



# Mifepristone (a.k.a. RU486, abortion pill)

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## **Mifepristone: Introduction**

**Mifepristone is an anti-progesterone, sometimes referred to as RU486. The drug was developed by Roussel-Uclaf, the French pharmaceutical company, hence the letters RU in RU486.**

The drug was synthesised in April 1980 and was first licensed for use in France in September 1988.

## **History**

On 26 October 1988 Dr Edouard Sakiz, chairman of Roussel-Uclaf, suspended sales of Mifepristone. The press claimed that Sakiz's action was due to anti-abortionist threats to the company and its employees[1]. The threats referred to were related to a commercial boycott of Roussel's pharmaceutical products. Two days later the French government, which then had a 36% share in Roussel-Uclaf, ordered the drug to be re-released.

On May 16, 1994, Roussel-Uclaf announced that it was donating without remuneration all rights for medical uses of mifepristone in the U.S. to the Population Council, which subsequently licensed mifepristone to Danco Laboratories, a new single-product company, which won Food and Drug Administration (FDA) approval as Mifeprex on September 28, 2000. However, RU-486 is manufactured for the USA by Hua Lian Pharmaceutical Co, China.

On April 8, 1997, after buying the remaining 43.5% of Roussel-Uclaf stock in early 1997, the rights to Mifepristone outside of the USA were transferred to a new company formed by Dr Sakiz named Exelgyn which markets the drug under the name of Mifegyne or Mifiprex in the USA.

Mifepristone was licensed in Britain as an abortion drug by the Medicines Control Agency in July 1991, Sweden 1992, then Austria, Belgium, Denmark, Finland, Germany, Greece, Luxembourg, the Netherlands, Spain, and Switzerland in 1999. In 2000, it was approved in Norway, Russia and Ukraine. Serbia and Montenegro approved it in 2001, Belarus and Latvia in 2002, Estonia in 2003, Moldova in 2004, Albania in 2005, Portugal in 2007, and Romania in 2008. In Italy the drug was approved on the July 30, 2009. It was approved in Hungary in 2005, but as of 2005 had not been released on the market. Mifepristone is not approved in Ireland or Poland. Globally, RU-486 is approved for use in around 38 countries.

## **What is it used for?**

Mifepristone was developed specifically to kill unborn life in the womb. The description of the drug's product characteristics states, under "Therapeutic indications":

Therapeutic termination of pregnancy up to 63 days' gestation.

Softening and dilatation of the *cervix uteri* prior to mechanical cervical dilation for pregnancy termination.

For use in combination with a prostaglandin, *e.g.* Gemeprost, for termination of pregnancy between 13 and 24 weeks.

Labour induction in foetal death *in utero*.

In England, Wales and Scotland: "For termination of pregnancy, Mifepristone may only be administered in accordance with the Abortion Act 1967 as amended by the Human Fertilisation and Embryology Act 1990 [2]".

## **How does Mifepristone work?**

Mifepristone is a synthetic steroid which works by blocking the effects of progesterone, the natural hormone which is required to maintain the lining of the uterus during pregnancy. Mifepristone starves the womb of progesterone, the lining of the womb breaks down, and it is lost along with the developing embryo or foetus.

Up to four visits to a hospital or clinic are necessary to complete the process: consultation, taking of RU-486, taking of misoprostol, follow-up visit. The success rate of Mifepristone on its own is not high. Some studies have it as low as 54% (3) and Mifepristone is therefore often used with a prostaglandin, typically misoprostol (a synthetic hormone-like chemical given by vagina), which induces powerful contractions of the uterus and causes the dead embryo or foetus to be expelled from the womb (4).

The prostaglandin currently used in the UK and elsewhere in the world is misoprostol; and the regimen recommended by the Royal College of Obstetricians and Gynaecologists (RCOG), for medical abortions up to 9 weeks' gestation, is mifepristone 200 mg orally followed 1–3 days later by misoprostol 800 micrograms vaginally (RCOG guidelines 2004).

For pregnancies of 13 to 24 weeks' gestation, Mifepristone (600mg) is taken by mouth. This is followed by a prostaglandin by vagina (1mg every three hours up to 5mg). If abortion does not occur 24 hours after the start of treatment, a repeat course of Gemeprost (up to 5mg) will be given (6).

In both cases, if the treatment fails, the baby will be aborted by a surgical method (7), either vacuum aspiration or dilation and curettage.

## **Contra-indications**

The main contra-indications for Mifepristone/prostaglandin abortions, which exclude women from having them are:

- women who smoke
- those over 35 years of age
- women under 18 years of age

those who have asthma, obesity, high blood pressure, fibroids, glaucoma, ulcers, colitis, arthritis, epilepsy, kidney disease, pulmonary and cardio-vascular disorders, and suspected ectopic pregnancy (8)(9)(10)(11).

