



USE AND SAFETY OF RU486: THE INTERNATIONAL EVIDENCE

Mifepristone (commonly referred to as RU486) is a safe effective medical abortifacient that is registered for use in 33 countries around the world. Since it was first registered for use in France in 1988, approximately 2 million women in Europe and North America have been prescribed RU486 to terminate an unplanned and unwanted pregnancy.

Surgical vs Medical Methods of Termination of Pregnancy

While surgical abortion is a very safe procedure in Australia, medical methods of abortion have these advantages:

- Mifepristone can be administered to a woman as soon as she has decided to terminate an unplanned and unwanted pregnancy. By contrast, a woman must wait until the around the 6th week before she is able to have a surgical (vacuum aspiration) abortion.
- Pregnancy termination with mifepristone is non-surgical, requires no anaesthesia and puts women at no risk of perforation or damage to the cervix from instruments.

The Royal College of Obstetricians and Gynaecologists UK 'Guidelines for the Care of Women Requesting Induced Abortion' (2004) recommend the use of RU486 as the most effective and safest method for terminating pregnancies earlier than 7 weeks gestation (RCOG 2004).

IPAS, a well-respected international reproductive health care organisation, states: *"Both of the preferred methods for abortion in the first trimester, vacuum aspiration and medication abortion, are safe and effective. These methods are also appropriate and acceptable for many women. Women who have a choice of methods report greater satisfaction with their abortion care."*

What is RU486?

Mifepristone is an anti-progesterone steroidal medication. Progesterone is required for the maintenance and development of pregnancy. Using RU486 will cause the end of a pregnancy. It is most effective when used in combination with a prostaglandin (usually misoprostol), which causes the uterus to contract and expel its contents.

How is RU486 administered for termination of pregnancy?

The World Health Organisation has reviewed the international scientific and technical research evidence and recommends the following regimen up to 9 weeks (63 days) of gestation:

- Mifepristone is administered under medical supervision and is taken orally. This is followed 1-3 days later by misoprostol (or other prostaglandin) vaginally. The misoprostol may be administered by the clinician or self-administered by the woman. If the pregnancy is less than 7 weeks, misoprostol can be taken orally rather than vaginally (WHO 2003).
- Women should attend a follow up visit within 14 days of the administration of mifepristone to ensure there are no retained products or other complications.

Mifepristone may also be used for second trimester termination of pregnancy.

How effective is RU486?

According to the World Health Organisation, efficacy rates are up to 98% when used in the first 9 weeks of pregnancy (WHO 2003).

Up to 90% of women abort within 4-6 hours of the administration of the misoprostol (WHO 2003).

What 'back up' is required?

Mifepristone should be used under medical supervision. The treating medical practitioner must ensure that the woman can reach appropriate surgical facilities and trained personnel in case of an emergency. These facilities and skills are similar to those required to care for women who have a spontaneous miscarriage (WHO 2003).

What are the adverse reactions?

Mifepristone/misoprostol regimen is a very safe treatment when used under appropriate health care supervision. However, all medications have some risk attached and this must be managed appropriately.

Usual side effects, such as pain, cramping and vaginal bleeding, are similar to those of a spontaneous miscarriage. Women should be provided with appropriate pain control medication. Other side effects of the medications themselves may include nausea, vomiting, diarrhoea, chills, or fever.

Research studies show that between 2% - 5% of women treated with the mifepristone and misoprostol regimen will require surgical intervention to resolve an incomplete abortion, terminate a continuing pregnancy, or control bleeding (WHO 2003).

Research shows that excessive vaginal bleeding requiring transfusion occurs in approximately 1 - 2.5 in 1000 cases (De Costa 2005).

Recent discussion has focussed on 4 tragic deaths in relation to medical abortion in North America. These were due to the development of sepsis following the use of the mifepristone and vaginal misoprostol regimen. The US Food and Drug Administration (the equivalent to the Therapeutic Goods Administration) has investigated this situation, and has determined that the mifepristone/misoprostol regimen remains a safe method of medical abortion and can continue to be used. As a precaution, the FDA has recommended that women who experience nausea, vomiting, diarrhoea, or weakness (with or without fever) more than 24 hours after taking the misoprostol should contact a healthcare professional immediately (FDA 2005).

Risk of developing sepsis exists with any method of abortion, but is very low. This risk is reduced when prophylactic antibiotics are used and any existing genital tract infection is treated prior to the procedure (RCOG 2004).

Adverse event comparison with other medical treatments?

In the USA, the adverse drug event rate for mifepristone is very low – only 0.137%. This includes minor complications such as headaches and nausea (NARAL 2004).

Celebrex, the anti-arthritis drug, has an adverse drug event rate of 8.8% - over 64 times higher than mifepristone. *Claritin* (sold over the counter at pharmacies as *Claratyne* in Australia) has an adverse drug event rate of 12% - over 87 times higher than mifepristone (NARAL 2004).

Other uses of RU486?

RU486 may be used in treatments for: large, inoperable meningiomas; Cushing's Syndrome; breast and prostate cancer; glaucoma; depression; endometriosis, and uterine fibroids:

Who should decide if Mifepristone can be imported and distributed in Australia?

The Therapeutic Goods Administration (TGA) is responsible for "...assessment and monitoring activities to ensure therapeutic goods available in Australia are of an acceptable standard with the aim of ensuring that the Australian community has access, within a reasonable time, to therapeutic advances" (TGA 2005). Like with all other medications, the TGA, not the Minister for Health, should be responsible for determining whether mifepristone should be made available to Australian women and their medical practitioners, and how the drug should be distributed.

Bibliography

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