (see figure).⁷

Quick Facts

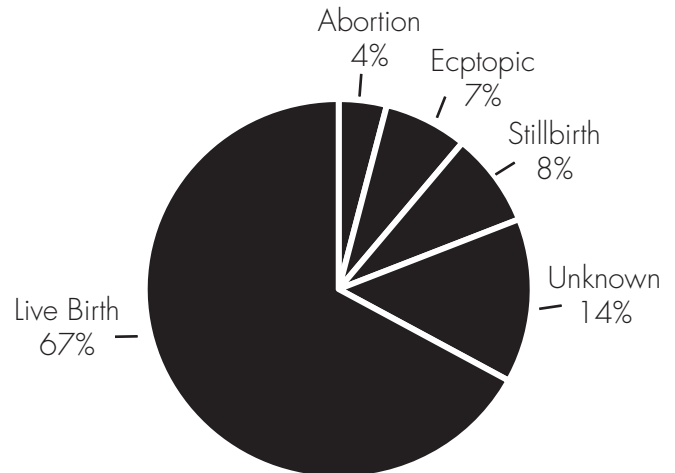
Product	Associated Deaths
Tylenol	150/year
Pregnancy Related	13/100,000 live births
Viagra	5/100,000 prescriptions
Mifepristone	1/100,000 prescriptions

www.arhp.org/factsheets

What You Need to Know is a publication of the Association of Reproductive Health Professionals (ARHP) for health care professionals, educators, and researchers working in the field of reproductive health.

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2. U.S. Food and Drug Administration. *Questions and Answers on Mifeprex (mifepristone)*. August 2007. Available at www.fda.gov/cder/drug/infopage/mifepristone/qa2007.htm Accessed on February 26, 2008.
3. Ostapowicz G, Fontana R, Schiodt F, et al. Results of a prospective study of acute liver failure at 17 tertiary care centers in the United States. *Ann Intern Med* 2002;137(12):947-954.
4. McNeil Consumer & Specialty Pharmaceuticals. *Aspirin and other OTC NSAIDs* Background information for Nonprescription Drugs Advisory Committee Meeting, September 20, 2002.
5. US Food and Drug Administration. *Executive Summary on Risk Issues Draft* presented at joint meeting of the Nonprescription Drugs Advisory Committee and the Pulmonary — Allergy Drugs Advisory Committee. May 11, 2001.
6. Mitka M. Some men who take Viagra die—why? *JAMA* 2000;283(5):5901-5591.
7. Chang J, Elam-Evans L, Berg C, et al. Pregnancy-related mortality surveillance—United States, 1991-1999. *MMWR* 2003;52(SS02):1-14.

Distribution of pregnancy-related deaths by outcome of pregnancy 1991-1999



EVENT	NUMBER	PERCENT	RATE/100,000
Patient sought treatment for side effects, no intervention required	14	0.018%	18
Allergic reaction (hives), treated with oral medication	6	0.0075%	7.5
Aspiration procedure for bleeding or persistent gestational sac	69	0.086%	86
Continuing pregnancy (requiring aspiration procedure for termination of pregnancy)	50	0.063%	63
Infection requiring antibiotics	10	0.013%	13
Blood transfusion	13	0.016%	16
Ectopic pregnancy (unrecognized)	5	0.0063%	6.3
Breast abscess from insect bite resulting in toxic shock syndrome	1	0.0013%	1.3
Disseminated intravascular coagulation	1	0.0013%	1.3
Myocardial infarction	1	0.0013%	1.3
Death (from ruptured ectopic pregnancy)	1	0.0013%	1.3
Overall event rate	139	0.17%	170