## **Side effects**

Use of Mifepristone/prostaglandin may cause any of the following: haemorrhage requiring blood transfusion, severe pain requiring strong pain killers, incomplete abortion, rupture of the uterus, vaginal bleeding, abdominal cramping, nausea, vomiting, diarrhoea, headache, muscle weakness, dizziness, flushing, chills, backache, difficulty in breathing, chest pain, palpitations, rise in temperature and fall in blood pressure (12)(13)(14)(15). The number and diverse nature of the side effects of Mifepristone/prostaglandin point to the fact that these are powerful chemicals.

Because of the way that Mifepristone is administered, the woman is involved in the whole process, she takes the tablets herself and is fully aware of the effects that the drugs are having on her body as they happen. It is possible for the embryo or foetus to come away while she is at home, possibly alone.

## **Use in the UK**

The level of use of Mifepristone/prostaglandin varies between England and Wales, and Scotland.

## England and Wales

In England and Wales use has risen steadily in recent years. Medical abortions accounted for 43% of the total in 2010. The proportion of medical abortions has more than trebled in the last ten years, from 12% in 2000. There has been a continuing upward trend in medical abortions since 1991 when Mifegyne was licensed for use in the UK, when only 4% of abortions were undertaken using a medical procedure. In 2010, 55% of abortions under 9 weeks were medical abortions compared with 18% in 2000.

- 1992: 1,566 (less than 1%)
- 1996: 9,737 (5.5%)
- 2010: 85,516 (43%)

Although the use of Mifepristone is growing steadily, vacuum aspiration is still the commonest method of abortion in England and Wales (16). Of the 184,993 abortions carried out in 2002, 149,262 (80.68%) were by vacuum aspiration. Of the 189,574 abortions carried out in 2010 for residents of England and Wales, 98,578 (52%) were by vacuum aspirator.

## Scotland

In the ISD Scotland National Statistics release, (17), the provisional figures for 2002 show that 49.8% of all abortions were carried out using medical abortion methods. Scottish abortion figures are presented under the headings "medical" (i.e. chemical methods, principally Mifepristone) and "surgical".

For abortions for less than nine weeks' gestation, the percentage of medical abortions is as 55.9%. In some regions of Scotland the rate of use of medical abortion is significantly higher. In Tayside in 2001, 78.2% of all abortions under nine weeks' gestation were medical abortions.

## Quotes and statements

***"As Abortifacient procedures go RU486 is not at all easy to use. In fact it is more complex to use than the technique of vacuum extraction...a woman who wants to end her pregnancy has to "live" with her abortion for at least a week using this technique. It's an appalling psychological ordeal". (Edouard Sakiz, Chairman Roussel-Uclaf August 1990)***

At a news conference on 17 May 2002, Dr Richard Hausknecht, medical director of Danco, the company which manufactures RU486 for the American market, admitted, **"it [RU486] is not safer than a surgical abortion"**.

**"There is much about RU486/PG that is fraught with risk and problems. As we have queried, what is the meaning of 'private' and 'de-medicalised' abortion that requires three or four doctor's visits to a specialised centre, includes the taking of two or perhaps five hazardous drug combinations, is accompanied by vaginal ultrasound, and too often has complications ranging from moderate bleeding to severe pain, and for some women blood transfusions? If this is a private and de-medicalised abortion experience, then the word 'private' has lost its definitional moorings."** (RU486 Misconceptions Myths and Morals: Janice J Raymond, Renata Klein, Lynette J. Dumble. Pub. Institute on women and Technology 1991)

**"Failures: The non-negligible risk of failure makes the follow up visit mandatory to check that the abortion is complete."** (Risks related to the method, from *Product Characteristics for Mifegyne*, [electronic Medicines Compendium](#).)

**"There is also the grisly possibility that a woman will deliver her tiny but unrecognisable dead foetus of 6-12 week's development alone and at home."** (Duffy A, Santamaria Dr J., *The How and Why of RU486*., Thomas More Centre Bulletin 1990;2:(9). 1-5)

**"I felt like I was dying...it hurt so much. I had contractions coming so fast, and I was sick to my stomach and dry heaving. I couldn't stop trembling and I felt so hot."** (RU486 patient, named Aimee, talking about her experience. Darton N., *Surprising journey for abortion drug*, New York Times, 23 March 1995 p.C12)

**"The cost of RU486/PG abortion, for example, is not cheaper for women, but it is much cheaper for the hospitals and clinics..."** (RU486 Misconceptions Myths and Morals, as above)

Dr Germaine Greer described RU486 as a powerful and unpleasant succession of experiences. **"These are violently active chemicals and they have violent reactions on the organism ... what is the situation in which a woman would undergo that kind of assault?"** (Dr Greer was a keynote speaker at the *Best For Women* gynaecologists' and obstetricians' conference in Sydney, October 2002. Reported in *The Age*, 4 October)

## References

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16. [2001 England and Wales abortion statistics](#), Office of National Statistics
17. [Abortion act statistics](#), Information and Statistics Division, NHS Scotland