

# What is RU-486?

Definition: RU-486 is the name commonly used for an artificial steroid that blocks progesterone, a hormone needed to continue a pregnancy.

## Do NOT use Mifeprex if:

- you are allergic to any ingredient in Mifeprex, misoprostol, or similar medicines
- you are taking blood thinners (eg, warfarin, heparin) or corticosteroids (eg, prednisone, dexamethasone)
- you have an intrauterine device (IUD) in place
- you have a pregnancy outside the uterus (ectopic pregnancy)
- you have adrenal gland problems (chronic adrenal failure) or Addison disease
- you have bleeding problems or certain blood problems (eg, porphyria)
- you have an undiagnosed growth in the abdomen
- you are unable to follow-up with your health care provider or you are unable to get emergency medical care for any serious problems that might occur within several weeks after taking Mifeprex
- you do not understand the effects of Mifeprex, the follow-up treatment procedures, or you are unable to comply with the instructions given by your health care provider

Contact your doctor or health care provider right away if any of these apply to you.

<http://www.drugs.com/cdi/mifeprex.html>

In U.S. trials of RU-486/misoprostol, at least 99% of patients experienced at least one of the following:

- abdominal pain (cramping) (97%)
- nausea (67%)
- headache (32%)
- vomiting (34%)
- diarrhea (23%)
- dizziness (12%)
- fatigue (9%)
- back pain (9%)
- uterine hemorrhage (7%)
- fever (4%)
- viral infections (4%)
- vaginitis (4%)
- rigors (chills/shaking)(3%)

"More than one adverse event was reported for most patients. ... Approximately 23% of the adverse events ... were judged to be severe."

<http://www.ru486facts.org/index.cfm?page=sideeffects#overview>



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# RU-486

## Mifepristone

## Mifeprex®

## Early Option®



# What you should know before you take these pills!

## **Note: An RU-486 abortion involves two drugs**

When taken alone, RU-486 causes a complete abortion only about 60% of the time. A second drug, a prostaglandin, is given 48 hours later to increase its effectiveness. The prostaglandin causes uterine contractions to help expel the embryo.

Misoprostol (brand name Cytotec) is the prostaglandin used with RU-486 in the U.S.

### **Important Notice: The manufacturer of Cytotec (misoprostol) has warned doctors that it recommends this drug not be used for abortion.**

The manufacturer of Cytotec, G.D. Searle (now part of the Pharmacia Corporation), recommends that Cytotec not be used for abortion:

"Searle regards the administration of misoprostol, either alone or in combination with other drugs to interfere with the course of pregnancy, as misuse of the product. ... We strongly condemn misuse of the product."<sup>68</sup>

Note: Cytotec is an anti-ulcer drug, intended for patients at risk of developing stomach ulcers from high doses of aspirin-like medications taken for conditions such as arthritis.

On August 23, 2000 Searle issued a letter to

all Health Care Practitioners entitled "Important Drug Warning Concerning Unapproved Use of Intravaginal or Oral Misoprostol in Pregnant Women for ... Abortion." It states in part:

Serious adverse events reported following off-label use of Cytotec in pregnant women include maternal and fetal death; uterine hyperstimulation, rupture or perforation requiring uterine surgical repair, hysterectomy [removal of uterus] or salpingo-oophorectomy [removal of ovaries and Fallopian tubes]; amniotic fluid embolism; severe vaginal bleeding, retained placenta, shock, fetal bradycardia and pelvic pain.<sup>69</sup>

The "black box" warnings on Cytotec's label state in part:

Uterine perforation has been reported following administration of combined vaginal-and-oral Cytotec in pregnant women to induce abortion. In each of these reported cases, the gestational age of the pregnancies was unknown.

<sup>68</sup> Letter to the Editor, signed W. Wilson Downie, International Medical Operations, G.D. Searle, The Lancet, vol. 338:247 (July 27, 1991).

<sup>69</sup> Letter from Michael Cullen, MD, Searle's U.S. Medical Director, dated August 23, 2000, available at

<http://www.fda.gov/medwatch/safety/2000/cytote.htm>.

## **Think about this!**

"Dr. Joseph Booker (former abortionist at Jackson Women's Health Organization) alleges in a lawsuit that he was retaliated against for refusing to perform an abortion procedure not approved by the FDA and discriminated against after he was replaced by a white doctor who would use the procedure."

Source: The Clarion Ledger, [Doctor seeks judgment in firing](#), December 3, 2011

Mifeprax is used, together with another medication called misoprostol, to end an early pregnancy (within 49 days of the start of a woman's last menstrual period). Since its approval in September 2000, the Food and Drug Administration has received reports of serious adverse events, including several deaths, in the United States following medical abortion with mifepristone and misoprostol.

<http://www.fda.gov/drugs/drugsafety/postmarketdrugsafety/informationforpatientsandproviders/ucm111323.htm>

## **Post-Marketing Adverse Events in U.S. Women Who Used Mifepristone for Termination of Pregnancy**

This cumulative reports covers events from September, 2000 until April 31, 2011

Cases with any adverse event	2207
Died	14
Hospitalized, excluding deaths	612
*Ectopic pregnancies	58
*Experienced blood loss requiring transfusions	339
*Infections (Severe infections)	256 (48)

\* The majority of these women are included in the hospitalized category.

<http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM263353.pdf>